

American College of Radiology White Paper on Radiation Dose in Medicine

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The benefits of diagnostic imaging are immense and have revolutionized the practice of medicine. The increased sophistication and clinical efficacy of imaging have resulted in its dramatic growth over the past quarter century. Although data derived from the atomic bomb survivors in Japan and other events suggest that the expanding use of imaging modalities using ionizing radiation may eventually result in an increased incidence of cancer in the exposed population, this problem can likely be minimized by preventing the inappropriate use of such imaging and by optimizing studies that are performed to obtain the best image quality with the lowest radiation dose. The ACR, which has been an advocate for radiation safety since its inception in 1924, convened the ACR Blue Ribbon Panel on Radiation Dose in Medicine to address these issues. This white paper details a proposed action plan for the college derived from the deliberations of that panel.

Key Words: Radiation dose, radiation safety, radiation risk, radiation exposure, radiations, exposure to patients and personnel

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INTRODUCTION

Ionizing radiation has been used for diagnostic purposes in medicine for more than a century. The benefits are immense and certainly exceed the risks. The more recent development of remarkable equipment such as multidetector row computed tomography and the increased utilization of x-ray and nuclear medicine imaging studies have improved the lives of our patients and, along with other new modalities, revolutionized the practice of medicine. However, this dramatic evo-

lution of imaging has also resulted in a significant increase in the population's cumulative exposure to ionizing radiation. Will this cause an increased incidence of cancer years down the line? Although the answer to that question is currently under debate, the presumption is that it will.

Consequently, there is increasing international and federal interest in, and scrutiny of, radiation dose from imaging procedures. Although there has been recent widespread interest in patient safety issues [1], the possible hazards associated with radiation exposure generally have not been brought into clear focus by the public or members of the medical community other than radiologists. The ACR, pursuing its commitment to radiation safety, currently supports the following activities: accreditation programs, practice guidelines and technical standards [2], Appropriateness Criteria[®] [3], a dose index registry (in progress), educational programs, the RadiologyInfo public information Web site (jointly developed with the Radiological Society of North America [RSNA]) [4], collaborations with government and legislators on safety issues, and research activities such as the ACR Imaging Network (ACRIN)[®]. To further enhance radiology's leadership role in the arena of patient safety, the chairman of the ACR Board of Chancellors convened the ACR Blue

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Table 1. Growth of computed tomography (CT) and nuclear medicine examinations in the United States (approximate) [5-8]

Examination	1980	2005
CT	3,000,000	60,000,000
Nuclear medicine	7,000,000	20,000,000

Ribbon Panel on Radiation Dose in Medicine to assess the current situation and to develop an action plan for the ACR that would further protect patients and inform the public. Panel members included private practice and academic diagnostic radiologists, medical physicists, representatives of industry and regulatory groups, and a patient advocate. This white paper is the result of the panel's deliberations.

SCOPE OF THE PROBLEM

Over the past quarter century, there has been a rapid growth in both the number of diagnostic x-ray examinations and the introduction of newer, very valuable, but also relatively high-dose technologies (see Table 1 [5-8]). In 1987, medical x-rays and nuclear medicine studies contributed less than 15% of the average yearly radiation exposure received by the US population; the large majority was attributable to radon and other natural sources [9]. Two decades later, because of the dramatic increase in the number of diagnostic examinations performed each year as well as the higher doses associated with these examinations, this fraction has most likely increased.

Before a new technology or procedure that uses ionizing radiation is introduced, there should be general agreement that the benefits exceed the risks and that an attempt has been made to reduce the potential risks as low as practicable [10]. Ionizing radiation, especially at high doses, has long been known to increase the risk for developing cancer. In fact, x-rays have recently been officially classified as a "carcinogen" by the World Health Organization's International Agency for Research on Cancer [11], the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention [12], and the National Institute of Environmental Health Sciences [13]. The most comprehensive epidemiologic study supporting the carcinogenic effect of radiation is that of the atomic bomb survivors in Japan. The data from this study show a statistically significant increase in cancer at dose estimates in excess of 50 mSv [14]. Whether there is a cancer risk at lower doses remains controversial. It is worth noting that many computed tomographic (CT) scans and nuclear medicine studies have effective dose estimates in the range of 10 to 25

mSv for a single study [15-18], and some patients have multiple studies; thus, it would not be uncommon for a patient's estimated exposure to exceed 50 mSv. In further validation of this concern, the International Commission on Radiological Protection has reported that CT doses can indeed approach or exceed levels that have been shown to result in an increase in cancer [19].

Although there are currently no data showing that high-dose medical diagnostic studies such as computed tomography and nuclear medicine have actually increased the incidence of cancer, a 2004 study (using survey data from 1991 to 1996) suggested that medical exposure might be responsible for approximately 1% of the cancer in the United States [20]. This rate can be expected to increase on the basis of the higher number of examinations performed today. On the other hand, as the use of medical radiation has increased, the incidence of some cancers has actually decreased. For example, lung cancer is decreasing in men because of smoking cessation, and breast cancer is leveling off [21], possibly because of less estrogen use. Does this mean that current radiation exposure can be neglected? The answer is no. Radiation-induced cancers typically do not occur until 1 or 2 decades or longer after exposure. Thus, any increase in cancer occurrence due to burgeoning medical exposures in the past 2 decades, as is the case for CT and nuclear medicine studies, may not be expected to be evident for many years. In addition, because radiation is a relatively weak carcinogen, it is difficult to isolate radiation-induced cancers (1/1,000 per 10-mSv effective dose) that are superimposed on the normal background risk for other cancers (approximately 40% of the population will be diagnosed as having cancer at some point in their lives) [22].

