Tracking Radiation Exposure from Medical Diagnostic Procedures: Workshop Reports

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TRACKING RADIATION EXPOSURE FROM MEDICAL DIAGNOSTIC PROCEDURES

WORKSHOP REPORT

Committee on Tracking Radiation Doses from Medical Diagnostic Procedures

Nuclear and Radiation Studies Board

Division on Earth and Life Studies

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Cover: Image titled "Drop in the Bucket," courtesy of Dr. Aaron Sodickson (Brigham and Women's Hospital). Drops signify the exposure of patients who undergo medical imaging exams that utilize ionizing radiation; exposure may vary by amount and frequency. The workshop explores how tracking radiation exposure from medical diagnostic procedures can improve health care.

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the Report Review Committee of the National Research Council. The purpose of this independent review is to provide candid and critical comments that will assist the National Research Council in making its published report as sound as possible and will ensure that this report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We thank the following individuals for their participation in the review of this report:

- David Brenner, Columbia University
- James Brink, Yale University
- Cynthia McCollough, Mayo Clinic
- Orhan Suleiman, U.S. Food and Drug Administration

Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the contents of this report, nor did they see the final draft of the report before its release. The review of this report was overseen by Theodore Phillips, Professor Emeritus, University of California, San Francisco. Appointed by the National Research Council, Dr. Phillips was responsible for making certain that an

independent examination of this report was carried out in accordance with institutional procedures and that all review comments were considered carefully. Responsibility for the final content of this report rests entirely with the authorizing committee and the institution.

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Overview

This report provides a summary of the presentations and discussions that took place during the December 8-9, 2011, workshop titled "Tracking Radiation Exposures from Medical Diagnostic Procedures." The workshop was organized by the Nuclear and Radiation Studies Board of the National Academy of Sciences and sponsored by the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Health and Human Services. This workshop report was authored by a six-member committee of experts appointed by the National Academy of Sciences. To respond to its statement of task (see Appendix A), the workshop committee brought together public health regulators, physicians, manufacturers, researchers, and patients to explore "why," "what," and "how" to track exposure from medical diagnostic procedures and possible next steps. The committee is responsible for the overall quality and accuracy of the report as a record of what transpired at the workshop, but the points discussed do not represent a consensus of the workshop participants or the authoring committee; instead, they represent views expressed by individual participants during the workshop.

The growing use of medical diagnostic procedures is correlated with tremendous and undeniable benefits in the care of most patients. However, it is accompanied by growing concerns about the risks associated with diagnostic computed tomography (CT) and other procedures that utilize ionizing radiation. A number of initiatives in radiation safety in medicine have taken place in the United States and internationally, each serving dif-

ferent purposes. Their ultimate goals are to provide higher quality clinical management of the patient and to ensure that reasonable steps are taken to keep the exposures as low as possible without compromising diagnostic efficacy.

Workshop participants discussed four goals of tracking radiation exposure from medical diagnostic procedures: justification, optimization, individual risk assessment, and research purposes. Many workshop participants emphasized that a primary motivator for tracking exposures was to implement and maintain dose reduction strategies through optimization and justification with the ultimate goal of improving care. These participants reiterated that such strategies ought to be adopted by all facilities that perform diagnostic imaging, including hospitals and imaging centers, as well as free-standing private physician, dental, and chiropractor practices. Several workshop participants also noted that although it would be desirable to have a national registry that tracks radiation exposures from medical diagnostic procedures, such a national effort is not likely to be implemented in the near future for many reasons including the following: lack of sharing of medical information across different health care facilities, lack of a unique patient identifier and integrated medical records, non-automated dose information collection processes, and data protection and patient privacy issues.

It is hoped that this workshop report will be a valuable testimony to the questions other groups will have to face, and the consensus they will have to achieve, if radiation exposure tracking is to become a reality institutionally or nationally in the future.

1

Introduction

This report provides a summary of the presentations and discussions that took place during the December 8-9, 2011, workshop titled "Tracking Radiation Exposures from Medical Diagnostic Procedures." The workshop was organized by the Nuclear and Radiation Studies Board of the National Academy of Sciences and was sponsored by the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Health and Human Services. To respond to its statement of task (see Appendix A), the workshop committee brought together public health regulators, physicians, manufacturers, researchers, and patients to explore "why," "what," and "how" to track exposure from medical diagnostic procedures and possible next steps. This six-member committee of experts appointed by the National Academy of Sciences prepared the workshop agenda (see Appendix B) and produced this workshop report. (Biographical sketches of the committee members are provided in Appendix C.) The committee met twice over the course of the study: in August 2011 to plan the workshop and in December 2011 to hold the workshop and finalize the workshop report.

This report does not contain findings, conclusions, or recommendations, and it does not represent a consensus of the workshop committee members or workshop participants. Although the workshop committee is responsible for the content of this report, any views contained in the report are not necessarily those of the committee or the National Academy of Sciences.

The report is organized into three chapters:

- Chapter 1 (this chapter) provides an introduction to the workshop.
- Chapter 2 contains background information intended to provide the context for this study to the reader.
- Chapter 3 provides the workshop summary.

2

Background

This chapter contains background factual information, much of which was distilled from remarks made by workshop committee members and workshop presenters.

2.1 TRENDS IN DIAGNOSTIC IMAGING

Dr. Hedvig Hricak, workshop committee vice-chair and chairman, Department of Radiology, Memorial Sloan-Kettering Cancer Center, explained the workshop's scope and discussed the current advances and trends in diagnostic imaging.

Advances in medical imaging in the past few decades using procedures such as computed tomography (CT), fluoroscopy, and nuclear medicine imaging exams have dramatically improved health care. Tissues deep within the body can be easily accessed using these procedures, permitting radiologists to make diagnoses that previously would have necessitated exploratory surgery (Wittenberg et al., 1978). Other direct benefits of modern imaging procedures include more effective surgical treatment (Godoy et al., 2011), potentially shorter hospital stays (Batlle et al., 2010), safer discharge of patients (Litt et al., 2012), better diagnosis and treatment of cancer (Wagner and Conti, 1991), more efficient treatment after injury (Philipp et al., 2003), better treatment of stroke and cardiac conditions (Saini and Butcher, 2009; Winchester et al., 2010), and rapid diagnosis of life-threatening vascular conditions (Furukawa et al., 2009). Today in the United States, medical

imaging occurs in hospitals and imaging centers, as well as free-standing private physician, dental, and chiropractor practices.

A report released in early 2009 by the National Council on Radiation Protection and Measurements (NCRP)[1] titled *Ionizing Radiation Exposure of the Population of the United States* indicated that in 2006 Americans were exposed to more than six times as much ionizing radiation from medical diagnostic procedures than in 1980 (NCRP, 2009). The average effective radiation dose[2] to which the U.S. population is now exposed is estimated to be 3 mSv,[3] which is comparable to the annual exposure from natural background radiation which has remained unchanged for the past 20 years.

The most significant changes in medical diagnostic imaging were attributed to rapid increases in usage of higher-dose procedures particularly CT and nuclear medicine (especially nuclear cardiology [Mettler, 2009]). Close to 82 million CT exams are now performed annually in the United States (IMV, 2011), up from 46 million in 2000 and 13 million in 1990 (Brenner and Hall, 2007). Cardiac diagnostic nuclear procedures increased from 1 percent of the total number of diagnostic nuclear medicine examinations performed in 1973 to 57 percent in 2005 (Mettler et al., 2009).

Many factors have been suggested as explanations for the sharp increase in CT use (Baker et al., 2008; Iglehart, 2009), such as advances in CT technology that have increased ease of use for physicians and comfort for patients during testing; increased CT scanner availability; favorable financial reimbursements for imaging procedures; and shifts in the practice of medicine including more time constraints and promotion of defensive medicine. Newer radiographic imaging modalities such as positron-emission tomography/CT (PET/CT), single-photon emission CT (SPECT/CT), and potentially CT for screening of high-risk asymptomatic patients (for example, smokers screened for early lung cancer detection) are likely to further increase the population's exposure (Brenner and Hricak, 2010).

[1] The NCRP is a congressionally chartered organization that formulates and disseminates information and research data related to radiation exposure and protection.

[2] Effective dose is a dose parameter used to normalize partial-body radiation exposures relative to whole-body exposures to facilitate radiation protection activities (ICRP, 1991). Effective dose can also be used to enable comparison of risks between procedures that utilize ionizing radiation. The International Commission on Radiological Protection (ICRP) does not recommend use of effective dose for estimating population or individual risks. Effective dose is expressed in sieverts (Sv).

[3] The exposures of particular individuals could be higher or lower than these reported averages depending on how many medical imaging procedures that use ionizing radiation they undergo. As discussed in Section 2.2, a number of individuals undergo multiple imaging exams in their lifetime. Others may not undergo any. Therefore, their exposure would be higher or lower than the estimated average.

2.2 POTENTIAL HEALTH RISKS FROM DIAGNOSTIC IMAGING

Although the growing use of medical diagnostic procedures is correlated with tremendous and undeniable benefits in care of most patients, it comes with growing concerns about risks associated with the use of ionizing radiation. A 2001 article in USA Today generated visibility and publicity and became a critical component in changing the prioritization of image quality alone to image quality balanced with radiation dose in both adults and children (Sternberg, 2001). Dr. David Brenner (Columbia University) noted that ionizing radiation is an initiator and promoter of carcinogenesis. In the absence of sufficient empirical knowledge regarding radiation effects at low doses[4] typically encountered in medical diagnostic procedures, it is assumed that the probabilistic (stochastic) risk of cancer proceeds in a linear fashion at lower doses without a threshold. Scientific groups such as the International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), NCRP, and the National Research Council Committee on the Biological Effects of Ionizing Radiation (BEIR), repeatedly review and endorse the use of the linear-no-threshold (LNT) model for assessing risk (NCRP, 1993; ICRP, 2005; NRC, 2006; UNSCEAR 2008). The LNT model is often considered to be conservative and gives emphasis to public health and is currently used to set radiation protection standards and operating policies, such as the "as low as reasonably achievable" (ALARA) policy. There is large scientific debate, however, on the nature of the shape of the dose-response curve for radiation-induced cancers at low doses.

Assuming a linear relationship between dose and cancer risk at low doses, a potential small increase in the chance of developing cancer is the main health effect of concern associated with the use of medical diagnostic procedures. The level of risk depends on the type of imaging procedure. For example, the typical radiation exposure from a CT examination is ~100 times larger than that from an x-ray examination.[5] The theoretical individual risk of fatal cancer from a single CT for a dose of 10 mSv is estimated to be around 1 in 2000 (Mettler et al., 2000).[6] For comparison, the natural occurrence of fatal cancer in the U.S. population is about 1 in 5.

When a diagnostic procedure is medically justified (e.g., in a symptom-

[4] There is near-universal agreement that epidemiologic studies have demonstrated that radiation doses above 100 mSv are associated with increased risk of developing cancer. However, scientific debate on the potential cancer risks exists at low doses (< 100 mSv).

[5] The average effective dose for a typical chest CT exam is 7 mSv and for a chest x-ray 0.1 mSv; an x-ray of the shoulder is around 0.01 mSv; the average effective dose for most nuclear medicine procedures varies between 0.3 and 20 mSv (Mettler et al., 2008).

[6] See also: http://www.fda.gov/radiationemittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/ucm115329.htm.

atic patient), it is apparent that the likely benefit to the patient is greater than the risk, although the imaging exam should be optimized to the lowest dose that provides acceptable diagnostic information (ICRP, 2008). Special care is needed, however, for evaluating nonsymptomatic screening protocols, such as for CT lung screening, where the estimated annual risk from low-dose protocols is ~1.8 percent (upper limit is 5 percent) (Brenner, 2004) and the estimated benefit (measured as reduction in mortality from lung cancer) among current or former heavy smokers is ~20 percent (NLST Research Team et al., 2011). Because large numbers of individuals receive radiation doses from medical imaging, whether for screening or diagnostic purposes, the possibility exists that even small potential risks per individual attributed to these exams could translate into many cases of cancer.

Not surprisingly, because CT is used to not only diagnose disease but also follow the course of therapy and complications, a number of individuals have multiple CT scans in their lifetime. Wiest et al. (2002) reported that in 2001 approximately 30 percent of their patients had more than three CT exams in their medical histories, 7 percent had more than five, and 4 percent had more than nine. The percentages of repeated exams were higher in a more recent study at one institution (33 percent of patients had 5 or more lifetime CT exams and 5 percent had between 22 and 132) (Sodickson et al., 2009). The patients who underwent large amounts of recurrent imaging in the study generally had substantial underlying disease such as cancer diagnosis (Sodickson et al., 2009). Irrespective of the presence or severity of underlying disease, multiple CT scans of a patient can result in absorbed doses that have been empirically shown to increase the risk of cancer. This may be one of the reasons why for tracking radiation exposure from medical diagnostic procedures, CT scanning has received the majority of interest.

In contrast to the stochastic effects following radiation (e.g., development of cancer and some cardiovascular diseases), accidental exposure to very high levels of radiation can cause acute effects such as skin reddening, skin necrosis, hair loss, and severe tissue damage. These acute effects are known as "deterministic" or "non- stochastic" radiation effects. The problem of skin reactions following fluoroscopy were reported and summarized by Shope (1996). Recently, several unfortunate and highly publicized radiation overexposure events have been reported, especially involving CT exams. In 2009 officials of the Cedars-Sinai Medical Center in California notified the Food and Drug Administration (FDA) of accidental overexposure of about 200 patients undergoing brain-perfusion CT examination, resulting in hair loss and skin redness. The FDA identified additional patients who received overexposures at other hospitals[7] and has subsequently issued advisory warnings to initiate preventive actions

[7] See: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm.

(Kuehn, 2010). These events have heightened the awareness of radiation dose among radiologists, technologists, patient populations, regulators, and international agencies.

Assuming compliance from both the medical provider and patient, confirming and reporting the visible events of direct radiation injury may be a relatively straightforward task. However, measuring the potential long-term risks associated with low-level radiation doses from medical diagnostic procedures is challenging and therefore the risks have not been fully quantified. This is because the number of excess cancer cases expected to result from exposure to ionizing radiation from medical diagnostic procedures is low and difficult to differentiate from background cancer rates, which normally affect 42 out of every 100 persons.[8] Studies to assess these small risks would require very large numbers of individuals and long follow-up periods (Land, 1980). Because any radiation-induced cancer would not appear for years, it would be difficult, if not impossible, to relate it to past imaging procedures. Results from large-scale epidemiologic studies assessing the risks of medical diagnostic procedures that utilize ionizing radiation are not available yet. However, a number of epidemiologic studies of risks associated with CT exams are underway (see Section 3.5.1). CT exams are likely the high-dose medical diagnostic imaging exams associated with the easiest exposures and dose parameters to collect both in terms of equipment output and in terms of estimation of actual patient doses.

An alternative to directly examining cancer occurrence or death from cancer in the exposed populations is use of risk projection models. Such models use population dose estimates and existing risk coefficients to extrapolate the effects of medical diagnostic procedures. Typically population risk estimates are derived from the atomic-bombing survivors cohort in Hiroshima and Nagasaki; today, this cohort is widely considered the "gold standard" in the assessment of radiation-induced cancer risks at low doses.[9] Medically exposed cohorts are also used to provide risk estimates for risk projection studies.

The risks determined from projection models represent theoretical risks rather than empirical observed risks and rely upon the assumption of a linear relationship between radiation dose and risk at low doses. A study with frequency data from Medicare claims and data from the IMV Medical Information Division estimated that 29,000 future cancers could be related to CT scan use in the United States in 2007 (Berrington de González et al.,

[8] See: http://www.cancer.org/Cancer/CancerBasics/lifetime-probability-of-developing-or-dying-from-cancer.