To put the issue in perspective, the current annual collective dose estimate from medical exposure in the United States has been calculated as roughly equivalent to the total worldwide collective dose generated by the nuclear catastrophe at Chernobyl [23,24]. Therefore, one can assume, using International Commission on Radiological Protection [25] risk factors and other data cited above, that this annual collective dose may likely result in an increase in the incidence of imaging-related cancer in the US population in the not-too-distant future.

The preceding information poses many challenges for referring physicians, radiologists, radiologic technologists, medical physicists, equipment vendors, regulators, and patients. Subsequent sections in this white paper recommend actions the ACR should take to manage this potential problem.

MEASUREMENTS

Recommendations

- The ACR should adopt the policy of expressing quantitative radiation dose values as dose estimates and replace the term *dose* with *dose estimate* as ACR publications are revised.
- The ACR should support the development of a national database for radiation dose indices to address the actual range of exposures for x-ray examinations.

There are references to radiation dose and radiation exposure throughout this paper. It is critical for the reader to understand the terminology, especially as it pertains to the difference between the easily measured radiation exposure from the various imaging modalities and the actual amount of radiation absorbed by a patient.

The determination of ionizing radiation dose to a living human from an x-ray examination or nuclear medicine study is very complex. Even during radiation oncology treatment, the radiation dose is actually measured only in extreme cases. This never occurs in diagnostic imaging. To determine the absorbed radiation dose, the initial x-ray beam exposure and the absorption in each organ must be known. It is the latter quantity that complicates this determination. This absorption is dependent on the amount and properties of each tissue encountered by the x-ray beam, and these parameters vary widely among patients. The situation is further complicated because it is not practical to insert radiation detectors into each organ of every patient.

For x-ray examinations, the radiation dose is estimated by a calculation that involves an actual physical measurement multiplied by various factors (Table 2):

$$\text{Dose Estimate} = \text{Radiation Measurement} \times \text{Factors.}$$

The various factors [25-29] are generated by Monte Carlo simulations [29] using mathematical representations of the human body. Although the latest research work in this area seeks to provide closer representations for the range of body sizes [30-32], these

calculations currently provide only an estimate for a single anatomic model. Furthermore, when estimating population doses, these calculated values are multiplied again by weighting factors [25] that change as scientific and professional organizations do their best to examine past exposures and subsequent biologic effects. Hence, it is important to understand that the reported numerical values for individual radiation doses may vary by factors of 5 to 10 depending on individual patients and the manner of image acquisition. Although there is little doubt that the absorbed radiation dose for an abdominal CT examination is larger than that for a radiograph of the ankle, the precise numeric quantity (particularly for an individual) is quite problematic. Therefore, the ACR should adopt a policy of expressing quantitative values regarding radiation dose as "dose estimates." Furthermore, in future ACR publications, the term *dose* should be replaced with *dose estimate*.

For population exposure measurements, a range of values would more accurately describe the situation. Currently, there are few data on which to base such estimations. However, with the growing applications of digital imaging, such data can now be easily acquired. Digital x-ray imaging systems, such as computed radiography, digital radiography, and computed tomography provide an index related to the amount of radiation that was generated to form an image. Currently, these quantities are either displayed at the operator's console or embedded with the image itself. If these data were to be extracted and a central database established for dose indices as a function of patient parameters (eg, gender, age, size) and examination type (eg, lateral lumbar spine, pelvic computed tomography), the relative range of radiation doses could be analyzed. The feasibility of such a database is currently being examined by the ACR, and continued support of this initiative is essential. The value of such a database lies in its ability to demonstrate changes in dose indices due to technologic advances and practice modifications. These trends would be useful to advisory radiation safety agencies as well as to individual

Table 2. Radiation quantities and units

Quantity	Unit	Determination
Exposure	Coulomb per kilogram (C/kg), roentgen (R)	Measurement
Dose	Gray (Gy), rad	Multiply exposure by f-factor or a conversion factor
Equivalent dose	Sievert (Sv), rem	Multiply dose by a quality factor
Effective dose	Sv, rem	Multiply equivalent dose by a tissue weighting factor

practices wishing to compare their own doses against established benchmarks.

REFERRING PHYSICIANS

Recommendations

- The ACR should work to convince the Liaison Committee on Medical Education and the Association of American Medical Colleges of the need for a standard methodology of introducing medical students to radiation exposure in medical imaging and offer to prepare learning materials in support of this initiative.
- The ACR should work with the American Medical Association to ensure the wide dissemination and enactment of its *Council Report on Diagnostic Radiation Exposure*.
- The ACR should request that the Council of Medical Specialty Societies (CMSS) address the critical issue of radiation exposure during medical imaging with its member societies.
- The ACR should add relative radiation dose levels to its Appropriateness Criteria[®] and work to ensure that the Appropriateness Criteria can be integrated into physician order entry systems for real-time guidance in ordering imaging examinations.
- The ACR should sponsor a summit meeting with leaders from emergency medicine to discuss developing consensus guidelines for imaging common conditions for which computed tomography may be overutilized.