[9] The effective dose from a typical CT exam is estimated to be about 8 mSv. This dose is comparable to the lowest doses of 5 to 20 mSv received by some of the Japanese atomic-bombing survivors.

2009). Fifty-seven million CT scans were used for the calculation of the potential future cancers. A second study showed that the lifetime cancer risk estimates for standard cardiac scans varied widely depending on age and gender, from 1 in about 3,000 for an 80-year-old man to 1 in about 140 for a 20-year-old woman (Einstein et al., 2007).

The risk estimates in the projection models used in the above-mentioned studies deal with particularly challenging problems related to uncertainty from various sources, in terms of both the dose for a given examination and the cancer risk per unit dose in the estimations. Moreover, the magnitude of cumulative individual doses from single or multiple procedures has not been fully characterized because of limited medical recording and the lack of sharing of medical information across different health care facilities.

2.3 APPROPRIATENESS OF DIAGNOSTIC IMAGING

The appropriateness of diagnostic imaging in terms of justification and optimization were discussed by Dr. Donald (Don) Miller, acting chief, Diagnostic Devices Branch, Division of Mammography Quality and Radiation Programs, Center for Devices and Radiological Health, FDA, and other workshop participants.

There are two ways to reduce doses from diagnostic imaging: (1) do imaging only when justified and appropriate and (2) for any given examination, use dose reducing approaches consistent with acceptable image quality and diagnostic performance.

Although based on limited data, one in four procedures is believed to be unjustified and therefore associated with unnecessary potential radiation risk. Examples include unnecessary CT scanning of the chest both with and without contrast or multi-phase scanning for patients undergoing abdominal and pelvic CTs (Guite et al., 2011). It is estimated that each year approximately 75,000 patients across the country have unnecessary pre- and post-contrast chest CT scans (Bogdanich and McGinty, 2011). A straw poll among pediatric radiologists indicated that about 30 percent of CT examinations in children were unnecessary or could have been replaced by imaging exams not using ionizing radiation such as ultrasound-based imaging modalities (Berdon and Slovis, 2002). Although the outcome of the straw poll does not constitute scientific evidence, it is an indicator that the issue of unnecessary exams is recognized by the medical community.

Lack of training regarding clinical decisions is one cause of the use of inappropriate examinations. In addition, ordering physicians may be unaware that recommended criteria can guide them in particular clinical decisions. Various professional organizations (e.g., the American College of Radiology [ACR]) have produced evidence-based guidelines, but several studies suggest that these guidelines have not been widely adopted by the

medical community. In a retrospective study of 200 trauma patients, for whom imaging decisions were made without the use of formal decision rules, 169 of 200 patients underwent one or more CT scans, resulting in an overall total of 660 CT scans. The authors found that application of the ACR appropriateness criteria could have prevented 44 percent of those CT scans from being ordered (Hadley et al., 2006). Other studies have found that similar percentages (20-40 percent) of CT scans could be avoided by following decision guidelines (Garcia Pena et al., 2004; Kuppermann et al., 2009; Holmes et al., 2009; Stein et al., 2009). A pilot study showed that two out of three nuclear cardiology scans performed were appropriate according to the American College of Cardiology criteria, while the remainder were either inappropriate or of uncertain appropriateness (Hendel, 2009).

A successful approach to increasing the use of decision guidelines has been to incorporate them into computerized imaging order entry systems (Sistrom et al., 2009). However, even when decision guidelines are readily accessible, a variety of factors may contribute to the ordering of unjustified CT scans such as emergency department patient throughput, fear of liability for a missed diagnosis, lack of information from other sources, and patient and physician self-referrals (Dunnick et al., 2005).

2.4 REDUCTION IN RADIATION DOSES

Reducing the dose per exam is the second way to reduce unnecessary exposure to radiation from medical diagnostic procedures, and this is discussed in the context of *optimization*[10] and the need to create reference values based on best practices (ICRP, 2008). Interest in this area has arisen because wide variations have been observed among radiation doses associated with particular imaging exams both within and across medical centers. Again, there is a specific interest in CT scanning, because of its amenability to significant dose reductions (or increases) by the ease of manipulation of technical factors during protocol adjustments.

One study in four San Francisco Bay Area institutions showed that radiation doses varied significantly among different types of CT studies performed on adult patients. A mean 13-fold variation between the highest and lowest doses for routine head CT exams and multiphase abdomen and pelvis CT exams was reported (Smith-Bindman et al., 2009). The authors state that this observed variation cannot be entirely explained by differences in patient size (which were not accounted for in the analysis) or the specifics of the clinical question that was being addressed. Large variability

[10] Radiation dose is optimized when imaging is performed with as low as possible amount of radiation required to provide adequate image quality for diagnosis or intervention.

in doses was also observed in a recent multicenter study in France that included children aged 0-5 years undergoing at least one CT scan between 2000 and 2006 (Bernier et al., 2012). In regard to nuclear medicine, a survey of 13 pediatric hospitals in North America identified a broad range of administered doses from institution to institution; these administered doses would directly lead to variability in radiation-absorbed doses to the pediatric patients (Treves et al., 2008).

Optimization of the techniques is viewed as a joint responsibility and effort of the radiology facilities and equipment designers. For example, manufacturers of CT scanners and fluoroscopy equipment have made many successful attempts to reduce the doses associated with particular exam types. These reductions have been accomplished through technological advances in equipment design, implementation of features such as automatic exposure control, and efforts to educate physicians and technologists and create awareness of potential adverse radiation effects. A comprehensive review of dose reduction efforts in nuclear medicine is presented elsewhere (Hricak et al., 2011).

One of the earliest success stories of procedure optimization was an effort to improve technical aspects of mammography, which culminated in the passage of the Mammography Quality Standards Act in 1992 (Spelic et al., 2007). This legislation set national standards for high-quality mammography, including standards for mammographic x-ray equipment, patient dose, and image quality and ensured that facilities in the United States would meet those standards.

Radiologists attempt to reduce dose through use of optimized protocols in accordance with national and international guidelines (ICRP 2000a,b, 2007a; McCollough, 2011). However, the information available to them is frequently inadequate. For example, on the technical side, although new CT and fluoroscopic devices include displays of dose metrics, some lack other safeguards, such as default parameter settings that optimize radiation dose or alerts when the radiation dose in a given exam exceeds a particular reference level or range. Even when these safeguards are in place, users may not have received adequate training in the proper use of these features and the importance of optimizing radiation dose. Additionally, training often takes place in the hospital or imaging center with all the concomitant distractions and without a verification of acquisition of knowledge at the end of the training sessions (Slovis, 2002) or quality assurance practices within the imaging facility.

On the dose side, Lee and colleagues (2004) performed a survey to determine the awareness of emergency department physicians and radiologists of the radiation exposure from the CT scans that they order. About 75 percent of the entire group significantly underestimated the radiation dose from a CT scan, and 53 percent of radiologists and 91 percent of

emergency department physicians did not believe that CT scans increase the lifetime risk of cancer. The risks and benefits of imaging procedures are rarely communicated to patients (Lee et al., 2004) and are not recorded in the patient's medical record. In addition, many medical imaging devices that communicate with radiology information systems do not forward data on radiation dose despite recommendations to the contrary from the ACR (Amis et al., 2007).

2.5 RECENT PROGRESS IN RADIATION SAFETY IN MEDICINE

A number of initiatives in radiation safety in medicine have taken place in the United States and internationally and were discussed by the workshop invited speakers. Each of these initiatives serves different purposes. The ultimate goal is to provide better quality clinical management of the patient and to reduce dose by adhering to the ALARA principle, without compromising diagnostic efficacy (ICRP, 2007b).

2.5.1 Image Gently and Step Lightly Campaigns

The Alliance for Radiation Safety in Pediatric Imaging[11] launched the Image Gently (in 2008) and Step Lightly (in 2009) campaigns aiming to reduce unnecessary exposure to radiation during pediatric imaging and interventional radiology, respectively. The campaigns' goal is to promote the special precautions required for children who undergo medical imaging that utilizes ionizing radiation (Sidhu et al., 2009; Goske et al., 2010). Through separate education material directed to patients, the health care team (radiologists, technologists, and pediatricians), physicists, and the news media, the Image Gently campaign has successfully disseminated its message by partnering with prominent medical organizations and agencies.

2.5.2 Image Wisely Campaign

In 2010, the ACR and the Radiological Society of North America (RSNA), together with the American Association of Physicists in Medicine and the American Society of Radiologic Technologists, established the Image Wisely campaign for minimizing radiation exposure in adults. The campaign resembles but does not exactly mirror the Image Gently campaign. The mission of the Image Wisely campaign is to raise awareness of opportunities to eliminate unnecessary imaging examinations and

[11] The Alliance for Radiation Safety in Pediatric Imaging is an organization of more than 60 national and international professional societies and agencies with the goal of promoting radiation safety for children.

to optimize the amount of radiation used in imaging examinations to only what is necessary to acquire appropriate medical images. Image Wisely has developed a web site with selected and logically indexed educational material for imaging professionals, referring practitioners, and the public and has partnered with imaging equipment vendors through the creation of vendor-specific web pages to provide the most current information on dose reduction techniques available on specific equipment. Participants in the program are asked to demonstrate their commitment to the Image Wisely principles by taking a pledge, pursuing accreditation, and participating in national dose index registries (Brink and Amis, 2010).

2.5.3 ACR's Dose Index Registry

The ACR launched the Dose Index Registry in May 2011 to address the lack of a substantial database for determining the average dose indices for a CT exam in the United States. Once these are determined, the data can be used to establish national benchmarks and practice patterns in dose indices and provide feedback to the participating facilities as to where they stand compared to those benchmarks and how far they are from achieving optimal practices. The Dose Index Registry collects and compares CT dose index information from facilities across the country and internationally. Information is collected using automated standardized techniques and includes exposure parameters (kVp, mAs) and dose indices (CT index volume [$CTDI_{vol}$],[12] dose length product [DLP][13]). Currently the Dose Index Registry does not collect information on dose estimates because they are not available.

2.5.4 IAEA Smart Card

In 2006 the International Atomic Energy Agency (IAEA) initiated an ambitious program named Smart Card with the purpose of tracking the radiological procedures of individual patients and radiation dose. The program, launched in 2009, will be implemented in some countries in three to five years. Until the program was launched, the only way to track a patient's lifetime (cumulative) exposures was by manual search of physical or electronic records in a hospital or hospitals or reliance on the patient's memory. The Smart Card program emphasizes the need for a more systematic tracking method resulting from the substantial increase in the use of high-dose radiation exams (Rehani and Frush, 2011). The major goals of tracking are

[12] CTDI describes the amount of radiation that machines emit during one scan; that is, CTDI is not the amount of radiation that enters the body.

[13] DLP combines all the scans from an examination into one value.

stated in the recent Joint Position Statement on patient exposure tracking[14] and include: supporting accountability for patient safety, justification, and optimization; providing information for assessment of radiation risks; and establishing a tool for use in research and epidemiology.

The original name of the Smart Card program tended to give the impression that the card would contain the patient's estimated dose data; thus, the name Smart Card/SmartRadTrack was subsequently adopted to place the emphasis on tracking. The estimated patient doses are not available on the card. Instead, like an ATM card or a credit card, the card simply provides the methodology (digital signature) to access dose information, which is available online. The IAEA Smart Card/SmartRadTrack is considered to be an improvement over a more basic tracking approach such as a vaccination card, which stays in the possession of the patient. Such a method would rely fully upon compliance and maintenance by the patient and may not have an impact on the quality of radiation dose management.

2.5.5 National Institutes of Health Clinical Center Initiative

The National Institutes of Health (NIH) Clinical Center has mandated that imaging equipment manufacturers provide for electronic reporting of patients' radiation exposures from their equipment in this setting. The information on radiation exposure reports will be logged into the patient's electronic medical record (EMR). Exposures from CT and PET/CT will be the first to be recorded using this system, because CT and PET/CT scanners already output this information (Neumann and Bluemke, 2010). The goal of this policy within the NIH Clinical Center is to achieve an accurate assessment of whether low-dose radiation exposure from medical imaging exams increases the patient's risk of developing cancer. It is understood that steps taken within a single institution will not be sufficient to allow a precise population-based assessment of cancer risk from lose-dose radiation and that tracking of medical imaging doses from a truly large number of individuals in the United States will ultimately be necessary. This initiative is, however, necessary to begin building a prototypical data set (Neumann and Bluemke, 2010).

Besides building a database for population-based risk assessment, the NIH Clinical Center will require that vendors ensure that radiation expo-

[14] The joint statement was endorsed by the World Health Organization, FDA, the European Society of Radiology, the International Organization for Medical Physics, the International Society of Radiographers and Radiological Technologists, and the Board of Directors of the Conference of Radiation Control Program Directors. See: https://rpop.iaea.org/RPOP/RPoP/Content/Documents/Whitepapers/iaea-smart-card-position-statement.pdf.

sure can be tracked by patients via personal electronic health record platforms such as Google Health and Microsoft HealthVault.

2.5.6 California Legislation

California became the first state in the United States to regulate CT scans.[15] The law dictates that facilities with CT systems capable of calculating and displaying radiation dose index document the dose index of each CT exam within the patient's radiology exam report. (The deadline for meeting the requirement is July 2012.) The law also requires that a medical physicist verify annually the dose index for each protocol and that any reported errors are communicated to patients and physicians. (The law does not set a limit as to what the dose indices should be.) For the purposes of this bill, the radiation dose that should be recorded is defined as any metrics such as $CTDI_{vol}$ and DLP or a dose unit as recommended by the American Association of Physicists in Medicine (AAPM).[16] This legislation was enacted in response to multiple events where patients were exposed to excessive radiation by diagnostic CT scanners, with the intent to prevent such events.[17]

[15] Florida, New York, and Texas are also considering similar legislation (Schmidt, 2012).

[16] AAPM is a member society concerned with the topics of medical physics, radiation oncology, and imaging physics with a primary goal of identifying and implementing improvements in patient safety for the medical use of radiation in imaging and radiation therapy.

[17] See: http://www.leginfo.ca.gov/pub/09-10/bill/sen/sb_1201 1250/sb_1237_bill_20100929_chaptered.html.

3

Workshop Summary

For increased readability, the chapter is organized by theme rather than chronologically based on the workshop agenda (see Appendix B). An integrated summary of the presentations and discussions are reported in this chapter. This summary should not be construed as reflecting consensus or endorsement by the workshop committee members (see Appendix C for committee roster), the invited workshop presenters (see Appendix D) and other participants, or the National Academy of Sciences.

3.1 OPENING COMMENTS

The organizing committee invited two speakers to provide opening remarks to help establish the context for the workshop discussions: Charles Miller (chief, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC) and Donald (Don) Miller (acting chief, Diagnostic Devices Branch, Division of Mammography Quality and Radiation Programs, Center for Devices and Radiological Health, FDA). Both the CDC and FDA have been active in the discussions of tracking radiation exposures from medical diagnostic procedures.

The CDC initiated studies in 2004 on the feasibility of a tracking system for medical diagnostic procedures involving ionizing radiation (CDC 2004a,b, 2006). The specific question explored was: "How could the procedure code in patient medical records be used to derive a radiation dose?"

This effort culminated in a 2006 CDC workshop that concluded that it would be extremely difficult to monitor actual doses received by patients.

The FDA recently published the *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging* (http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/UCM200087.pdf), aiming to promote safe use of medical imaging devices, support informed clinical decision making, and increase patient awareness.

Charles Miller proposed that the workshop participants consider the following question: Is now the appropriate time to reconsider the impact of radiation doses from medical procedures? Specifically:

1. Can we measure and record real doses that patients receive?
2. Can we track individual doses, and should we?
3. How can we potentially use such data to inform decisions by patients and health care providers without interfering in the use of potentially life-saving medical procedures?