Although some referring physicians are very knowledgeable regarding radiation safety issues and incorporate such information into their imaging decisions, others have had little or no training in radiation exposure and do not routinely consider this factor when ordering imaging examinations. Furthermore, non-physician health care providers (eg, physician assistants, nurse practitioners) may be granted the authority to order imaging studies, and their ordering patterns are likely to reflect the behavior of their supervising physicians. Subsequent references to referring physicians in this paper assume that their imaging preferences would likely be reflected in those they supervise.

Educating future referring physicians on radiation exposure to patients during diagnostic imaging must begin during medical school. Radiology clerkships, in which students can be easily introduced to radiation safety issues, are not required by all medical schools. A more practical solution might include integrating mandatory material on radiation safety into the general curriculum. The method of instruction, clerkship, or general curriculum is not as important as the goal of inculcating the awareness of radiation exposure in students during training. The ACR should approach the

Liaison Committee on Medical Education, the accrediting body for medical schools, with a proposal to incorporate such a requirement into the standards that schools must meet for accreditation. The Association of American Medical Colleges may prove an effective ally in accomplishing this goal. Furthermore, the ACR should offer to develop learning materials on radiation dose in medicine and should approach the Alliance of Medical Student Educators in Radiology for input in support of this initiative.

The issue of radiation exposure associated with diagnostic imaging should be reinforced for nonradiology residents during their postgraduate years. Although core competencies for residents typically address patient safety issues, they generally lack the curriculum content specific to radiation safety. Academic practices should be encouraged to provide appropriate guidance for nonradiology house staff regarding both the risks associated with radiation and the appropriate clinical indications for imaging in an effort to develop knowledgeable referral patterns on the part of these physicians as they enter practice.

Education regarding the risks of radiation exposure provides a good foundation for physicians as they consider imaging preferences, but it is always beneficial to reinforce theory with tangible information. The ACR Appropriateness Criteria[®] [33,34] offers an important decision-making framework for radiologists, referring physicians, and trainees at all levels. Incorporating relative radiation dose levels into these guidelines will produce a powerful tool for influencing the proper utilization of imaging examinations, based not only on efficacy but also on potential radiation exposure of the patient. The ACR should enact this revision and work to ensure that the Appropriateness Criteria are in a compatible electronic format that would allow them to be used within, or linked to, hospital information systems and physician order entry systems. By prominently displaying the relative radiation exposure level for a particular examination during order entry, a clinician may be steered toward an imaging regimen that minimizes radiation. Furthermore, the display of the appropriateness rating for an examination (on a scale of 1 to 9, with 9 being the most appropriate) at the time of order entry is designed to influence an ordering physician to choose the most efficacious examination for a given clinical condition. It is likely, though not proved, that more appropriate utilization of imaging will reduce overall radiation exposure of patients. When imaging guidelines such as those just described are built into order entry systems, regularly posting individual physician ordering patterns (both appropriate and inappropriate) may positively influence physician ordering behavior through peer pressure.

There are other ways in which the ACR can raise and redirect awareness of referring physicians regarding the relative radiation doses associated with various imaging examinations and the risks associated with diagnostic radiation exposure. The ACR should approach the American Medical Association, as a follow-up to its *Council Report on Diagnostic Radiation Exposure* [35], with an offer to develop collaborative programs or Web content directed at nonradiologist physicians. The Council of Medical Specialty Societies is another organization that could provide an appropriate venue for raising the awareness of referring physicians about imaging-related radiation exposure of patients. The CMSS vision calls for convening specialty societies to identify critical issues, defining common policies and positions, and influencing decisions in the best interest of the public [36]. The ACR, which is a member in good standing of CMSS, should request that CMSS make its other member societies aware of this increasingly urgent problem.

Influencing referral patterns from emergency departments, for example, poses a major challenge. Patients arriving at emergency departments are acutely ill or injured, may have incomplete medical records, and may not be able to communicate their medical histories accurately. The Emergency Medical Treatment and Labor Act (part of the Consolidated Omnibus Budget Reconciliation Act of 1986) [37] requires that any patient who comes to an emergency department be provided with "an appropriate medical screening examination" to determine if the patient is suffering from an emergency medical condition. If such a condition is present, the institution has the duty to treat the patient. Emergency department physicians are aware that computed tomography can provide quick, reliable answers to many clinical questions. The Emergency Medical Treatment and Labor Act and other concerns regarding medical liability, along with the known clinical efficacy of CT scans, have been significant drivers of CT referrals.

Merely providing educational programs for emergency physicians regarding the radiation risks associated with computed tomography is likely to do little to alter their referral patterns. Rather, the ACR should proactively sponsor a summit meeting between leaders of radiology and emergency medicine to address the growing issue of increasing radiation exposure to patients due to the overutilization of medical imaging. This group should discuss developing consensus statements and guidelines for evaluating common clinical presentations, such as suspected pulmonary embolism or ureteral calculus, and for reviewing a patient's history to identify excessive imaging that may have unnecessarily resulted in high levels of radiation exposure. Such consensus guidelines could be powerful tools for improving the appropriate utilization of imaging. If successful, this collabora-

tive process should be extended to include other specialties.

RADIOLOGISTS

Recommendations

- The ACR should support the current multiorganizational effort to improve radiology resident training in medical physics.
- The ACR should include additional questions on radiation safety and patient dose in its Annual In-Training Examination.
- The ACR should request that the American Board of Radiology consider requiring at least 1 self-assessment module on patient safety, to include radiation dose, every 10 years as an integral part of the maintenance of certification.
- The ACR should develop and implement maximum radiation dose estimate pass/fail criteria for the ACR CT Accreditation Program.
- The ACR should review and update the CT Accreditation Program's recommended scanning protocols on a routine basis and make them available on its Web site.
- The ACR should request that the editor of the *Journal of the American College of Radiology (JACR)* add a monthly column on patient safety (to include radiation exposure issues).
- The ACR should create a prominent safety link on its Web site's home page to facilitate access to this information and to demonstrate the priority given to patient safety.
- The ACR should include in its *Practice Guidelines and Technical Standards* additional considerations for special radiosensitive populations, such as children and pregnant and potentially pregnant women.
- The ACR should encourage radiology practices to record all fluoroscopy times, compare them with benchmarks, and evaluate outliers as part of ongoing quality assurance programs.
- The ACR should encourage radiology practices to define a surveillance mechanism to identify patients with high cumulative radiation doses due to repeated imaging.

It has been suggested that radiologists embody 3 principal attributes: clinical acumen, mastery of technology, and dedication to safety and quality [38]. A compelling argument exists that mastery of imaging technology is the linchpin to these attributes, and that one cannot master the technology without learning the principles and applications of the physics underlying the technology. It is then essential that all radiologists continually refresh their knowledge regarding the basics of radiation safety to be able to effectively apply them when imaging and

when consulting with their patients and referring physicians.

To ensure that every radiologist is committed to the safe practice of radiology, especially in the daily application of radiation safety principles, a more standardized approach to physics education at the resident level is necessary. The panel was pleased to learn that the American Association of Physicists in Medicine (AAPM) held a forum on physics education in January 2006, to address the issue [39]. The RSNA sponsored a multiorganizational follow-up meeting in February 2007. The draft curriculum being considered by the participants in this educational initiative covers radiation safety in detail. Definitive planning is under way for improving training in medical physics by strengthening residency program accreditation requirements, linking physics topics to professional certification examinations, and reinforcing clinically relevant physics issues through continuing education and the maintenance of certification. The panel fully endorses this process as a means of better incorporating the tenets of radiation safety into the training of all radiology residents. To supplement these efforts, the ACR should include additional questions on radiation safety and patient dose in the ACR Annual In-Training Examination.

The maintenance of certification in radiology, administered by the American Board of Radiology, requires completion of a minimum of 20 self-assessment modules during each 10-year recertification period [40]. In light of the above comments regarding physics education and the need to continually reinforce the lessons learned, it seems reasonable for the ACR to approach the American Board of Radiology with the request that diplomates be required to complete at least 1 module addressing patient safety, including material specific to radiation dose, among the 20 needed every 10 years.

Since its development, the ACR CT Accreditation Program [41] has been attracting a steadily increasing number of practices to seek accreditation. This is occurring for several reasons, including: the desire for a public display of practice excellence, as a marketing strategy, and to meet the requirements that some payers impose for reimbursement. The program has gathered credible data on the range of radiation exposure factors associated with various CT examinations and therefore is able to define good practice regarding radiation exposure [42]. The ACR should now take this a step further and implement maximum radiation dose estimate pass/fail criteria for its CT Accreditation Program.

Default settings and vendor-supplied protocols for computed tomography may be designed to provide optimal imaging quality. However, it is often the case that sufficient image quality for the examination may be maintained by using alternative protocols that also sig-

nificantly reduce radiation exposure. The Committee on CT Accreditation currently provides recommended scanning protocols as part of the accreditation program. The committee should review and update these routinely and post them on the ACR's Web site.

More information on general patient safety, as well as radiation safety, needs to be made available to the practicing diagnostic radiologist. The aim of the *JACR* is to "fill the need for information on clinical parameters, practice management, education, health policy, and research on radiology health services" [43]. In keeping with this mission, the ACR should request that the editor of *JACR* add a monthly column on patient safety (to include radiation exposure issues) in the journal. Because *JACR* is widely read by ACR members, this column could provide an effective vehicle for keeping the issue of radiation dose squarely in front of practicing radiologists.

Although the ACR's Web site allows members and other interested parties access to many resources related to patient safety (eg, *Practice Guidelines and Technical Standards* [2], a magnetic resonance imaging safety white paper [44], accreditation guidance [45]), these resources are scattered throughout the site and may not be readily apparent. The ACR should create a prominent safety link on its Web site's home page to facilitate finding all ACR safety information. This link would also serve to demonstrate the priority the ACR places on patient safety.

There are special patient populations, notably children and pregnant and potentially pregnant women, that radiology departments and organizations should target for additional radiation protection. The ACR is currently developing a practice guideline for appropriate screening for pregnancy before radiology testing that uses ionizing radiation. Because children have greater risks from ionizing radiation than adults, the ACR should also develop additional practice guidelines and technical standards to protect them.