He emphasized that information about patient doses from medical diagnostic procedures today is based on estimates and not actual measurements. He provided an overview of the efforts that have been initiated during the past five years to raise awareness about radiation exposure in the United States, which include the Image Gently and Image Wisely campaigns. Without endorsing them, he mentioned the many web-based applications that encourage patients to keep records of their imaging exams and share the information with their doctor. Patients can easily enter the type of imaging they received, their age when they had the procedure and, assuming some standard effective dose for a procedure (e.g., 8 mSv for an abdominal CT exam) the applications calculate the induced risk.

Don Miller stated that any discussion on "whether," "what," and "how" to track exposure regarding CT, fluoroscopy, radiography, and nuclear medicine should be initiated with a clear understanding of the tracking's purpose. Table 3.1 (adapted from Don Miller's presentation) summarizes the information that in his view needs or does not need to be tracked to achieve the goal(s) of a tracking system. The four goals discussed were:

- Justification
- Optimization
- Individual risk assessment
- Research purposes

As an example, Don Miller explained that if the purpose of tracking is to help the physician, dentist, or other health care provider to decide

TABLE 3.1 Reason to Track Radiation Exposure from Medical Diagnostic Procedures and Information Needed to Achieve the Goal

Purpose	PHI	Facility Identifiers[a]	Dose Data[b]
Justification	Yes	Yes	No
Optimization	No	Yes	Yes
Risk Assessment	Yes	No	Yes
Research	Yes	Yes	Yes

PHI=Personal Health Information

[a]Facility identifiers may include name, location, and type of facility (e.g., hospital or independent imaging center).

[b]Dose data may include dose indices and dose estimates. In this content, the term does not refer to information on frequency and type of imaging exam or body part irradiated, which would be needed for all tracking purposes.

SOURCE: Presentation by Don Miller (acting chief, Diagnostic Devices Branch, Division of Mammography Quality and Radiation Programs, Center for Devices and Radiological Health, FDA).

whether an imaging exam is necessary (justification), the registry should contain information that can answer the following questions: Are there previous exams that could answer the clinical question? What were the findings? Where are the images? Having this information in a registry (which would likely be an electronic medical record rather than a "dose registry") could avoid repetition of an exam that has already taken place. In such a case, the registry/record must contain personal health information (PHI, to identify the individual patient) and facility identifiers (to be able to retrieve the results and images of the past imaging exam) but not dose data, in order to serve the purpose of justification as described. In a later presentation (see Section 3.6.1), justification was also discussed in terms of "known clinical benefit" of an exam; in that case, tracking dose data through clinical trials that would provide the answers regarding the clinical benefits of the exams ordered may be necessary.

In contrast, to optimize radiation delivery from medical imaging and establish reference levels, a registry would need to contain facility information and dose information for examinations from a number of patients but would not need patient-specific information (i.e., PHI). A registry that fits this purpose is the ACR Dose Index Registry discussed in Sections 2.5.3 and 3.2.4. Information needed to achieve the goals of risk assessment and research was also described.

3.2 POPULATION UTILIZATION OF IMAGING

Several workshop participants affirmed that comprehensive and detailed data concerning diagnostic imaging utilization and associated radiation doses would help to evaluate whether concern over the dramatic increase in the population's exposure to radiation is warranted. Dr. Mythreyi Chatfield (director of data registries, American College of Radiology) separated the issue of the measurement of population utilization of medical diagnostic procedures into two challenges: a) counting the number of imaging procedures performed on the population and b) grouping these procedures into meaningful categories that represent a single imaging procedure with comparable radiation dose levels across patients and facilities.

A number of data sources that cover patient populations in the United States are available, and several were discussed during the workshop. Dr. Chatfield categorized the sources of existing information on population utilization of imaging as surveys of patients or providers, administrative claims, and registries. However, the information from these sources exists only fragmentally and not in the detail required for assessment of the associated risks and benefits.

3.2.1 FDA Surveys

David Spelic, physicist with the FDA, provided an overview of the FDA's past and present efforts to characterize U.S. population doses from diagnostic x-ray imaging. The predominant means by which FDA has gathered such data is by nationwide surveys. Covering a period of roughly five decades, these surveys document the state of practice for a broad scope of diagnostic x-ray procedures, capturing indicators of patient dose, image quality, and an array of related technical parameters that characterize surveyed exams.

The U.S. Public Health Service (USPHS) conducted the first national, large-scale surveys, the X-ray Exposure Studies (XES), in 1964 and 1970. These surveys captured comprehensive data regarding the state of practice in diagnostic radiography. Dr. Spelic said that each survey consisted of two components: a household interview of selected members of the U.S. population and the capture of technical information from clinical sites regarding x-ray equipment and radiologic practices for selected exams. Data regarding x-ray exam history were collected for 31,289 persons representing 9,653 households in 1964 and 67,000 persons or 22,500 households in 1970. Major outcomes from these surveys included publications providing comprehensive statistical summaries of findings as well as detailed dosimetry for the exams covered by the surveys (USPHS, 1966, 1969, 1973). Their scope was large and included dental, medical x-ray, fluoroscopy,

and x-ray therapy. Film packs were sent to clinical sites to capture beam size and dosimetry (USPHS, 1973); separate film packs were used for each modality. Because dosimetry was an important endpoint for these surveys, the Bureau of Radiological Health developed models to compute patient exposure based on reported x-ray technique, collimation, and film packet measurement. Doses were computed using phantoms; exposure ratios and scatter were measured for dose calculations.

Dr. Spelic then discussed the Breast Exposure Nationwide Trends (BENT) project that begun in the late 1970s. It was a joint effort by the FDA and the National Cancer Institute (NCI) to study the current practice of mammography with the aid of state radiological programs. Among the survey findings was a broad variability of patient exposures ranging from 2.2 mGy to 140.0 mGy. Direct exposure film provided the highest exposures, while screen film the lowest. The Dental Exposure Normalization Technique (DENT) program followed a similar pattern to the BENT program.

The Radiation Experience Data (RED) study was conducted in 1980 by the FDA's Center for Devices and Radiological Health (CDRH) to estimate numbers and types of diagnostic imaging procedures performed in hospitals in the United States; no dosimetry data were collected. Data were collected on all types of imaging procedures including CT, ultrasound, and nuclear medicine from 81 sites, which is a small population compared to the XES surveys. Among the findings was that 130.2 million x-ray procedures were performed annually in short-stay hospitals, a 59 percent increase from the number of procedures performed in 1970 (81.7 million). There were 2.2 million CT exams performed, and 73 percent of these exams were of the head.[1]

Dr. Spelic also discussed the current FDA program. The Nationwide Evaluation of X-ray Trends (NEXT) program was conceived in the early 1970s to address the lack of a program to collect comprehensive population exposure data representing the state of practice in diagnostic x-ray imaging. A committee of federal and state radiation control representatives was formed to develop such a program, and within a few years NEXT was annually collecting data on 12 commonly performed diagnostic x-ray exams. State radiation control personnel conducted site visits to randomly identify clinical facilities and captured data regarding patient exposure, clinical technique factors, and exam workloads. By the early 1980s, NEXT abandoned the annual collection of data for multiple exams in favor of focusing on a single procedure. The surveys became more comprehensive, and patient-equivalent phantoms were developed to invoke radiation output representative of a typical patient. Film processing quality and the integrity of the darkroom were evaluated.

[1] Primarily because at that point body CT exams were in their infancy.

TABLE 3.2 Summary of NEXT Surveys and Survey Years

Examination	Survey Years
Chest radiography	1984, 1986, 1994, 2001
Mammography	1985, 1988, 1992
Abdomen and lumbo-sacral (LS) spine radiography	1987, 1989, 1995, 2002
Fluoroscopy	1991, 1996, 2003, 2008
Computed tomography	1990, 2000, 2005
Dental radiography	1993, 1999, 2013
Pediatric chest	1998

SOURCE: Presentation by David Spelic, FDA.

Surveys now routinely collect data regarding patient exposure, indicators of image quality, facility exam/procedure workloads, and staffing levels, as well as features of quality-control and quality-assurance practices, Dr. Spelic said. Surveys of particular exams are repeated periodically to capture trends in the state of practice. Statistical summaries of past NEXT surveys are available from the Conference of Radiation Control Program Directors.[2] Approximately 40-43 states participate in each survey. A summary of the NEXT surveys and survey years is presented in Table 3.2.

The 2005 NEXT CT survey is an excellent example of the mutual benefits gained from collaboration with representatives from the manufacturing sector, Dr. Spelic said. Representatives from the National Electrical Manufacturers' Association (NEMA) supported the survey planning efforts with insight into the state-of-art CT technology. CDRH also has active representation on a number of International Electrotechnical Commission (IEC) committees, with standards activities directed at various sectors of diagnostic imaging from CT to digital-based imaging. He said that the wide acceptance of such standards by the international community underscores the need for continued presence at the federal agency level. NEXT supports these efforts with population data for exam frequencies, patient exposure, image quality indicators, and trends in the practice. Finally, IAEA has recognized the NEXT chest and abdomen/spine phantoms and associated protocols as scientifically established methodologies for conducting dosimetry for these exams.

Dr. Spelic identified several challenges that NEXT faces, including limited human and financial resources.[3] Moreover, the technology is changing faster than the ability to develop, execute, and publish surveys. NEXT aims to continue to complement and coordinate with newer efforts to capture

[2] See: http://www.crcpd.org.

[3] For example, an analysis of CT survey data from 2005 has not been completed because of insufficient resources.

complex data via dose registries and to focus on surveys of exams and modalities that are presently outside the scope of current efforts to automate dose data collection.

3.2.2 IMV Surveys

IMV is a market research and database provider that uses a variety of survey methods to track diagnostic medical procedures, including those that expose patients to radiation. Although IMV covers a large number of imaging facilities, it does not provide a detailed categorization of procedures. Instead it provides estimates of the number of procedures overall or of the numbers by broad categories such as CT or MRI.

Mr. Shah (general manager, IMV) and Ms. Prochaska (vice president, IMV) provided an overview of the data collected by IMV and perspectives on large-scale data collection.

IMV classifies its studies into two categories: census databases and market reports. Census databases cover about 65 percent of the universe and include both hospitals and independent imaging centers. Time required for data collection depends on the modality. For example, it may take one year to complete the data collection process for PET, whose universe is about 2,000 sites, while it might take two years for CT, whose universe is 8,000 sites. Collection costs increase significantly after about 30-40 percent of the sample has been interviewed. Because the census database information is quite detailed and covers a large population, it can be segmented and drilled down depending on the question to be answered. For instance, by facility type or geography, summary information can be obtained on:

- Availability of services (i.e., CT, PET, nuclear medicine)
- Adoption of new technology
- Number and/or age of systems in use

A powerful tool that IMV uses to achieve its satisfactory participation rates for the census databases (and a motivator for facilities) is that it donates a free benchmark report to participating institutions (price of report: $750), which contains information that they can use to compare their status and performance to the national average. Variables of interest to institutions may include number of clinical patient studies, variation of patient studies per site, productivity, radiopharmaceutical utilization and budgets, and inpatient versus outpatient composition.

In contrast, IMV's market reports cover approximately 300-400 sites (participation rates >10 percent), interviews are conducted by telephone and online, and collection of information takes about 8-12 weeks.

Mr. Shah explained that recent changes in the health care environment

have increased the workload of potential respondents who now have less time to participate in surveys. Additional challenges include an increasing number of providers to survey; a larger number of entities who survey the health care community (for example many manufacturers now survey their customers); facilities that do not allow their employees to participate in surveys; and the almost inevitable routing of calls to voice mail. Regardless of survey method, a trade-off exists between the level of detail requested and the response rate achieved.

Workshop committee member Fred Mettler (New Mexico VA Health Care System) acknowledged IMV's great contribution as a source of information on the utilization of medical diagnostic procedures for the NCRP report 160 (NCRP, 2009).

3.2.3 Medicare Administrative Claims

Although there was no workshop presentation dedicated to administrative claims as a source of information about population utilization of medical imaging, Dr. Chatfield briefly discussed this source. She said that detailed data on counts of procedures by current procedural terminology (CPT) code (or equivalent) for large populations have historically been available from administrative claims such as Medicare claims. She explained that CPT codes offer an advantage over the broad categories often used in surveys but still may not be granular enough to capture the full range of appropriate variation in radiation doses, protocols used to image patients for a broad range of indications, or amongst practices. Information is automatically collected using claim submissions from Medicare beneficiaries and is publicly available. However, it is limited to patients aged 65 or over who use this social insurance program. When available, data from private payers only cover each plan's participants.

3.2.4 ACR Dose Index Registry

The Dose Index Registry could serve as a source for both procedure counts and dose index measurements. Workshop committee member Richard (Rick) Morin (chair, ACR Dose Index Registry) provided an overview of the registry (see Section 2.5.3 for additional information).

By sending information to the Dose Index Registry, facilities can optimize protocols, implement standards, and contribute to the development of reference levels with the ultimate goal to improve imaging performance over time. Using a report (currently generated semi-annually) with descriptive statistics (mean, median, 25th and 75th percentiles) of the reported dose indices of participating facilities broken down by location, region, and type, the sample facilities can compare where they rank in these categories

and against the Dose Index Registry. The indices are expected to become less variable and more aligned with the benchmarks. Dr. Morin suggested that each facility should task a qualified "safety committee" with reviewing the report and evaluating whether the facility's dose indices are too high or too low compared to the ACR benchmarks. The committee could be comprised of diagnostic radiologists, physicists, technologists, and diagnostic imaging experts. Participation of imaging experts was deemed essential by many workshop participants who stressed that monitoring the dose indices detached from image quality does not provide the required overall quality assurance.

It is not surprising that "when somebody is watching, behavior changes," Dr. Morin said. Using the Advanced Cardiovascular Imaging Consortium in Michigan as an example, he stated that voluntary, collaborative quality improvement programs have proven to be successful in the past. The consortium achieved a marked reduction in estimated radiation doses following implementation of a radiation dose-reduction program, with no impairment of image quality. The one-year program used educational intervention to disseminate to participating sites the best-practice recommendations for radiation dose reduction followed by a two-month monitoring stage (Raff et al., 2009).

At the time the workshop took place, about 300 facilities were in the process of participating in the ACR Dose Index Registry and more than 100 had initiated data submission.[4] These facilities are of different types (academic, community hospital, multi-specialty clinic, freestanding center) and are distributed around the country. Data from more than 350,000 CT exams were recorded.

Drs. Morin and Chatfield described several challenges associated with the Dose Index Registry, which reflect general outstanding issues in the radiology community. For example, in the early pilot phase of the registry, naming conventions were largely inconsistent. Even if they used the same machine, different facilities may have named the procedure referred to as "CT head" differently. The issue also existed within a facility if different machines or different software were used. Now all exam names are standardized and mapped to RadLex[5] terms. As a result, procedures can be grouped into standard categories. However, even though the names are standardized, the protocols between facilities may differ. Therefore, what

[4] The number of institutions participating in the ACR Dose Index Registry increased to 400 between the times the workshop took place and the report was completed (communication with Rick Morin, chair, ACR Dose Index Registry).

[5] RadLex is the lexicon for uniform indexing of radiology terminology implemented by the Radiological Society of North America (RSNA).

is really needed is a standard name for acquisition protocol, Dr. Chatfield said.

The second challenge relates to the variability in dose indices due to patient size. This issue was discussed many times throughout the workshop (see, in particular, Section 3.4) and highlighted by Dr. James Brink, professor and Chair of the Department of Diagnostic Radiology at Yale University School of Medicine. Dr. Brink, together with colleagues, recently published findings that, for body CT examinations performed with automatic exposure control, the radiation used to examine a 100-kg patient is approximately three times that for a 60-kg patient and results in organ doses that are generally twice as high as those in a 60-kg patient (Israel et al., 2010).