Although the ACR plans to be a resource for implementing many new programs designed to help protect patients, it is incumbent on radiology practices and departments to accept responsibility for minimizing radiation dose. In this regard, increased oversight of fluoroscopy time will promote acute awareness of radiation exposure levels. Although the ACR currently recommends that radiation dose-related information or fluoroscopic exposure times be recorded in patients' medical records for procedures involving more than 10 minutes of fluoroscopic exposure [46], it should now encourage practices to record actual fluoroscopy time for all fluoroscopic procedures. The fluoroscopy time for various procedures (eg, upper gastrointestinal, pediatric voiding cystourethrography, diagnostic angiography) should then be compared with benchmark figures, such as those pub-

lished by the AAPM [47]. More complete patient radiation dose data should be recorded for all high-dose interventional procedures, such as embolizations, transjugular intrahepatic portosystemic shunts, and arterial angioplasty or stent placement anywhere in the abdomen and pelvis [48]. Excessive exposure times and doses should warrant further evaluation as part of practices' quality assurance programs and Joint Commission sentinel event policy [49].

One of the more important processes that can be implemented in any radiology practice, whether outpatient or hospital based, is review of the imaging histories of all patients presenting for studies. For example, it is not uncommon since the advent of noncontrast computed tomography for evaluating patients with suspected ureteral calculus to find patients who have had multiple scans over a period of months or years. In some of these cases, and at least on some occasions, the combination of a kidney, ureter, and bladder radiograph (KUB), and ultrasound might also be diagnostically effective and therefore provide a safer imaging regimen. Routine reviews of patients' detailed imaging histories will alert radiologists that such alternatives should be considered. However, the imaging records must be scrupulously reviewed to identify these patients. The ACR should encourage practices to make this review a standardized element of practice policy.

TECHNOLOGISTS

Recommendations

- The ACR should encourage radiology practices to provide in-service training on radiation safety issues for their technologists on a regular basis.
- The ACR should phase in the requirement that at least 1 technologist per accredited CT site hold the American Registry of Radiologic Technologists advanced registry in computed tomography and that at least 1 technologist per accredited nuclear medicine site hold the advanced registry in nuclear medicine or certification by the Nuclear Medicine Technology Certification Board.
- The ACR should continue to support the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy ACT (known as the CARE bill).

A radiologic technologist is typically the first, and may be the only, health care professional to interact with a patient presenting for a radiologic procedure. To respond to patients' imaging-related questions, technologists need to be familiar with all components of the particular examinations, including not only the technical aspects but also the associated radiation dose and risk. Furthermore, it may be a technologist who recognizes

that a duplicate or questionably indicated examination has been ordered for a patient or that a patient has undergone multiple similar examinations. An alert technologist should notify the radiologist in such a case and thereby possibly avoid exposing the patient to unnecessary radiation.

Technologists are responsible for determining the need for additional radiation safety actions before a radiation exposure. Considerations include the identification of high-risk patients (ie, children and pregnant or potentially pregnant women) and the imaging of body parts in which sensitive tissues (ie, fetus, thyroid, breasts, bone marrow, gastrointestinal tract, gonads, and eyes) might be irradiated. For such patients, technologists may need to use individualized shielding or collimation; for others, technologists may need to consult with radiologists about substituting lower dose examinations (eg, fewer images or radiography instead of computed tomography). In addition, technologists are responsible for limiting radiation exposure to patients by ensuring that proper procedures and techniques are followed to prevent the need for repeated imaging because of suboptimal image quality.

It is generally accepted that technologists are appropriately trained and expected by radiology practices to perform the functions described above. To enhance performance in this arena, the ACR should encourage practices to provide regular in-service training in radiation safety issues for their technologists and to make sure they know to communicate any related problems to radiologists for resolution.

Patient exposure considerations are more critical in computed tomography and nuclear medicine because the doses are typically much higher than for radiographic or fluoroscopic procedures. To produce high-quality images with the lowest possible patient doses, CT technologists need to understand and use well-established protocols. In nuclear medicine, there has been increasing complexity of cardiac procedures and positron emission tomographic examinations. Such examinations require more expertise on the part of technologists. Therefore, both CT and nuclear medicine technologists should be specially trained, as is currently required by the ACR's CT Accreditation Program and Nuclear Medicine Accreditation Program. Furthermore, the ACR should phase in a requirement that at least 1 technologist per accredited CT site hold the American Registry of Radiologic Technologists advanced registry in computed tomography and at least 1 technologist per accredited nuclear medicine site hold the advanced registry in nuclear medicine or certification by the Nuclear Medicine Technology Certification Board.

The American Society of Radiologic Technologists has supported the introduction of legislation in the US

House of Representatives (HR 583, the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Act, known as the CARE bill) [50] as a means of providing safer medical imaging examinations by setting federal standards for personnel who perform them. This bill specifically requires certification, licensure, testing, training, or experience for individuals who will be involved in performing medical imaging services. The ACR should continue its current support for this legislation.

PATIENTS

Recommendations

- The ACR should, in collaboration with the RSNA, install a prominent patient safety link on the RadiologyInfo home page and regularly review and update information on the Web site regarding the risks and benefits of imaging procedures.
- The ACR should install a prominent patient safety link on the ACRIN[®] home page that will lead patients to information on risks and benefits associated with participation in current ACRIN research protocols.
- The ACR should work with patient advocacy organizations to more effectively communicate the potential radiation risks and health benefits of imaging procedures.