The ACR Dose Index Registry currently does not cover all imaging modalities. It includes only CT but plans to also include computed radiography and digital radiography and fluoroscopy within the next year or two. Despite rapid growth, the registry currently includes only a small fraction of the CT facilities in the country. Participation is voluntary and therefore unlikely to be nationwide any time soon, Dr. Chatfield said. The fee to participate is modest ($500 one-time registration and additional charges scaled to the size of the practice) but may prevent participation by some facilities. Data transmission to the registry is completely automated, with high accuracy and minimal effort by the facilities, but some facilities may still hesitate to participate because of a reluctance to undertake a new and "unknown" effort. The registry uses industry standard practices for data protection and signed Business Associate Agreements (BAAs)[6] to protect patient privacy. Facility information is shared only with the facility, and facility permission is sought before the facility's name is included on the list of participants.

Dr. Chatfield addressed the question of whether the Dose Index Registry could be potentially used for population exposure monitoring. She responded that before that could happen there must be expert consensus and AAPM guidance on how to measure organ doses. If a system is implemented without expert consensus or without having adequate scientific justification for its value, then facilities will be reluctant to participate in the registry. This would hinder the main goal of developing better diagnostic reference levels for dose indices and would deprive facilities of a much needed tool for protocol review and radiation dose optimization. Because patient data are currently anonymized, multiple exams on the same patient cannot be identified, and patients cannot be followed as they move from facility to facility.

[6] A BAA is a standard contract for the purpose of providing services involving the use of protected health information.

3.3 NATIONAL AND INTERNATIONAL EFFORTS IN DOSE TRACKING

Many workshop participants emphasized that there is momentum for archiving of radiation exposure but multiple substantial barriers remain. These barriers include the questions of how to translate the various dose indices into a single quantity, whether the dose should be organ dose or effective dose, how to automate the collection process, how to account for individual variation in patient size, shape, and age, how to manage patient privacy and security issues, and how to control the multiple disparate purposes for which the data might be used.

3.3.1 Veterans Health Administration (VHA)

The Veterans Health Administration (VHA) health system is the largest integrated health system in the United States, treating a specific patient population and only few young patients. VHA has developed an open source electronic medical records system, which facilitates communication of the medical history of the patient, including access to the patient's imaging exams. VA practitioners are protected from personal malpractice liability and their salary is not dependant on procedure volume. Despite the absence of these potential motivational parameters,[7] diagnostic imaging and especially body CT usage in the VA is increasing at a rate similar to the private sector, noted Charles Anderson, chief consultant for diagnostic services at VHA. Many of these CT exams are performed as part of cancer screening, diagnosis, treatment, and surveillance protocols.

In light of recent FDA notices regarding potential CT overexposures, the VHA surveyed all its hospitals for dose parameters associated with brain perfusion studies and found that none had exceeded the threshold for deterministic effects.

VA has taken several steps to minimize the radiation dose received by patients, including the requirement for a national dose registry, although it is not clear whether funds will be available to develop the software, Dr. Anderson said. The plan is to send Digital Imaging and Communications in Medicine (DICOM)[8] dose structured reports from CT scanners and fluoroscopes to the VA image storage system (VistA Imaging). From there, dose parameters (volume CTDI and DLP for CT, cumulative air kerma and dose area product for fluoroscopy) will be extracted and placed in the procedure

[7] These parameters have been discussed as few of the many reasons of increased diagnostic imaging utilization (Baker et al., 2008).

[8] DICOM is an information technology standard designed to automatically capture and electronically report machine settings from various imaging procedures. DICOM is managed by the Medical Imaging and Technology Alliance, a division of NEMA.

file of the VA radiology information system. The dose parameters from 150 VA hospitals will be transmitted to a national data warehouse.[9] The sum of doses will be displayed at order entry and may be released to the patient as a dose summary, although there are outstanding issues with acquisition of historical data and data from exams performed outside the VA hospitals. There are no plans to calculate organ-based doses.

Dr. Anderson described further efforts within the VA to minimize the radiation dose received by patients. A protocol optimization guide was written to reduce CT dose while maintaining image quality. The protocol explains the factors that control radiation dose, states the diagnostic reference levels, and provides alerts and notifications. After testing the guide at several facilities, the VA has made protocol optimization mandatory. The VA is considering having privileges for physicians who operate fluoroscopes. An on-line course and test was posted on the employee education website, and successful completion of the test can be tracked. For fluoroscopy, peak skin dose in excess of 3 Gy must be documented in the record, while peak skin dose in excess of 5 Gy must be reported to the radiation safety officer (RSO).[10] Cumulative dose in excess of 15 Gy, or permanent patient injury, is a sentinel event.

Moreover, CT patients are given an educational brochure, which explains that there is small increase in cancer risk associated with the procedure. Consent is obtained for fluoroscopic studies that might exceed 3 Gy peak skin dose as well as CT studies that might exceed 3 Gy $CTDI_{vol}$ to advise patients of the deterministic complications of epilation or erythema in advance; however, in practice, "in the case of CT we do not *ever* expect this threshold to be met," Dr. Anderson said.

3.3.2 International Atomic Energy Agency (IAEA)

Dr. Madan Rehani (radiation safety specialist at the International Atomic Energy Agency (IAEA) in Vienna, Austria) provided a summary of the IAEA's Smart Card/SmartRadTrack program (presented in Section 2.5.4) and highlighted the unresolved issues that include using a patient identifier and incorporating nuclear medicine exams and studies that are performed on equipment that is not electronically connected to a central dose recording system. He noted that the world is moving in the direction of dose tracking. The revised International Basic Safety Standards and

[9] A place for data both internal and external to an organization to be stored together for analytical and informational processing regardless of the platform or application.

[10] Dr. Anderson clarified that VHA has not specified how to account for the cumulative effect of multiple procedures; the handbook states that studies done on the same day should be summed (personal communication with Ourania Kosti, May 3, 2012).

European Basic Safety Standards, aiming to establish basic requirements for the health protection of the public and patients from ionizing radiation, indicate that the referring physician is required to take into account previous radiological examinations; however, there is no explicit mention of dose tracking.

Advances in many practical issues such as movement toward electronic medical records, provision of dose indices by modern equipment, improvement in understanding the most relevant dose quantities, communication of doses to picture archiving and communication system (PACS), and transfer of patient files from one part of the country to another via inter-PACS links have improved both the public acceptance of medical recording and the technical possibility of systematically collecting radiation dose data. The crucial point is the necessity for a permanent patient identifier, which constitutes the major problem in countries where there are no permanent identification numbers for the patient population, Dr. Rehani said.

Dr. Rehani noted that patient exposure tracking is now a reality in some countries. Countries like Estonia and Malta can achieve nationwide coverage using these systems, whereas Sweden, Finland, and Denmark, which have nationwide PACS plans, are among the countries that can track radiological examinations performed within a county, covering few dozens of hospitals.

To indicate that a smart card type of tracking method has the potential to become a reality, Dr. Rehani discussed the recently proposed, European Commission directive on patients' rights to cross-border health care that would entitle patients to obtain health care in any European Union Member State other than own and to have the associated health care costs reimbursed by their national health system. This directive is a step toward the cooperation of the national health systems of different countries with the ultimate goal of improving patients' cross-border care. The directive also supports the implementation of a smart card system to hold medical information including radiation exposure. Efforts are under way to sign a Memorandum of Understanding between the United States and the European Union on the interoperability of health data exchange. International systems, particularly those outside Europe, require political consensus and interface.

Dr. Rehani noted that in 2010, IAEA conducted a survey to assess the current status of patient dose tracking in the world. The survey covered 76 countries including Brazil, China, India, Indonesia, and the United States. Eight countries were actively considering patient exposure tracking systems, and three were considering tracking systems for exposure but not dose. Seventy-four percent were aware of IAEA's Smart Card/SmartRadTrack program (see Section 2.5.4 for a description), and all but one were interested in joining and promoting the program in their country. Assuming practicalities

were attended to, 29 percent responded that a radiation exposure tracking program would be extremely useful, 60 percent responded very useful, and 11 percent moderately useful; no country responded that such a program would be mildly useful or not useful at all. All of the countries that had immediate plans to track radiation exposures included quality assurance and quality improvement as a goal of the planned program. Other goals included policy development, licensing/certification, regulation, and decision support for ordering exams.

Because a key issue with the implementation of the Smart Card/SmartRadTrack program is the existence and use of a unique permanent identification number, IAEA conducted a survey of 36 countries to determine if such a number is widely in place. The survey showed that 81 percent of the respondent countries have a unique permanent identification number in place and is valid for life, but only 44 percent of those countries use this number for medical care purposes. Most countries indicated that "lack of technology" was the primary reason for not using the permanent identificatin number; only 8 percent indicated a concern for the confidentiality of the patient. Although the United States was not included in this survey, Dr. Rehani mentioned the many privacy issues in the United States as a barrier to implementing such a program.

Dr. Rehani described a third IAEA survey that captured responses from 622 referring physicians from 28 countries. Eighty-three percent of the physicians responded that knowing their patient had undergone 10 or more CT scans in the near past would affect their decision to order the next CT scan; 8 percent of the respondents were not sure that this knowledge would affect their decision. Twenty-one percent of the physicians responded that they rarely come across situations where clinical indications are enough to prescribe a CT scan irrespective of previous history of CT scans. To the question "How often in your clinical practice do you think knowing the history of CT scans will help you take a better decision," 24 percent of the physicians responded "always", and 48 percent "mostly". Sixty-two percent of the physicians agreed that having in place a system that provides quick information about a patient's dose history would be helpful; 30 percent responded that it might be helpful. The IAEA survey results described by Dr. Rehani were not published at the time this workshop report was being prepared.

3.4 FROM DOSE INDICES TO DOSE ESTIMATES

Dr. Walter Huda (professor of radiology at the Medical University of South Carolina and workshop committee member) and Dr. Michael McNitt-Gray (associate professor of radiology, University of California,

Los Angeles) were invited to discuss the current status of estimating patient doses from dose indices and to provide their perspectives on what to track.

Because it is not possible to directly measure absorption of radiation in body tissues, patient dose is calculated from measurements of the energy that is incident on the patient. If these measurements are directly used to reflect patient dose, then they may lead to misleading information, both experts emphasized. This is because the absorbed dose to the patient is affected by factors related to the radiation source as well as the patient (size, morphology, composition, and anatomic region), which can vary widely across patient populations (McCollough et al., 2011).

3.4.1 Radiation Metrics in Medical Imaging

The two experts explained that the CT dose index ($CTDI_{vol}$) was developed to provide a standardized method to compare radiation output levels between different CT scanners using a reference phantom. Dose Length Product (DLP), which is the product of $CTDI_{vol}$ (mGy) and scan length (cm), is related to the total ionizing energy imparted to the reference phantom. Both $CTDI_{vol}$ and DLP are sensitive to changes in scan parameters such as tube voltage and current, but they do not account for the physical characteristics of the patient undergoing the CT examination. $CTDI_{vol}$ is determined for either a 16 cm "head" or 32 cm "body" acrylic phantom. The (air) kerma area product [KAP] in radiography and fluoroscopy, and the administered activity [MBq] in nuclear medicine, are corresponding measures of the "amount of radiation" used to perform these respective radiological exams. These system measures can be used to quantify system performance, quality control, and establish routine clinical protocols. Moreover, these are the key inputs into all methods that have been developed to estimate patient doses.

In CT, given a constant scanner output (i.e., $CTDI_{vol}$ and DLP), Dr. Huda estimated that reducing patient weight from 70 to 50 kg might increase doses (and risks) by 20 to 25 percent, whereas increasing the patient weight to 120 kg might reduce doses (and risks) by 30 to 35 percent. Whether such dose adjustments were justified and required, however, will always depend on the specific context and the reason that any specific dose (and risk) estimate is being obtained. Inherent in current models of radiation dose are the many uncertainties and assumptions one must make to arrive at a patient's estimated dose. On that, Fred Mettler commented that any attempt to improve dosimetric precision must account for current risk uncertainties.[11]

[11] For more information, see Martin, 2007.

3.4.2 Organ and Effective doses

Dr. McNitt-Gray focused his presentation on organ dose as a dose metric that reflects the absorbed dose to the patient and that attempts to account for both patient- and source-related factors. He said that if organ doses could be estimated reasonably accurately and robustly, then they would provide an extremely useful basis for estimating and tracking patient dose. Doses to specific organs could be tracked over time and could be combined (added or by other math operation) in a much more meaningful way than we are currently able to do (e.g., combining radiation dose indices such as $CTDI_{vol}$ and/or administered activity). This could be done for very different procedures or multimodality procedures such as PET-CT.

Organ absorbed dose conversion factors can be estimated by using either clinically validated anthropomorphic phantoms with internal dosimeters or Monte Carlo computer programs. Obtaining organ dose estimates in a robust fashion is not easy to do on a routine basis. However, each of the modalities (radiography/fluoroscopy, nuclear medicine, and CT) has methods that are being developed to obtain reasonable organ dose estimates. Dr. McNitt-Gray pointed out that it will take some effort to fully develop these methods and implement them into clinical practice to track patient dose in a routine fashion. To do so requires cooperation between equipment manufacturers, standards organizations (e.g., DICOM), professional organizations (e.g., AAPM, SNM), possibly some software developing companies (to develop databases), and finally users and patients.

Dr. Huda stated that if the goal is to estimate risk at a particular part of the patient, then organ dose may be the dose metric of interest, and he described one of the methods available in the literature to calculate embryo dose estimates following a CT of the mother (Huda et al., 2010). He noted, however, that most often the physician and patient are interested in knowing the dose that the patient received (which means in all exposed organs and tissues combined and not in one organ alone). For this purpose, in his view, the realistic way to present information on the dose distributions that occur in all radiological examinations is to use effective dose. Use of the effective dose also permits the radiation dose of diverse diagnostic procedures to be quantified and thereby made understandable to medical imaging practitioners, as well as the general population, he explained. Because the effective dose is directly related to the stochastic risk associated with a given diagnostic procedure, it also permits determination of the risk associated with a procedure.

However, Dr. Huda noted that the effective dose is not a radiation risk parameter per se, and, although possible, obtaining radiation risks must be performed with great care. More specifically, when converting effective doses into radiation risks, the following factors must be taken into account:

the exposed patient region, the size of the exposed individual, and the patient demographics such as age and gender (Huda and He, 2011).

Dr. Brink was invited to provide a physician's perspective on the suitable dose metric for tracking purposes. He argued that effective dose is an imperfect metric for this purpose, even though it has been used as the driver for risk estimation from medical imaging for many years. Many medical imaging decisions would benefit from a focus on organ dose rather than effective dose, he said.

For example, a study conducted to evaluate the relative radiation risk of CT versus nuclear medicine evaluation for suspected parathyroid adenoma showed effective doses that were nearly equivalent between the two tests. However, analysis of mean organ dose and risk showed that the thyroid was the most radiosensitive organ affected by the CT scan, while the colon was the most radio sensitive organ affected by the nuclear medicine study (Mahajan et al., 2011). When analyzed by age and gender, it became apparent that women under the age of 30 have a relatively high risk of thyroid cancer from the CT scan as compared to the risk of colon cancer from the nuclear medicine exam. Over age 30, the risk of colon cancer from the nuclear medicine exam was significantly greater than the risk of thyroid cancer from the CT scan, in both men and women.

3.5 FROM DOSE TO RISK ESTIMATES

Dr. David Brenner (professor of radiation biophysics, Columbia University) discussed a number of issues regarding cancer risks from low-dose radiation exposure, and Dr. Kiyohiko Mabuchi (senior scientist, National Cancer Institute [NCI]) summarized the current evidence regarding non-cancer risks in the low-dose range. Dr. Amy Berrington de González (senior investigator, NCI and workshop committee member) described a risk calculator for projecting potential cancer risks from low-dose radiation exposures that has been developed at NCI.