Radiologists understand the potential dangers from ionizing radiation far better than patients do, yet not every radiologist provides a balanced assessment of the risks and benefits of imaging when patients undergo testing [51]. It is incumbent on radiologists to assume the responsibility for their patients' safety with regard to radiation exposure. They should also educate their patients on these issues so they may make informed decisions about their health care. To facilitate this educational process, the ACR should continue collaborating with the RSNA in reviewing and updating their cosponsored patient education Web site, RadiologyInfo [4], to make sure it includes current and understandable information on the risks and benefits of imaging procedures. This material should be easy to customize, download, and print for use by practices and patients. The ACR should advertise the availability of this resource to its members. As with the ACR's Web site, there should be a prominent patient safety link on the RadiologyInfo home page allowing easy patient access to safety information for all types of imaging examinations. The ACR should work with the RSNA to accomplish this. In addition, a safety link on the ACRIN Web site's home page [52] should lead patients to easily understood information on the risks and benefits associated with participation in any of the current ACRIN protocols.

Although patients frequently want to know the radiation "dose" they will receive during examinations, they are generally unfamiliar with radiation terminology and may not understand the level of risk involved. Consequently, any dose estimates should include information on comparative risks. An example of such comparative information is available on RadiologyInfo [53]. Patients should also be informed of the risks to their health should alternative examinations, or perhaps even no examination, be performed.

A review of several patient support Web sites found little information on the benefits and risks associated with imaging examinations. That said, there are many patient advocacy groups (eg, the American Cancer Society, the Susan G. Komen Foundation) with sincere interest in providing accurate information on various diseases. These groups are familiar with their constituencies and have well-established communication systems to reach them. The ACR should work with such patient advocacy groups to improve availability and accessibility of information on radiation exposure associated with medical imaging. For example, direct links to RadiologyInfo on appropriate advocacy Web sites would be of significant benefit to patients.

MEDICAL PHYSICISTS

Recommendations

- The ACR should work with the AAPM to develop a credentialing program for nonradiologist physicians who use fluoroscopy.
- The ACR should task its Commission on Education and Commission on Medical Physics to develop more effective teaching methodologies for medical physics in support of the AAPM-RSNA initiative on physics education for radiology residents.
- The ACR should implement a periodic review and update of its primer on radiation risk [54].

Although much of the ACR's effort regarding radiation safety is focused on computed tomography and nuclear medicine, other modalities such as fluoroscopy also contribute to the public's radiation burden. Fluoroscopy is frequently performed outside radiology departments in cardiac catheterization laboratories, endoscopy suites, operating rooms, pain management clinics, and orthopedic procedure rooms. Medical physicists need to routinely survey these systems to ensure that they are producing acceptable image quality at the lowest possible dose. In addition, medical physicists, working with radiology practices and their facilities' radiation safety officers, should implement programs for credentialing and monitoring the activ-

ities of nonradiologist physicians using radiation. The purpose of these programs would be to maximize patient safety, not to limit the use of fluoroscopy, and they should therefore enjoy strong support by hospital administration. Such programs typically involve preparing brief primers on radiation safety pertaining to fluoroscopy, administering tests on the material in the primers that must be passed by physicians requesting such privileges, and awarding certificates documenting compliance with these educational requirements. This process should also be incorporated into the overall credentialing program of the hospital. Several institutions have already successfully implemented such programs [55,56]. Involving medical physicists in this process is essential, and the AAPM is currently developing such a program. Therefore, the ACR should offer to work with the AAPM on a model credentialing program that includes educational and testing materials. Ideally, the program would be available through the ACR's Web site when complete so that ACR members could share it with their hospitals' credentialing boards and encourage them to adopt the program. If such a program is successful, it should be expanded to credential physicians other than radiologists, radiation oncologists, or nuclear medicine physicians who are responsible for the operation of CT or nuclear medicine equipment in the hospital setting.

As mentioned previously in the section on radiologists, there is a current multiorganizational effort to improve the quality of physics education for radiology residents that the panel finds worthy of ACR support. A comprehensive curriculum on radiologic physics has been developed. In academic institutions with residency programs, the responsibility for teaching this curriculum will belong in large part to medical physicists. For this initiative to succeed, the faculty must be qualified and the material well structured. To this end, the ACR should task its Commission on Education and Commission on Medical Physics to develop and disseminate effective teaching methodologies to medical physicists to ensure that they present their courses clearly, concisely, and in a clinically relevant manner. Such an initiative will hopefully result in radiology residents' discovering that instruction in medical physics is interesting and memorable, so that they will subsequently be able to apply the principles learned throughout their careers.

Because radiology technology and practice are still evolving, and more information on the risk of radiation is constantly being reported, the ACR should task its Commission on Medical Physics to update the 1996 primer on radiation risk [54] and keep this material current by creating a mechanism to regularly review and update this document. A similar publica-

tion, the *Contrast Media Manual* [57], is now in its fifth revision and has become an invaluable resource for radiologists.

VENDORS

Recommendations

- The ACR should work with the National Electrical Manufacturers Association (NEMA) to encourage vendors to ensure that their application specialists are familiar with imaging protocols that emphasize the standard of as low as reasonably achievable for their new equipment.
- The ACR should work with NEMA to encourage vendors to adopt a standardized approach describing exposure indices for computed radiography and digital radiography.
- The ACR should continue working with NEMA to encourage vendors to standardize digital equipment using ionizing radiation so that it automatically captures complete dose information for each examination.

The operational parameters of imaging devices should always be optimized to achieve patient doses that are as low as reasonably achievable. Understanding the imaging demands of the multitude of clinical examinations for multiple sizes of patients, from neonates to large adults, is a challenge for vendors' design engineers and physicists. For example, in the fluoroscopy mode of an interventional unit, voltage, tube current, pulse width, pulse rate, filter material and thickness, focal spot size, exposure level at the image receptor, field of view, and at least a half dozen image-processing parameters can affect not only image quality but also radiation dose. Although vendors automate many of these parameter choices into a single default selection, this automation needs to be based on the need to minimize radiation exposure as well as the desire to produce an optimized image. To address the safety concerns of a procedure, appropriately trained radiologists and medical physicists need to be involved in the selection of imaging parameters. Vendors typically accomplish this collaboration by introducing new equipment at designated clinical sites, often academic departments with which the vendors have formal research agreements. A review of several major computed tomography vendors' Web sites found references to protocols for reducing radiation dose in pediatric patients or during cardiac studies in all cases.

Too often, practicing radiologists unrealistically expect vendors' application specialists to have "all the answers." Vendors need to continually train and update their application specialists to make sure that improved, validated parameter choices are introduced to its entire customer base. To this end the ACR should work with NEMA to encourage vendors to ensure such preparation of their application specialists.

Imaging equipment needs to display and record more information about patient dose. Although the US Food and Drug Administration (FDA)-mandated display of radiation air kerma rate and cumulative air kerma from new fluoroscopic equipment [58] was a good first step, a single, standardized exposure indicator has not been adopted by vendors, particularly across digital radiographic and computed radiographic systems. This confuses imaging staff members, prevents comparison of exposure indices among rooms or institutions, and impedes image quality analysis. The AAPM, with input from vendors, has drafted a standardized exposure indicator for digital radiographic equipment [59]. An International Electrotechnical Commission standard is also being developed through user-vendor cooperation [60]. The ACR should work with the NEMA to encourage adoption of this standard by all vendors.

The displayed radiation dose information should automatically be recorded without operator intervention to eliminate errors and incomplete records that may result from the manual recording of this information. International standards that enable such automatic dose data preservation have already been issued for digital radiography and fluoroscopy [61] and will be issued for computed tomography in 2007 [62]. Vendors, radiologists, and medical physicists have been collaborating on these standards. The ACR should work with the NEMA to ensure this collaboration continues.

REGULATORY AGENCIES, ACCREDITING BODIES, AND THIRD-PARTY PAYERS

Recommendations

- The ACR should approach the FDA and the US Nuclear Regulatory Commission (NRC) and seek input on how it can better support their efforts to minimize unnecessary radiation exposure.
- The ACR should continue working with the Conference of Radiation Control Program Directors (CRCPD) task force developing the document “Suggested State Regulations for Control of Radiation” and encourage its member states to uniformly adopt appropriate regulations.
- The ACR should encourage the Joint Commission to apply its existing credentialing and privileging standards to nonradiologist physicians who wish to use fluoroscopy.
- The ACR should encourage third-party payers to develop a process for identifying patients who have frequent imaging examinations using ionizing radiation and to provide feedback regarding these patients to their referring physicians.

In the United States, regulatory agencies, accrediting bodies, and third-party payers all have important roles to play in reducing unnecessary radiation dose to patients.

Although there is a literal “alphabet soup” of regulatory agencies with some degree of responsibility over ionizing radiation, the FDA, the NRC, and individual state radiologic health agencies have the primary responsibility for medical radiation.

The FDA regulates the manufacturers of medical devices and other electronic products that emit radiation and has promulgated regulatory standards for medical x-ray equipment safety and performance. In general, the FDA has no legislative authority to regulate the users of these devices, with the exception of facilities performing mammography (the Mammography Quality Standards Act of 1992 [63] gave the FDA authority in this case). The FDA takes an active role in providing radiation protection guidance through the Center for Devices and Radiological Health. For example, in 2001, in response to concerns in the pediatric radiology community, the center issued a public health notification warning of the potential risks of radiation-induced cancer from helical computed tomography in young patients [64].

The NRC regulates the use of radioactive materials in medicine, as well as for other applications, except in so-called agreement states, where that regulatory authority has been assumed by the state. The NRC and agreement states need to continue focusing efforts on physician and patient education concerning radiation exposure from nuclear medicine procedures. Given the vital involvement of both the FDA and the NRC in minimizing unnecessary radiation exposure, the ACR should approach both organizations seeking input on how it can better support their efforts.

State regulations on ionizing radiation are variable in scope and enforcement, with a traditional focus on radiation-producing machines and radioactive materials. Although not a regulatory agency, the CRCPD plays an important role in the content of state regulations. This nonprofit organization of state regulators serves as a “common forum for the many governmental radiation protection agencies to communicate with each other and to promote uniform radiation protection regulations and activities” [65]. The ACR should continue working with the CRCPD to encourage its member states to adopt appropriate regulations covered in its document “Suggested State Regulations for Control of Radiation.” In addition, the CRCPD has a partnership with the FDA to periodically characterize radiation exposures to patients from current diagnostic imaging procedures. This program, the Nationwide Evaluation of X-Ray Trends [15], is partially funded by the ACR and has tracked x-ray exposure trends for the past 30 years. The ACR should continue its support of this program.