3.5.1 Cancer Risks

Dr. Brenner explained that to evaluate the potential risks we first need to understand the range of doses received from radiological examinations, and for this purpose a distinction must be made between lower dose radiological exams (e.g. conventional plain film, mammography, dental) and higher dose exams (CT, PET, fluoroscopy). He explained that most of the population dose and potential risk currently in the United States come from the higher dose exams. Taking into account a) inter- and intra-institutional variability, b) machine variability, c) age variability, d) scans done with and

without contrast, and e) multiple scans, the key organ doses of relevance for CT are 5-100 mSv for a single series of CTs, and 5-250 mSv lifetime.

For organ doses corresponding to higher dose exams, some current knowledge comes from direct evidence in other exposed populations, Dr. Brenner said. From the atomic-bombing survivor data, there is some evidence of a small but statistically significant increase in cancer risk in the 5-125 mSv range (and higher) for cancer mortality (Preston et al., 2003) and in the 5-150 mSv range (and higher) for cancer incidence (Preston et al., 2007). Other supportive evidence of a statistically significant increase in cancer risk at the lower end of these dose ranges come from studies of childhood cancers after in utero exposure (mean dose ~6 mGy) (Doll and Wakeford, 1997) and of 400,000 nuclear workers (mean dose ~19 mGy) (Cardis et al., 2007), although the results of the nuclear worker studies are still under evaluation.[12]

According to Dr. Brenner, the challenge is to predict the biological impact of exposure to doses less than 1 mGy. For the region below which epidemiologic evidence is robust, the assumption of linearity is used. One of the issues associated with extrapolating data from the atomic-bombing survivors to medical diagnostic patients is that one involves whole body exposure while the other exposures to only certain organs. However, evidence exists that within the limits of an epidemiologic study, organ-specific dose-dependent risks are roughly independent of whether the exposure is whole body or partial body. Another issue with extrapolations is that the exposures from the atomic bomb were acute while the exposures in medical diagnostic procedures are fractionated. However, current knowledge is that the effects of fractionation are not as big as initially thought, and therefore the dose and dose-rate effectiveness factor (DDREF) that is used to extrapolate risk per unit dose from high doses of acute exposure to risk per unit dose at low doses and low dose rate is now considered to be 1.5-2.0 (NRC, 2006; ICRP, 2007b).[13] In Dr. Brenner's view, one can state with relative confidence that the risks associated with exposure to radiation from medical diagnostic procedures are considered to be small but non-zero; but, the uncertainties may be three-fold in either direction, thus potentially leading to over- or under-estimation of the risk.

The cancer risks are age-dependent with those exposed in childhood

[12] A major problem of the nuclear workers' study, known as the 15-country study, is the fact that the results were driven by the contribution of only one country, Canada (Ashmore et al., 2010). The Canadian Nuclear Safety Commission (CNSC) requested a reexamination of the Canadian portion of the data for their quality and validity. The resulting report confirmed that there is no increased cancer risk among the Canadian nuclear power plant workers for the time period examined (CNSC, 2011).

[13] For example, a DDREF of 1.5 to 2.0 suggests that the risk associated with an acute dose of 100 mSv is equivalent to a protracted dose of 150 to 200 mSv.

being at greatest risk. Furthermore, in the past, pediatric patients received higher doses from CT scans because imaging parameters were not adjusted for patient size (Brenner et al., 2001; Paterson et al., 2001). However, there is increasing understanding that earlier estimates of the dependence of risk on age at exposure probably underestimated radiation risks in middle age. Recent studies suggested that for radiation exposure in middle age, most radiation-induced cancer risks do not, as often assumed, decrease with increasing age at exposure (Shuryak et al., 2010). This observation suggests that promotional processes in radiation carcinogenesis become increasingly important as the age at exposure increases, Dr. Brenner said. Because most CT scans are given in middle age, exposures to patients of all ages are of concern (Shuryak et al., 2010).

Hedvig Hricak, vice-chair of the workshop committee, asked whether special care should be given to cancer survivors who, because of their possible inherent predisposition to DNA damage, may be more sensitive to radiation. David Brenner and John Boice (Vanderbilt University/ International Epidemiology Institute) agreed that this may be true, but the direct evidence is currently limited (Broeks et al., 2007; Bernstein et al., 2010; Figueiredo et al., 2011).

Dr. Brink commented on the recent findings that reduced life expectancy further reduces the risk of ionizing radiation in individuals with comorbid conditions (Brenner et al., 2011).

Dr. Brenner explained that to date no studies have directly evaluated whether the risk of cancer increases after CT scans. However, several epidemiologic studies of cohorts of patients who had pediatric CT exams are under way.

UK[14]	~200,000 children
Ontario[15]	~275,000 children
Israel[16]	~80,000 children

[14] Study cohort includes individuals under 22 years of age at first CT who received CT scans during 1985-2002 in the United Kingdom. Information on the types and dates of CT scans was collected from the radiology departments in approximately 100 hospitals, and patients were linked with the national health service central registry to obtain cancer registrations and death information. At the time this workshop report was published, results from the study had been submitted for publication.

[15] Study cohort includes individuals under 18 years of age who received CT scans during 1985-2005 in Ontario. Information is collected from the Ontario health insurance plan and Hospital for Sick Children.

[16] Study cohort includes individuals under 18 years who received CT scans during 1985-2005. Information is collected from Maccabi Health Care and a large pediatric medical center in Israel.

Australia[17]	~150,000 children
France[18]	~25,000 children
Sweden[19]	~35,000 individuals

Dr. Brenner noted that the studies are large, but the expected numbers of cancer cases are still relatively small because the follow-up will only be through childhood and early adulthood. Therefore, power may be sufficient to identify an increased risk of cancers that occur earlier in life such as leukemia, thyroid, and brain cancers. Larger and longer studies are needed to assess most of the possible risk, especially of those adulthood cancers with longer latency periods. After the individual studies are completed, a planned pooled analysis will be performed to increase statistical power. In a later discussion, Dr. Brenner expressed that he does not think that over the next few years there will be dramatic increases in knowledge regarding the cancer risks from low-dose radiation exposures or more precise estimates of the potential risks, even after the results from the epidemiologic studies of pediatric CT scans become available.

3.5.2 Risk Calculator for Research Purposes

Amy Berrington de González, together with her colleagues at NCI, developed the NCI Radiation Risk Assessment Tool (RadRAT), an interactive computer software that uses risk projection models to estimate cumulative lifetime cancer risks related to any low-dose radiation exposure (not exclusively from medical diagnostic procedures). The tool was developed for research purposes and not for patient purposes, Dr. Berrington de González emphasized. One of the main reasons the program is not suitable for patient risk assessment is that it requires organ-specific radiation doses rather than effective doses. She mentioned that several simpler risk assessment tools are available online that can be used by patients. These usually just require the user to input the type of exposure (e.g., head CT scan) and age at exposure.

The NCI risk calculator can take into account multiple exposures over time, organ doses for multiple doses, whether the exposure was acute or protracted, and also type of radiation. A total of 18 cancer sites are covered in the calculator. The underlying risk models for 11 sites were based on the National Academy of Sciences BEIR VII report (NRC, 2006), developed

[17] Study cohort includes individuals under 19 years who received CT scans during 1985-2005. Information is collected from Medicare-funded services.

[18] Study cohort includes children under 5 years who received CT scans during 2000-2006. Information is collected from several centers in France, covering almost all regions.

[19] Study cohort includes children and adults who received CT scans at the Department of Neuroradiology, Karolinksa University Hospital, Stockholm.

primarily from studies on the Japanese atomic-bombing survivors, although some medical exposure studies were included. Seven additional models were added for sites that are particularly important for radiation exposure from medical diagnostic procedures, such as the brain, and that were not covered in the BEIR VII report.

Dr. Berrington de González said that the key aspect of the NCI risk calculator is that it incorporates Monte Carlo simulation methods to quantify the impact of uncertainties in the assumptions and data. This includes subjective uncertainties, for example how to transfer data from the Japanese atomic-bombing survivor cohort to the populations of interest and the magnitude of the dose response at low doses, as well as statistical uncertainties in the model parameters. Importantly, the risk calculator provides an estimated uncertainty interval for the lifetime risk estimate. The NCI investigators are currently working on making the program publicly available in 2012 by developing a web-based version.

3.5.3 Non-Cancer Effects

Although risk of developing cancer is the primary concern following exposure to low radiation doses, non-cancer diseases may also be associated with exposure from medical imaging procedures. According to Dr. Mabuchi, the key questions to be addressed in estimating the risk of non-cancer disease relate to identification of the diseases of concern, dose response, and the magnitude of risk at low diagnostic doses. As with cancer risk estimates, the long-term follow-up study of the atomic-bombing survivors is a unique opportunity to study these questions.

For the atomic-bombing cohort, mortality data have provided evidence of causal associations for radiation and several disease categories, including circulatory disease (heart disease and stroke), digestive system disease, and respiratory system disease. The relative risks associated with radiation for these diseases are relatively low compared to the radiation-related cancer risk, but the absolute risk as measured by excess numbers of deaths, especially from circulatory disease, is substantial because these diseases are more common.

Dr. Mabuchi said that the latest data indicate a significant linear dose response for heart disease at dose levels higher than 0.5 Gy, while the stroke data suggest a possible non-linearity. The dose response for heart disease in the range of 0-0.5 Gy is not statistically significant, but excess relative risk per Gy at doses below 0.5 Gy are comparable to those derived from high doses (Shimizu et al., 2010). The dose response for circulatory disease has also been investigated in numerous other populations with occupational and medical exposures at medium or low dose levels. The circulatory disease risk estimates vary significantly among different studies,

but recent meta-analysis by the Health Protection Agency has shown that the heterogeneity is diminished (but not eliminated) if allowance is made for confounding by endpoints and dose fractionation effects. A significantly elevated overall excess relative risk of 0.09 per Gy was estimated in that meta-analysis.

Regarding the age and time patterns of the radiation-related non-cancer diseases risk, the atomic-bombing survivor data suggest that the non-cancer patterns are similar to those for radiation-related risk of solid cancer, with age at exposure or attained age modifying the temporal pattern and risk persisting throughout the lifespan. However, the patterns cannot be characterized with precision because of the low radiation-related risk for non-cancer and the high and varying baselines rate over the long follow-up time. The excess digestive disease risk observed may be unique to this population, likely involving an interaction of radiation with hepatitis C virus infections, and may not be directly extrapolated to other populations (Sharp, 2003). Reasons for the increased respiratory disease risk need to be clarified. Among other non-cancer conditions, cataract needs special attention because of the latest evidence of an increased risk of not only posterior lenticular opacity (known to be radiogenic) but also more common types of cataract at dose levels much lower than until now considered to be a threshold.

3.6 WHY TRACK DOSES?

The reasons for tracking dose (used generically to imply exposure or dose index) were discussed during the workshop, mainly in terms of justification, protocol optimization, individual risk assessment, and research purposes.

3.6.1 Justification

Many workshop participants suggested that the greatest change in reducing radiation exposure may come from ensuring that the exams ordered are clinically justified. This could be achieved by informing the physician on whether the exam he/she is about to order has been performed previously or elsewhere and can be used for current clinical decisions (see discussion on justification in Section 3.1) and by providing the physician that orders the exam with evidence-based decision support systems that could inform his/her decision at the point of care.

The benefits versus risks associated with medical imaging procedures are more often discussed with emphasis on the fact that the risks are often unknown. Dr. Michael Lauer (director, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute [NHLBI]) stated that the

clinical benefits of imaging procedures currently are also not always clear. Collecting good quality data through randomized clinical trials that involve tracking patient exposures and doses would help to inform the decision support systems and justify (or not) a procedure based on whether it would improve overall health. These systems may lead to a cultural shift, he said, such that fewer imaging tests are performed and only when supported by evidence from high-quality randomized trials or as part of ongoing trials.

Dr. Lauer provided two scenarios that lead to increased imaging today with no apparent improvement in health. First, as imaging techniques become more sensitive, cardiologists and other physicians are diagnosing diseases that they previously could not and the threshold of defining disease is getting lower. That gives the impression to the clinicians but also to the patients and the public that the prevalence of disease, or the prevalence of severe disease is increasing. As "awareness" of a disease increases, more testing is performed to detect it.

Second, with intense and improved imaging, clinicians now diagnose early disease or less severe forms of disease with the assumption that this translates to improved patient outcome. Patients probably respond well when treated for their mild disease, giving the impression and statistical artifact that the imaging saved their lives, which, in turn, leads to more imaging. In reality, little was done to improve health.

In Dr. Lauer's view, only by taking a step back and insisting on large-scale high-quality randomized clinical trials can the true value of new imaging tests be determined. He noted that these randomized trials could answer many critical clinical questions within a relatively short time, but should continue indefinitely to enable long-term follow-up. Because uncertainties regarding the magnitude of harm will possibly continue, an accurate understanding of the magnitude of benefit is a moral imperative, and Dr. Lauer suggested national discussions for randomized clinical trials.

A successful story and relevant example is the NCI-funded National Lung Screening Trial, which showed that helical-CT can be life-saving for early detection of lung cancer among heavy smokers (Aberle et al., 2011). However, not all trials have the expected outcome; for example, a recent trial of myocardial perfusion imaging in patients with diabetes showed no improvement in the outcome despite an accurate prediction of the events (Young et al., 2009). At the time of this writing, the NHLBI is funding a large-scale trial of CT angiography in patients with suspected coronary disease.[20]

[20] See: https://www.promisetrial.org/.

3.6.2 Protocol Optimization, Standardization, and Quality Assurance

Many workshop participants highlighted the need to optimize techniques and standardize practices and processes among medical institutions in an effort to reduce doses.[21]

Many of the parameters related to an imaging exam are under the control of the radiologist or technologist and ideally would be tailored to the particular exam and individual. One point made by many workshop participants was that programs such as the ACR's Dose Index Registry are needed to educate the medical community about the benchmark dose indices and provide appropriate uniformity by reducing the variability among and within facilities. Efforts like the ACR Dose Index Registry can help to inform understanding of how much doses can be lowered without compromising the image quality. Although lowering the doses could lead to lowering the potential associated risks, it was many times stated that the focus should be on dose optimization.

Don Miller commented that one needs to know what the source of the dose variability is before trying to reduce it. For example, variability sourcing from the patient characteristics, purpose of the imaging, and complexity of the procedure is expected and justified. Some variability in dose comes from the fact that not all facilities have the same opportunities to update their older scanners. For example, major hospitals represented at the workshop are bound to be among the most compliant with regard to dose optimization efforts compared to the typical community hospital that lacks the funds, or to non-hospital settings.

Interventional CT

Dr. Thornton (vice chair for quality, safety, and performance improvement, Department of Radiology, Memorial Sloan-Kettering Cancer Center [MSKCC]) emphasized during his presentation that comparable efforts are needed for interventional CT use, which has several unique characteristics. Instead of scanning through entire body cavities, the interventionalist typically limits the scan range to the anatomic territory, determined from prior diagnostic imaging, where the target lesion is located. This ability to limit the scan range is one component of the interventionalist's dose reduction efforts. The work of a CT-guided procedure entails repetitive scanning of

[21] The Working Group on Standardization of CT Nomenclature and Protocols of the American Association of Physicists in Medicine (AAPM) is charged with publishing a set of "reasonable" scan protocols for frequently performed CT examinations (such as brain perfusion imaging), providing recommendations on notification and alert values, as well as providing education on equipment terminology (see: http://aapm.org/pubs/CTProtocols/ for more information).

the target anatomic territory in order to plan the needle trajectory from the skin surface, to display the course of the needle as it is introduced and iteratively corrected, to document arrival at the target, to record the result of interventions (biopsy, ablation, drain insertion) at the target, and finally to document the anatomic outcomes following intervention. Thus, at various points during a CT-guided procedure, "noisier" lower dose images may be adequate to accomplish the task of image guidance; in other instances, the intent of imaging may require higher dose images similar in quality to CT scans used for diagnostic purposes.