The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) has been active in the nationwide promulgation of extensive

patient safety initiatives through its hospital accreditation process. However, it has not routinely addressed radiation safety or patient exposure issues occurring outside of radiology. A recently published Joint Commission reviewable sentinel event, an estimated exposure of more than 15 Sv (1,500 rads) during fluoroscopy, is indicative of interest in this arena [49]. More oversight of radiation use at diagnostic levels might serve to prevent such an event. Just as its emphasis on hand washing has positively affected the rate of nosocomial infections, the Joint Commission, by further application of its current credentialing standard requiring relevant training to perform a requested privilege [66], could help prevent the misuse of radiation in hospitals. Therefore, the ACR should encourage the Joint Commission to apply this standard during the accreditation process by requiring nonradiologist physicians who use fluoroscopy to be privileged to do so on the basis of documented training in the safety aspects of this procedure. A credentialing program that could provide relevant training in the safe use of fluoroscopy for nonradiologist physicians was described above in the section on medical physicists.

Third-party payers have played only a small active role in reducing unnecessary radiation exposure until recently. The efforts of third-party payers to control the utilization of imaging have been primarily economic, first with the concept of requiring preauthorization for certain examinations and, more recently, with pay-for-performance incentives. Despite these measures, the number of CT studies performed has risen significantly over the past few years. At the national level, the Blue Cross Blue Shield Association recently commissioned a special report from its Technology Evaluation Commission titled *Potential Health Risks Associated with Radiation Exposure from Diagnostic Imaging*. On November 2, 2006, the Medical Advisory Panel of the Blue Cross Blue Shield Association approved publication of this report [67]. This report, now in draft form and due to be published in the near future, reviews the current literature and issues nonbinding recommendations to the various state Blue Cross/Blue Shield plans (B. Rothenberg, senior scientist, Blue Cross Blue Shield Association, personal communication, 2007).

There are, however, individual state health insurers that have proactively implemented radiation safety programs. In the past year, Anthem Blue Cross/Blue Shield of New Hampshire, Maine and Connecticut, in conjunction with National Imaging Associates (NIA), has embarked on a comprehensive dose reduction initiative that is scheduled for rollout in 2007. This program consists of an educational component, available on the Anthem Web site [68], and a preauthorization tracking software system developed by the NIA, which identifies patients who have reached certain radiation exposure levels

(T. Dehn and F. Apgar, NIA, personal communication, January 2007). Anthem also is exploring a pay-for-performance component of quality-based reimbursement for hospitals and providers centered around the setup and maintenance of meaningful radiation safety programs focused on dose reduction in multidetector row computed tomography (E. Malko and R. LaFleur, medical directors, Anthem New Hampshire Blue Cross Blue Shield, personal communication, 2006). To expand these programs beyond the current, somewhat isolated regional efforts, the ACR should encourage third-party payers to develop a process, such as that planned by Anthem and the NIA, for identifying patients who have frequent imaging examinations using ionizing radiation and to provide feedback regarding these patients to their referring physicians.

CONCLUSIONS

Many questions remain unanswered regarding the fundamental mechanisms of radiation injury. Deoxyribonucleic acid breakage, chromosomal aberrations, and gene mutations caused by radiation exposure, as well as the potential for deoxyribonucleic acid to repair itself between radiation exposures, are important avenues for further investigation. The intensive study of actual occurrences, such as workplace exposure of radiologists, the long-term fate of patients treated with radiation therapy, and the events at Hiroshima, Nagasaki, and Chernobyl have provided some answers and form the basis for the assumptions in this paper regarding the carcinogenic effects of ionizing radiation.

There is no question that the benefits of diagnostic imaging are immense. However, information gleaned from the above events suggests that the rapid growth of CT and certain nuclear medicine studies over the past quarter century may result in an increased incidence of radiation-related cancer in the not-too-distant future. Pending future studies that contradict this assumption, there should be special attention paid to the practical suggestions set forth in this paper, such as education for all stakeholders in the principles of radiation safety, the appropriate utilization of imaging to minimize any associated radiation risk, the standardization of radiation dose data to be archived during imaging for its ultimate use in benchmarking good practice, and, finally, the identification and perhaps alternative imaging of patients who may have already reached threshold levels of estimated exposure from diagnostic imaging.

The recommendations derived from the deliberations of the blue ribbon panel are felt to be feasible, apolitical, and efficient methods to further minimize unnecessary radiation exposure to patients. That said, there is little question that some of these recommendations, were they

to be enacted, would require significant resources in staff time and monetary expense on the part of the ACR. The decision as to which should be pursued, therefore, rests with the ACR leadership.

ACR BLUE RIBBON PANEL ON RADIATION DOSE IN MEDICINE

The members of the ACR Blue Ribbon Panel on Radiation Dose in Medicine are E. Stephen Amis, Jr, MD, chair (radiologist); Kimberly E. Applegate, MD, (radiologist); Steven B. Birnbaum, MD (radiologist); Libby F. Brateman, PhD (medical physicist); Priscilla F. Butler, MS (medical physicist, ACR staff member); James M. Hevezi, PhD (medical physicist); Kalpana M. Kanal, PhD (medical physicist); Paul A. Larson, MD (radiologist); Barbara LeStage (patient advocate); Richard T. Mather, PhD (NEMA representative); John McCrohan, MS (FDA representative); Fred A. Mettler, MD (radiologist); Richard L. Morin, PhD (medical physicist); Michael J. Pentecost, MD (radiologist); Geoffrey G. Smith, MD (radiologist); Keith J. Strauss, MS (medical physicist); James H. Thrall, MD (radiologist); Stephen Vastagh (NEMA representative); Jeffrey C. Weinreb, MD (radiologist); Michael V. Yester, PhD (medical physicist); and Robert K. Zeman, MD (radiologist).

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