In this context, management of radiation dose during CT-guided procedures is a dynamic, real-time process that requires the interest and knowledge of both the radiologic technologist and physician, Dr. Thornton said. Important issues for tracking the radiation dose related to CT-guided intervention include reporting a summary exam dose metric (currently, DLP is clinically available in real time) and its components (i.e., contributions from helical scans, CT-fluoroscopy—and increasingly in multi-modality environments, any additional components attributable to traditional fluoroscopy and PET imaging).

Uniformity in the terminology may be essential to the ability to organize and retrieve information, and unless the information is stored using standard terms in a structured format, it will not be possible to evaluate the progress. Some workshop participants suggested that using RadLex is a suitable way to unify language in radiology.

The Role of the Manufacturers

Representatives from four CT vendors were invited to participate in a panel discussion on the role of manufacturers in dose tracking and dose reduction efforts: Kenneth Denison (GE Healthcare), Katharine Grant (Siemens), Richard (Rich) Mather (Toshiba), and Dominic Siewko (Philips Healthcare). It was noted that vendors face tremendous pressure to reduce doses and are responding with a number of initiatives aimed at addressing the issue of overutilization in medical imaging. Collaborating through the Medical Imaging and Technology Alliance (MITA) the manufacturers' main efforts fall under the following four categories:

- Reduction of exposures through equipment hardware features
- Standardization of dose reporting
- Integration of radiation dose into reports
- User training

It was noted that vendors are too often expected to optimize protocols, making them universal rather than vendor specific and using common

nomenclature that would facilitate any method or purpose of tracking. However, the manner in which radiation output, radiation doses, and any corresponding radiation risks are to be presented on medical imaging equipment must be based on a consensus by the medical imaging scientific community. Walter Huda commented that it is unrealistic and impractical to expect manufacturers to play a leading role in any such endeavor.

Dominic Siewko (Philips Healthcare) noted that now more than ever it will take a coordinated effort of transparent communication between researchers, manufacturers, regulators, and care providers to ensure that the industry moves forward in lock-step.

Tracking the Physician's History of Ordering

A member of the audience asked whether tracking the physician's ordering history could reduce unnecessary imaging. Dr. Hricak (chair, Department of Radiology, MSKCC and workshop committee vice-chair) responded that given the fact that the end result of this group effort is to improve patient care, it is essential to track the physician's history. Dr. Sodickson (section chief, Emergency Radiology, Brigham and Women's Hospital) clarified that comparisons between clinical practices to assess physicians' ordering histories should account for justified differences due to the patient populations being cared for.

Dr. Morin shared examples of how a system that tracks the physician's history of ordering improved practices at the Massachusetts General Hospital. The hospital adapted and modified the ACR appropriateness criteria for exam ordering, and ordering physicians with low scores were consulted and subsequently received feedback regarding their ordering behavior (personal communication with Dr. Keith Dreyer, Harvard University, 2005). Physicians do not try to do something inappropriate, Dr. Morin said, "they just do not know." Fred Mettler noted that easy and relatively quick checks on the ordering habits of the physicians can happen by routine review of the billing databases. Dr. Denison added that tracking a physician's history with respect to dose (rather than number of procedures) even in a somewhat anonymized way is particularly important in interventional radiology. It is important to share the values with all physicians and alert them when important steps should be taken to lower doses.

3.6.3 Dose Monitoring and Individual Risk Assessment

Although they voiced no arguments against tracking radiation exposures or doses and dose indices for the purposes of justification and optimization, some workshop participants disagreed about the desirability of tracking for the purposes of individual dose monitoring and risk assessment.

A member of the audience asked Dr. Huda for his opinion as to whether patients should be given their dose periodically. In response, Dr. Huda rephrased the question to "Do I—as a patient—want to know my cumulative risk?" and categorically responded, "No! What an individual needs to know is whether he or she will benefit from the exam that is about to be ordered."

Dr. Mettler added that focusing on either dose or risks may become a problem in the future if patients refuse to have or physicians refuse to give an exam that the patient needs because of anxiety over the risks rather than appreciation of the benefits. Although for stochastic effects such as cancer risk dose tracking for individual risk assessment may not be needed, for deterministic effects, it may be good to know when those limits have been reached.

Although not arguing with the points made, Dr. Brink reminded the workshop participants that if the medical community does not monitor individual doses responsibly and with control, then somebody else will provide (in fact, already has started to provide) cumulative dose and risk to the patient, potentially in a poor and inconsistent manner. The question remains, however, about what one does with the tracked information. Dr. Brink's statement that the medical community should take the lead in tracking individual doses was supported by others.

What to Track and Communicate

Although patients rely on their physician to guide them through clinical decisions, many workshop participants identified a trend in health care worldwide whereby patients want to know and understand more about the procedure they are about to have with the ultimate goal to improve their health care. This trend was compared to that of the implementation of nutritional information facts at the back of the products two decades ago. Although initially consumers were unsure about how to use the information, today many look at it for different reasons and want to know how to use the information effectively to make good choices.

Dr. Hricak emphasized that because the physician still plays a fundamental role in informing the patient, the only way to provide the necessary reassurance to the patient or help the patient understand the risks and benefits of a procedure is by helping the physician understand the potential risks and benefits of the procedures ordered. It is important that the physician is able to provide the answers by being familiar with the current status and limitations of radiation dose estimations and risks. Today, many physicians are not adequately familiar with the radiation exposure effects, and training is crucial.

Dr. Donald Frush (chief, Division of Pediatric Radiology at Duke Uni-

versity Medical Center) identified elements of reassurance related to radiation exposure that come from knowing that the patient is about to get a good quality exam based on standard practice; the treating facility has active programs of optimizing exams; the providers are mindful of safety; and the scanners are accredited by an organization.

However, some patients seek more than reassurance and ask about the dose received or the risks associated with a particular exam. Therefore the question remains: What is the most effective way to communicate doses or risks with those patients? Although there was no obvious approach as to how the dose or risk would best be communicated to the patient, or which of the two parameters should be tracked and communicated, many workshop participants said that little would be gained by communicating dose index metrics with the patient, especially because dose index metrics vary by modality and therefore do not provide a uniform recording system. Seemingly more meaningful is translating the dose index metrics to doses or risks or communicating in some generic way the increase of risk per exam (for example a 0.3 percent increase on top of the 42 percent baseline cancer risk) based on current knowledge.

An alternative is to translate the risk to something more familiar to the patients, for example, the exposure to radiation during a flight from East to West coast, exposure to background radiation when living in Denver versus living in New York. (This approach was found to be too simplistic by some workshop participants including Drs. Brink and Sodickson who spoke against it.)

Dr. Kevin Crowley (director, Nuclear and Radiation Studies Board, National Academy of Sciences) commented that there is substantial literature on risk communication, including some National Academy of Sciences reports. It is known that different risks mean different things to different people based on subjective factors, and although numbers and statistical evidence may mean less to the general public, comparisons of risks from other sources, when risks are sufficiently similar, may prove useful to put risks into perspective.

Regardless of the preferred method, a number of workshop participants commented that communication must be catered to both the patient's interest to know and prior knowledge on the topic and should be done in an appropriate language and in a way to avoid causing panic. Uncertainties in the dose and risk estimations also should be clearly communicated.

Related to the need for effective communication is an increasing debate regarding informed consent for ionizing radiation in diagnostic imaging (Nievelstein and Frush, 2012).

Where to Report the Information

Dr. Mettler compared the ordering of an exam with the ordering of a prescription, which makes it obvious that documenting the amount of radiation used in an exam is a reasonable thing to do. The question of where to document the amount of radiation—in the radiology report or the medical record—was further discussed.

A member of the public pointed out that documenting doses in the radiology report, which is a legal document, may lead to future problems because doses are based on nonaccurate models and, in pediatrics in particular, may differ from the actual doses received. Dr. Frush responded that these doses do not necessarily need to be recorded in the report but can be archived in some fashion in the medical record, and whether or not they go in the report will depend on state requirements while being mindful of the issues mentioned.

Because the methods to estimate patient doses are not yet fully developed and it is uncertain which are the most relevant, it might be necessary to record all parameters and dose indices provided by a scanner. This is in agreement with the prototype used in the California's legislation (see Section 2.5.6), which notes that metrics such as $CTDI_{vol}$ and DLP or a dose unit as recommended by AAPM should be recorded. Dr. McNitt-Gray noted that such a recommendation is not likely to be implemented before the July 2012 deadline, but the AAPM can make a future recommendation for a more meaningful metric to be reported.

For patients that want more information about their exposure and the possible health effects, different levels of information covering the different levels of interest could be incorporated into the report. Dr. Frush suggested that the report could include links directing the patient to the appropriate organization (such as ACR, RSNA, IAEA) or federal agency (such as FDA and NIH) for general dose information, specific dose information per modality, or risk estimations with an option to contact the institution's radiology program if more patient-specific dose information is desired. The debate of whether the reported amount of radiation should be converted to dose or risk continued, with Dr. Brenner asserting that risk is what the patient most cares about. Fred Mettler pointed out that the idea of reporting risk in relation to radiation amount in the medical record does not agree with current practices, for example in radiotherapy, chemotherapy, and other treatment options, which may also carry some risks.

Assuming that a dose-recording system is needed for individual purposes, it has to be portable and cross boundaries to facilitate information tracking for all, including the mobile populations, Dr. Hricak said. Several possible approaches were discussed, including Smartphone technologies or

centralized technologies that enable patients to enter treatment information not matter where they receive the treatment.

Past Exposure Informing Decision Making

Section 3.1 of this report discussed that insufficient information about a patient's history of exams (e.g., whether a procedure was done in a different facility and its outcome) may lead to unjustified ordering of an exam. The opinions discussed in this section regarding past exposure informing decision making are not related to the issue of insufficient information resulting in duplicate or questionable ordering. Instead, they relate to whether and how the history of exposure to medical radiation (e.g., too many CT exams in a patient's record) fits into the clinical decision of ordering the next exam that utilizes ionizing radiation.

A member of the audience stated that, even within the walls of a hospital, a database that is easily accessed from a workstation and provides the ordering history for a patient can affect practices and reduce the number of exams ordered. In such a database, collecting information on the number of procedures rather than the doses may provide a sufficient wake-up call for the chief technologist. Dr. Sodickson agreed with the comment and added that real-time support rather than dose registry type of implementations can be factored into clinical decision making. Furthermore, the clinical model of taking clinical decision today based solely on clinical presentation today is changing; practice must move from episodic decisions to more long-term care of the patient by looking at the entire medical history and exposure. This may be more evident at the primary care level, when deciding whether physicians are doing the right thing over the course of a patient's treatment.

Ms. Gwen Darien (at the time of the workshop, executive director, Samuel Waxman Cancer Research Foundation; currently, director, The Pathways Project), representing the cancer survivors' views, shared the idea that ordering history information should fit with clinical decision making. It is critical to have knowledge of the previous exposures to radiation and potential harms from past, present, and future exposure as well as how those exposures might interact with medical treatment of the specific patient. To truly improve patient outcomes, it is vitally important to consider the long term when making decisions, she said.

Other participants, including Drs. Huda, Brenner, and Frush disagreed and stated that if an exam is clinically justified, then it is justified regardless of the past history; however, knowing the exposure history of a patient may serve as an important reminder that other means to diagnose a problem are possible.

Dr. Brenner described screening as an area where a risk versus benefit justification discussion is valid. Dr. Sodickson responded that in the emer-

gency room setting many exams border on being screening exams, and the yield is low. For example, the positive rate for a study to rule out dissection in a patient with chest or back pain is only 2 percent; however, the importance of making a life-or-death diagnosis in these few patients is critical. He also emphasized that justification of an exam is often a grey area, and the right thing to do is not always obvious.

Although past exposures might be part of the decision-making process for ordering the next exam, there is no threshold above which you cut off some patient from further imaging, Dr. Sodickson clarified.

Dr. Berrington de González noted that the United States could possibly make use of the justification systems that are in place in other countries such as the United Kingdom, where CT use is seven-fold lower than in the United States. All requests for diagnostic imaging procedures that involve ionizing radiation have to be approved by a radiologist, and the process requires justification of the need for the test.[22]

The Patients' Perspective

Gwen Darien discussed the patients' perspectives on the risks and benefits of radiation exposure from medical diagnostic procedures. As a cancer survivor herself, her perspective was that of the cancer survivor rather than the typical symptomatic or asymptomatic patient. Ms. Darien explained that the health goals and concerns of cancer survivors may be different from those of other patients, and therefore their perspectives and expectations may also differ. In order to pose a question to their health care provider, they need to know that there is a question to ask. It is not clear whether most cancer survivors know that there is a question to ask regarding risks associated with medical imaging. She noted that overall there is little discussion between patients and health care providers on the risks and benefits of radiation exposure from medical diagnostics.

Although the benefits are often assumed even when not explicitly discussed, the risks are rarely mentioned. In the absence of risk/benefit discussions between patient and health care providers, there is often a tendency for patients to request more procedures, Ms. Darien said. For many cancer survivors there is fear and anxiety of "not knowing" and of disease recurrence. From the perspective of a cancer survivor, it is critical to understand how radiation exposure might interact with medical treatment. With the ultimate goal of informed decision making, patient-provider interactions must include a discussion of the need for test, what knowledge will be gained from the test, and how that knowledge will be used to benefit

[22] Royal College of Radiology—A guide to justification for clinical radiologists. See: http://www.rcr.ac.uk/publications.aspx?PageID=310&PublicationID=2).

the patient. Ms. Darien noted that cancer survivors would be primarily concerned with not being able to get the tests they perceive they need if a tracking system for radiation dose were in place.

Are We Ready to Track?

On the topic of whether—if desirable—we are ready to track individual doses, Dr. Sodickson described an effective system of individual dose tracking, which is based on electronic medical records as likely the most efficient way to store information about the patient's history of radiation exposure. This system would include all care sites, and as a patient moves from one state to another his/her doses would be recorded via a unique patient identifier. The system would be able to track all modalities and sources of exposure and modality-specific exposure metrics or technique parameters together with accurate patient-centric dosimetry. The database format would be standardized, and all systems would be connected without firewalls or barriers.

This system differs from the current reality, which involves some independent modality-specific efforts, he said. This is because exposure metrics and platforms are different, and most of the captured modalities are for CT, because of its high doses and public attention, and for fluoroscopy, because it is more regulated in terms of the deterministic effects. Important data elements have been missing, such as exposure metrics, dose, and parameters related to the patient's size. Moreover, data access is limited, and data collection processes are not often automated. The format is largely inaccessible such as screen captures and text reports and is buried in disconnected systems.

For these reasons, many workshop participants asserted that—even if desirable—tracking cumulative dose estimates from a single or multiple modalities of a patient at the national level cannot happen today. At an institutional level, dose indices or dose estimates of a patient associated with a single procedure could be tracked, and possibly some institutions could track cumulative dose estimates from a single but not multiple modalities.

In support of isolated institutional efforts to track cumulative dose estimates from a single modality of a patient, Dr. Sodickson presented efforts developed at the Brigham and Women's Hospital. The team developed an open source informatics toolkit named GROK (General Radiation Observation Kit), which can locate and retrieve CT exposure metrics $CTDI_{vol}$ and DLP from existing digital image archives and convert them to text. Moreover, anatomy assignment algorithms use the combined dose report screen text and DICOM attributes data to determine the anatomic regions irradiated, creating large repositories of historical anatomy-specific radiation exposure metrics information from CT (Sodickson et al., 2012).

Using similar logic, an open source toolkit, PARSE (Perl Automation for Radiopharmaceutical Selection and Extraction), was created to extract exam- and patient-specific dosimetry from the medical records of patients, which contain unstructured text including the administered activity and the radiopharmaceutical name (Ikuta et al., 2012). Both methods proved satisfactory validation yields in data retrieval (97-99 percent) and anatomic assignment precision (94-99 percent) and may prove to be promising tools for estimating patient-specific radiation dose and cumulative risk.

3.6.4 Research

The gaps in current knowledge and the need to explore and refine models of biological effects at low doses were demonstrated by the presentations of Drs. Brenner and Mabuchi. Dr. McNitt-Gray argued that as the natural experiment of the effects of medical imaging procedures that use radiation is happening, it would be wise to collect good dosimetry data. This effort could answer the epidemiologists' questions and improve current knowledge of the biological effects of low-level radiation without the need to extrapolate from other population sources, which introduces uncertainty into measurement and interpretation.

Dr. Berrington de González responded to this idea by saying that, although using a tracking system would be beneficial for epidemiologic studies, capturing the study end point, such as cancer occurrence or death from cancer, and linking it with the exposure information is necessary for an epidemiologic investigation. In the absence of a centralized cancer registry in the United States that could provide the cancer ascertainment information, this is a difficult task.

Dr. Lauer added that attempting to find the potential association of imaging and cancer risks is important, but other risks not related to cancer also need to be tracked to assess the appropriateness of an imaging exam. All medical procedures contain an element of danger, and a potential to discover incidental findings that require subsequent medical evaluations. These evaluations may not only not improve outcomes but are likely to induce harm (Lauer, 2009).

3.7 LESSONS LEARNED FROM PEDIATRICS

Dr. Frush was invited to discuss the exposure reduction efforts and lessons learned from pediatrics. The pediatric radiology subspecialty is not typically on the horizon-defining medical trajectory, he said. Exceptions to this are efforts related to medical radiation, specifically radiation dose and potential risk from CT imaging, and education and advocacy for radiation

awareness and protection. Dr. Frush described some of the accomplishments resulting from efforts through pediatric imaging.

First, he said, we can lower doses and read noisier examinations, and we ought to do this. A number of reports in the pediatric population as well as a growing body of literature in the adult population promote dose reduction with maintenance of image quality. There is systematic work in dose reduction in adult and pediatric renal calculus evaluation (Karmazyn et al., 2009; Paulson et al., 2008). A study that compared the diagnostic capabilities of standard- and reduced-dose CT in the detection of nephroureterolithiasis in children showed that use of the 80 mA setting for all children and 40 mA for children weighing 50 kg or less does not significantly affect the diagnosis of pediatric renal stones (Karmazyn et al., 2009).

Second, multiphase (repeated scanning before and after contrast injection) examinations should be justified in adults, as has been promoted in the pediatric population, although multiphase examinations in children are generally not protocol driven, Dr. Frush said. When necessary, they could be based on a more case-by-case approach. Overall, multiphase examinations constitute fewer than 5 percent of all pediatric body CT examinations. This philosophy is less pervasive in adult imaging. One recent investigation noted that the frequency of "double scans" of the abdomen was highly variable, and the mean effective dose could have been reduced by about one-third overall with adherence to ACR appropriateness criteria (Guite et al., 2011).

He recognized the success of the Image Gently campaign, whose main pillars stand upon the foundations of a respected organization and leadership with independence and integrity, and consensus involvement. The messages are simple, important, and promoted in a positive and constructive (rather than alarmist) manner, with carefully controlled delivery of content, timing of releases, and schooled spokespersons to assure consistency and maximized penetration and impact.

He noted, however, that one must still be mindful of the various remaining needs in both pediatric and adult imaging, which include helpful dose alerts and notifications, improved dose estimations that account for the patient's characteristics (age, weight, size, gender), and establishment of reference values. Although templates exist on new scanners, without reasonable guidance for their use, these capabilities may be underutilized or incorrectly utilized, and therefore ineffective.

Dose estimations for CT in children are often inaccurate. The availability of improved dose estimations, such as through the AAPM task group 204 (AAPM, 2011), is a clear improvement. Current work in many laboratories focuses on patient-specific (i.e., age, weight, size, gender) organ dose estimations and resulting effective dose estimations. Dr. Frush discussed that a pilot registry for pediatric body CT (QuIRCC) is working in parallel

with the ACR Dose Index Registry. Early results from this pediatric registry demonstrate that the body CT dose indices at six pediatric institutions are below those reported in the European community (personal communication, Dr. Marilyn Goske, Cincinnati, Ohio).

3.8 SOME POSSIBLE NEXT STEPS SUGGESTED AT THE WORKSHOP

This section summarizes the key points and suggestions on some possible next steps discussed throughout the 1.5-day workshop and highlighted during the final panel session moderated by Dr. Barbara McNeil, professor and head of the Department of Health Care Policy at Harvard Medical School and workshop committee chair. The four panelists were Drs. Brenner, Frush, Hricak, and Mettler.

Many workshop participants noted that a primary motivator for tracking doses was to implement and maintain dose reduction strategies through optimization and justification with the ultimate goal to improve care. Several participants asserted that such strategies ought to be adopted by all facilities that perform diagnostic imaging, including hospitals and imaging centers, as well as free-standing private physician, dental, and chiropractor practices. Dr. Hricak emphasized that although it may be straightforward for major hospitals to adapt and adhere to practice guidelines, it may be challenging for free-standing imaging centers and small community hospitals to do so. Still, the goal of any imaging facility ought to be to improve radiologic services to the patient independent of the available resources.

Some workshop participants stated that it would be desirable to have a national registry that tracks radiation exposures and/or doses from medical diagnostic procedures. However, such a national effort is not likely to be implemented in the near future for many reasons, including lack of sharing of medical information across different health care facilities, lack of a unique patient identifier and integrated medical records, non-automated dose information collection processes, and data protection and patient privacy issues. Similarly, the current health care delivery system and cancer registration system precludes a longitudinal study of dose for large populations in the United States that are exposed to ionizing radiation from medical diagnostic procedures.

In view of the above mentioned barriers, the key points and suggestions on some possible next steps discussed by the panelists and workshop participants were to:

- Continue to track and monitor overall trends and patterns of use of medical imaging.

- Continue ACR dose index registry efforts and expand them to include additional modalities (e.g., nuclear medicine, computed radiography and digital radiography, interventional radiology) and other sites, particularly outpatient facilities.
- Within each institution, routinely report dose metrics performance with benchmarks.
- Create or use existing committees within institutions and outside facilities to ensure that imaging protocols are being followed; create routine reports for this purpose for technologists and radiologists.
- Work with industry and information technology vendors to incorporate dose metrics directly into medical records; ensure that dose metric information is attached to images.
- Encourage the performance of national-level clinical trials that quantify the benefits of imaging exams.
- Implement informed decision support systems at all stages of patient care to optimize procedure use and ensure that only appropriate examinations are performed.
- Have institutions and ambulatory settings implement or continue to implement comprehensive safety programs and educational tools promoting awareness of radiation doses.

The above mentioned points do not represent a consensus of the workshop participants or the authoring committee. Instead, they represent some of the important points made by individual participants during the workshop.

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Appendixes A

Project Statement of Task

A workshop will be organized to examine the feasibility and implications of tracking radiation doses to the U.S. population from medical diagnostic procedures. This workshop will examine:

- The quality and availability of data on patient doses resulting from diagnostic procedures, including individual dose estimates, dose uncertainties, and availability of patient dose information from different types of health care facilities.
- Possible mechanisms and supporting technologies for collecting and evaluating data on patient doses from diagnostic procedures.
- Potential obstacles for tracking patient radiation doses from diagnostic procedures and strategies for addressing them. Such impediments may include, for example, technical, logistical, regulatory, as well as achieving patient/physician acceptance.
- Prospective uses of radiation dose information obtained from tracking medical diagnostic exposures and the potential consequences of collecting such data.

A report will be prepared that summarizes the workshop presentations and discussions.

Appendix B

Workshop Agenda

Chair: Barbara McNeil, Harvard Medical School
Vice-Chair: Hedvig Hricak, Memorial Sloan Kettering

Thursday , December 8, 2011

8:30 am Welcome and Introduction
Hedvig Hricak—Memorial Sloan Kettering

8:40 am Why and how to track radiation exposure
Donald Miller—U.S. Food and Drug Administration
Charles Miller—Centers for Disease Control and Prevention

Session 1: National and International Efforts in Volume and Dose Tracking
Moderator: Fred Mettler—University of New Mexico

9:05 am Introduction to Session 1
Fred Mettler—University of New Mexico

9:15 am 1.1: IAEA activities and overview of global activities
Madan Rehani—International Atomic Energy Agency

9:35 am 1.2: Radiation exposures in medical imaging: FDA's past and present efforts
David Spelic—U.S. Food and Drug Administration

10:00 am 1.3: Strategies to minimize patient radiation exposure in the Veterans Health Administration
Charles Anderson—Veterans Health Administration

10:25 am BREAK

10:45 am 1.4: American College of Radiology (ACR) Dose Index Registry
Richard Morin—Mayo Clinic

11:10 am Discussion Session 1

Session 2: Appropriate Radiation Dose Metrics and Estimation Techniques
Moderator: Richard Morin—Mayo Clinic

11:30 am Introduction to Session 2
Richard Morin—Mayo Clinic

11:35 am 2.1: Radiation metrics in medical imaging
Walter Huda—Medical University South Carolina

11:50 pm 2.2: Patient Dose: What to record and track and the role of organ dose
Michael McNitt-Gray—University of California, Los Angeles

12:10 pm 2.3: Protocol optimization and dose variability for CT-guided interventions
Raymond Thornton—Memorial Sloan Kettering

12:30 pm LUNCH BREAK

1:30 pm Panel: Physician's perspective on what to report
Michael Lauer—National Heart, Lung, and Blood Institute
James Brink—Yale University

2:10 pm Discussion Session 2

Session 3:	Volume—Methods for Collecting and Evaluating Data *Moderator: Walter Huda—Medical University South Carolina*
2:40 pm	Introduction to Session 3 *Walter Huda—Medical University South Carolina*
2:45 pm	3.1: Measuring population utilization of medical diagnostic procedures: data sources and challenges *Mythreyi Bhargavan Chatfield—American College of Radiology*
3:05 pm	3.2: Automated electronic medical record (EMR) dose history extraction and monitoring *Aaron Sodickson—Brigham and Women's Hospital*
3:30 pm	BREAK
3:50 pm	3.3: Procedure volume trends in the United States and perspectives on large-scale data collection *Ashok Shah and Gail Prochaska—IMV Ltd*
4:15 pm	Panel: Manufacturers' perspective on what to report *Richard Mather—Toshiba Medical Research Institute* *Kenneth Denison—GE Healthcare,* *Christian Eusemann—Siemens Healthcare,* *Dominic Siewko—Philips Healthcare*
4:55 pm	Discussion Session 3
5:20 pm	Closing Remarks and Adjournment *Hedvig Hricak—Memorial Sloan Kettering*

Friday , December 9, 2011

8:15 am	Welcome, opening remarks *Barbara McNeil, Harvard Medical School*

Session 4: Risk—What We Know and What We Need to Know
Moderator: Amy Berrington de González—National Cancer Institute

8:25 am Introduction to Session 4
Amy Berrington de González—National Cancer Institute

8:30 am 4.1: Understanding radiation-induced cancer risks at radiological doses
David Brenner—Columbia University

8:50 am 4.2: Non-cancer effects at radiological doses
Kiyohico Mabuchi—National Cancer Institute

9:10 am 4.3: Patient's perspective
Gwen Darien—Samuel Waxman Cancer Research Foundation

9:25 am Discussion Session 4

9:45 am Lessons learned from pediatrics
Donald Frush—Duke University

10:10 am Panel: Next Steps
Fred Mettler—University of New Mexico
Hedvig Hricak—Memorial Sloan Kettering
Barbara McNeil—Harvard Medical School
David Brenner—Columbia University
Donald Frush—Duke University

10:25 am Discussion

11:25 am Closing Remarks and Adjournment
Barbara McNeil - Harvard Medical School

Appendix C

Committee and Staff Biographical Sketches

Chair

BARBARA J. MCNEIL

Barbara J. McNeil, M.D., Ph.D. (IOM) is the Ridley Watts Professor and was the founding head of the Department of Health Care Policy at Harvard Medical School (HMS) in 1988. She was one of the first women professors in the quad at HMS. She is also a professor of radiology at Harvard Medical School and at Brigham and Women's Hospital (BWH). She continues to practice nuclear medicine one day a week at BWH. She was interim dean of Harvard Medical School during summer 2007. Dr. McNeil received her A.B. degree from Emmanuel College, her M.D. degree from Harvard Medical School, and her Ph.D. degree from Harvard University. She is a member of the Institute of Medicine of the National Academy of Sciences and the American Academy of Arts and Sciences. Dr. McNeil is also a member of the Blue Cross Technology Evaluation Commission; she formerly chaired the Medicare Evidence Development Coverage Advisory Committee (MedCAC), and she is now a member of that committee. She currently chairs the Science Board of the FDA. She serves as an advisor for several other federal and private organizations. Dr. McNeil formerly served on the Publications Committee of the *New England Journal of Medicine* as well as on the Prospective Payment Assessment Commission. Dr. McNeil's original career involved research in decision analysis and cost-effective analysis. More recently, her work has focused on quality of care and technology assess-

ment. Her research involves relationships with payers, providers, and the federal government. Her largest ongoing study compares quality of care in the VA system with that in the private setting for patients with cancer. For several years she coordinated several large studies comparing the value of alternative imaging modalities for patients with cancer.

Vice-Chair

HEDVIG HRICAK

Hedvig Hricak, M.D., Ph.D. (IOM) is chairman of the Department of Radiology at Memorial Sloan-Kettering Cancer Center. She holds a senior position within the Program of Molecular and Pharmacology Therapeutics at the Sloan-Kettering Institute. She is a professor at Gerstner Sloan-Kettering Graduate School of Biomedical Sciences and is a professor of radiology at the Weill Medical College of Cornell University. She earned her M.D. degree from the University of Zagreb and her Dr. Med. Sc. from the Karolinska Institute. In 2005 she was awarded an honorary doctorate in medicine (Dr.h.c.) from Ludwig Maximilian University in Munich, Germany. She has helped develop applications in ultrasound, magnetic resonance (MR), and CT for gynecological cancers as well as MR and MR spectroscopy for prostate cancer. She continues to investigate diagnostic methods for cancer detection, staging, and management and is involved in developing clinical approaches for molecular imaging of cancer. She was elected to the Institute of Medicine (IOM) in 2002. In recognition of her career accomplishments, she has received the Marie Curie Award of the American Association of Women Radiologists (2003), the gold medals of the International Society for Magnetic Resonance in Medicine (2003) and the Association of University Radiologists, the Béclère medal of the International Society of Radiology (2007), the Morocco Medal of Merit (2008), and the Katarina Zrinska Croatian presidential award (2009).

Members

AMY BERRINGTON DE GONZÁLEZ

Amy Berrington de González, received a Ph.D. in cancer epidemiology from the University of Oxford in 2001. She conducted post-doctoral research in Oxford before joining the faculty there. In 2005 she became an assistant professor in epidemiology and biostatistics at the Johns Hopkins Bloomberg School of Public Health. She joined the Radiation Epidemiology Branch as an investigator in 2008. She is currently serving on the UK Health Protection Agency's Advisory Group on Ionising Radiation, and she has previ-

ously served on the UK Breast Screening Programme's Advisory Group and as a special advisor to the World Health Organization (WHO) on radiation effects and health. Dr. Berrington has conducted a series of risk projection studies to estimate the potential cancer risks from both diagnostic and screening examinations, including cardiac stress tests, CT colonography, and lung CT screening. To perform these studies, she and other collaborators developed the NCI Radiation Risk Assessment Tool (RadRAT), which is interactive computer software that uses state-of-the-art risk projection models to estimate lifetime cancer risks and incorporates Monte Carlo simulation methods to assess the impact of uncertainties in the assumptions and data. She recently became the NCI principal investigator for the UK Pediatric CT scans study, which is a retrospective cohort study of 250,000 children who had one or more CT scans as children or adolescents.

WALTER HUDA

Walter Huda, Ph.D., trained in England (B.A., physics at Oxford University; Ph.D., medical physics at the Hammersmith Hospital/University of London) and worked from 1976 to 1981 at Amersham International, a commercial company specializing in radioactive products. He has worked as a diagnostic medical physicist at the Manitoba Cancer Treatment and Research Foundation in Winnipeg, Canada (1982-1990), University of Florida in Gainesville, Florida (1990-1997), and SUNY Upstate Medical University in Syracuse, New York (1997-2007). He is currently professor of radiology at the Medical University of South Carolina. Dr. Huda is actively involved in the clinical use of medical imaging equipment, particularly maximizing the diagnostic information while keeping patient doses as low as reasonably achievable (ALARA). Dr. Huda's primary research activities relate to medical imaging and radiation dosimetry. Since the early 1980s, Dr Huda pioneered the use of the effective dose to quantify the radiation dose received by patients undergoing radiological examinations that use ionizing radiation. Dr. Huda has also developed quantitative methods for quantifying imaging performance. Dr. Huda is currently actively involved in the use of Alternative Forced Choice (AFC) methods for measuring imaging performance in CT and the investigation of the tradeoff between dose and image quality in this imaging modality. Dr. Huda has published more than 200 scientific papers and has been awarded 24 research grants with a total value approaching $4 million.

FRED A. METTLER, JR.

Fred A. Mettler, Jr., M.D., M.P.H., is professor emeritus and former chair of the Department of Radiology at the University of New Mexico, School of

Medicine. He is currently in radiology and nuclear medicine service at the New Mexico VA Medical Center. He earned an M.D. degree from Thomas Jefferson University and an M.P.H. from Harvard University, and he completed his residency in radiology and nuclear medicine at Massachusetts General Hospital. Dr. Mettler has authored more than 300 scientific publications, including 18 books, and holds 4 patents. He is currently the U.S. representative to the United Nations Scientific Committee on the Effects of Atomic Radiation, an emeritus commissioner of the International Commission on Radiation Protection, and a member of the National Council on Radiation Protection.

RICHARD L. MORIN

Richard L. Morin, Ph.D., received his Ph.D. in radiological sciences from the University of Oklahoma in 1980. His dissertation concerned the use of Monte Carlo simulation and pattern recognition for artifact removal in CYT. He is a fellow of the American College of Radiology and a diplomate of the American Board of Radiology in Diagnostic Radiological Physics and Nuclear Medical Physics. Dr. Morin is the secretary-treasurer and trustee of the American Board of Radiology and the chair of the Board of Trustees of the American Board of Imaging Informatics. Dr. Morin is a former president and chairman of the Board of the American Association of Physicist in Medicine and the Board of Chancellors of the American College of Radiology. Dr. Morin has presented numerous lectures at international and scientific meetings and has published more than 80 research papers. His current research interests include computer applications in the radiological sciences with emphasis on electronic medical imaging and CT physics with emphasis on CT cardiovascular imaging.

Staff

OURANIA (RANIA) KOSTI

Rania Kosti, Ph.D., joined the staff of the Nuclear and Radiation Studies Board in January 2011. Prior to her current appointment, Dr. Kosti was a post-doctoral fellow at the Lombardi Comprehensive Cancer Center at Georgetown University Hospital in Washington, D.C., where she conducted research on biomarker development for early cancer detection using case-control epidemiologic study designs. She focused primarily on prostate, breast, and liver cancers and trying to identify those individuals who are at high risk of developing malignancies. She contributed on hypotheses generation, study design, data analysis, and management of clinical databases and biospecimen repositories. Dr. Kosti also trained at the National Cancer

Institute (NCI) (2005-2007) in the Cancer and Developmental Biology Laboratory; during the same period she volunteered in NCI's Division of Cancer Epidemiology and Genetics. Dr. Kosti received a B.Sc. in biochemistry from the University of Surrey, United Kingdom, an M.Sc. in molecular medicine from the University College London, and a Ph.D. in molecular endocrinology from St. Bartholomew's Hospital in London.

Appendix D

Workshop Speakers Biographical Sketches

Charles M. Anderson, M. D., Ph.D., is the chief consultant for diagnostic services in the Veterans Health Administration. He prepares policy and coordinates national diagnostic initiatives. Dr. Anderson received a Ph.D. in molecular biophysics and biochemistry from Yale University, an M.D. from Stanford University, and residency training in diagnostic radiology from University of California, San Francisco (UCSF). Dr. Anderson was a clinical professor of radiology at UCSF until 2008. He is a practicing radiologist at Durham North Carolina VA Medical Center.

David J. Brenner, Ph.D., is the director of the Center for Radiological Research at Columbia University, as well as the director of the Radiological Research Accelerator Facility and principal investigator of the Center for High-Throughput Minimally-lnvasive Radiation Biodosimetry, which focuses on developing mechanistic models for the effects of ionizing radiation on living systems, both at the chromosomal and animal levels. He divides his research time between the effects of high doses of ionizing radiation (relating to radiation therapy) and the effects of low doses of radiation (relating to medical, environmental, and occupational exposures).

James A. Brink, M.D., is professor and chair of the Department of Diagnostic Radiology at Yale University School of Medicine. He earned a B.S. degree in electrical engineering at Purdue University and an M.D. at Indiana University before completing his residency and fellowship at Massachusetts General Hospital. While he has broad experience in medical

imaging, including utilization and management of imaging resources, he has particular interest and expertise in issues related to the monitoring and control of medical radiation exposure, which can be compounded if testing is superfluous, unnecessary, or redundant.

Mythreyi Bhargavan Chatfield, Ph.D., is the director of data registries at the American College of Radiology (ACR) in Reston, Virginia. In this position, she manages national registries focused on improving practice quality in radiology. Dr. Chatfield's current areas of focus include practice quality in radiology, performance metrics, and radiation doses from medical procedures. She is a council member of the National Council on Radiation Protection and Measurements (NCRP), an organization chartered by the U.S. Congress to develop expert consensus on issues related to radiation protection using independent scientific analysis. She has a Ph.D. in economics from Rutgers University.

Gwen Darien is a cancer survivor who brings a wealth of personal and professional experiences to her position as executive director of the Samuel Waxman Cancer Research Foundation. She was the founding director of the American Association for Cancer Research's (AACR) department of Survivor and Patient Advocacy. Ms. Darien was editor-in-chief of *CR* magazine and director of the American Association for Cancer Research Survivor and Patient Advocacy Program. She was previously the editor-in-chief of *MAMM*. Ms. Darien is chair of the National Cancer Institute (NCI) Director's Consumer Liaison Group and is a member of the Board of Directors of Education Network to Advance Cancer Clinical Trials. She has served as member of the Secretary's Advisory Committee on Health, Genetics and Society and the faculties of the AACR/American Society of Clinical Oncology Methods in Clinical Cancer Research Workshop, Accelerating Anti-Cancer Agent Development and on the advisory board of the Health Advocacy Program at Sarah Lawrence College.

Kenneth Denison, Ph.D., is responsible for leading all dose-related activities for General Electric (GE) Healthcare's CT business including lower-dose technologies, dose monitoring and tracking systems, new services and solutions, education and training, and coordination of industry, public, and government relations activities relative to the dose issue. His focus is on helping GE Healthcare customers worldwide lower the radiation doses used in their practices. He holds seven patents, all in the design of MRI systems. He received both his B.S. and Ph.D. degrees in chemical engineering from the University of Kentucky in Lexington.

Donald P. Frush, M.D., F.A.C.R., F.A.A.P., is professor of radiology and pediatrics, chief of pediatric radiology and vice-chair for safety and quality, Department of Radiology, Duke Medical Center. He is also a councilor for NCRP, and he is on the boards of both the ACR and American Board of Radiology (ABR). He is a fellow in the Society of Computed Tomography and Magnetic Resonances, a steering committee member of the Alliance for Radiation Safety in Pediatric Imaging (Image Gently Campaign), and works with the International Atomic Energy Agency (IAEA) Smartcard Radiation Tracking Project. Research includes CT image quality, dose assessment, and dose reduction in children.

Katharine Grant, Ph.D., is currently a CT staff scientist for Siemens Medical Solutions USA and serves as a collaboration manager/scientific liaison between luminary customers and Siemens' physicists. Dr. Grant joined Siemens in 2009 after being awarded a post-doctoral fellowship from the Director of Central/National Intelligence and working as a research associate within the Special Purpose Processor Development Group (SPPDG) at the Mayo Clinic. She received her B.S. in physics from Miami University in 2000 and her Ph.D. in biomedical engineering from the Mayo Clinic College of Medicine in 2005. Dr. Grant is also an adjunct assistant professor of radiology and physiology at the Mayo Clinic.

Michael S. Lauer, M.D., has served as director of the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute. Dr. Lauer is a cardiologist and clinical epidemiologist noted for his work on diagnostic testing, clinical manifestations of autonomic nervous system dysfunction, and clinical comparative effectiveness. Dr. Lauer received a B.S. in biology from the Rensselaer Polytechnic Institute and an M.D. from Albany Medical College; he also participated in the Program in Clinical Effectiveness at the Harvard School of Public. He received post-graduate training at Massachusetts General Hospital, Boston's Beth Israel Hospital, and the Framingham Heart Study. Prior to joining the National Institute of Health (NIH), Dr. Lauer was a professor of medicine, epidemiology, and biostatistics at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University.

Kiyohiko Mabuchi, M.D., M.P.H., deputy chief, Radiation Epidemiology Branch, head of the Chernobyl Research Unit, and senior scientist, in the Division of Cancer Epidemiology and Genetics at the NCI, currently directs epidemiological studies of thyroid disease and leukemia risks following the Chernobyl nuclear reactor accident and also is engaged in continuing follow-up studies of cancer in the Japanese atomic-bombing survi-

vors, collaborating with the Radiation Effects Research Foundation. He received an M.D. from Osaka University Medical School and an M.P.H./Dr.P.H. from the John Hopkins University School of Hygiene and Public Health. He has been a member of several international radiation committees, including the International Commission of Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and the UK National Radiological Protection Board's Advisory.

Richard Mather, Ph.D., has worked in medical imaging for more than 17 years including formal training at University of California, Los Angeles, in the biomedical physics graduate program. He received his Ph.D. in 1997. At Toshiba, Dr. Mather has been integrally involved in research projects that validate Toshiba's CT products in the medical community.

Michael McNitt-Gray, Ph.D., is professor of radiological sciences in the David Geffen School of Medicine at UCLA. He is also the director of the biomedical physics graduate program there. He received his Ph.D. in biomedical physics from UCLA in 1993; his MSEE from Carnegie Mellon University in 1980, and his BSEE from Washington University in St. Louis in 1979. He currently serves on the International Commission on Radiation Units (ICRU) Committee on Image Quality and Patient Dose in Computed Tomography, and he chairs both the ACR CT Accreditation Program Physics subcommittee and the American Association of Physicists in Medicine CT Subcommittee. His current research interests include investigations into x-ray computed tomography with specific research into the physics of CT image acquisition including estimating radiation dose and assessing image quality.

Charles W. Miller, Ph.D., joined the Centers for Disease Control and Prevention in January 1992. He is currently chief of the Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health. In this position, he develops goals and objectives that integrate organization and environmental public health programs on the potential effects of exposure to radiation and radiation-related health research, including providing leadership for the agency's radiological emergency response and consequence management efforts. Dr. Miller is a member of the NCRP, and he is a fellow of the Health Physics Society. Dr. Miller holds a B.S. in physics/math from Ball State University, a M.S. in meteorology from the University of Michigan, and a Ph.D. in bionucleonics (health physics) from Purdue University.

Donald L. Miller, M.D., is acting chief, Diagnostic Devices Branch, Division of Mammography Quality and Radiation Programs in the Center for Devices and Radiological Health of the FDA. He received a B.A. in molecular biophysics and biochemistry from Yale University in 1972 and an M.D. from the New York University School of Medicine in 1976. He is a fellow of the Society of Interventional Radiology and the ACR, a consultant to the IAEA, a member of Council of the NCRP, and a member of Committee 3 of the ICRP.

Gail Prochaska has been with IMV since 1987 during which time she has worked with vendors and professional societies to develop and use market data and census databases to capture procedures, consumables, and equipment for multiple diagnostic imaging modalities and radiation therapy. Prior to IMV, Ms. Prochaska held marketing, sales, and management positions at Amersham (now GE). She has a B.S. in biology from the University of Illinois at Champaign-Urbana.

Madan M. Rehani, Ph.D., has been working at IAEA, Vienna, Austria for the past 10 years and manages radiation protection of patients projects in more than 60 countries. He is responsible for initiating and directing patient radiation exposure tracking project at IAEA. Prior to joining IAEA he was professor and head at the Medical Physics Unit at the All India Institute of Medical Sciences, New Delhi. He has chaired three task groups of the ICRP, which led to Annals of ICRP.

Ashok Shah, M.B.A., is the general manager of IMV Ltd. and has more than 30 years' experience in the health care and scientific products markets. Prior to IMV, Mr. Shah held positions with IMS Health, Fisher Scientific, and Becton Dickinson & Co. He has an M.B.A. from McGill University, Montreal, and a B.S. in microbiology.

Dominic Siewko is the radiation safety officer for Philips Healthcare and has been in this role for two years. He previously worked for GE Healthcare for the past 10 years in a health physicist position supporting radiopharmaceutical manufacturing. He currently manages the radiation/product safety and radiation regulatory program for all nuclear and x-ray imaging modalities globally for Philips and is based out of Andover, Massachusetts. He is active in the Medical Imaging and Technology Alliance, Society of Nuclear Medicine, and Health Physics Society, and is certified by the American Board of Health Physics.

Aaron Sodickson, M.D., is the section head of emergency radiology at Brigham and Women's Hospital, medical director of CT for the Brigham Radiology Network, and assistant professor of radiology at Harvard Medical School. His primary research focus is on informatics methods to automatically extract radiation exposure data on a large scale from existing sources in the electronic medical record, and use of the resultant databases for quality control and patient safety applications. Related research and clinical quality improvement efforts involve CT technology assessment and imaging optimization to achieve high-quality imaging at low radiation dose.

David C. Spelic, Ph.D., is a physicist with the FDA's Center for Devices and Radiological Health. He joined the agency in 1994, and he is involved in public health activities regarding medical x-ray based imaging. He also has primary responsibility for the Nationwide Evaluation of X-ray Trends survey program, a cooperative effort with the Conference of Radiation Control Program Directors and state-level radiation control offices to characterize patient radiation doses from selected medical x-ray examinations performed in the United States.

Raymond H. Thornton, M.D., trained as a concert pianist at the Juilliard School before attending medical school at the University of Pittsburgh. He completed residency in diagnostic radiology and fellowship training in vascular interventional radiology at the University of California at San Francisco. At Memorial Sloan-Kettering Cancer Center, he serves as vice-chair of Radiology for Quality, Safety and Performance Improvement and Training Program Director for the Interventional Radiology fellowship, in addition to maintaining a busy clinical practice in interventional radiology.