

2010 ACR Presidential Address: Patient-Focused Radiology: Taking Charge of Radiation Dose

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Radiology and radiation oncology accidents involving radiation overexposure have caused increased scrutiny by the media, lawyers, our patients, and most recently the US Food and Drug Administration. We should add a new pillar for the ACR called “patient-focused radiology.” We have reached new heights of quality in imaging, but at the same time, we have dramatically increased the radiation dose to the US population. We need to take charge of radiation dose and demonstrate that radiology expertise is essential to safe imaging. We need to introduce computerized order entry software that protects patients and educates physicians about the indications and contraindications of radiology examinations. We need to support the ACR in requesting federally mandated accreditation of all “advanced imaging” and radiation oncology accreditation, whether inpatient or outpatient. We need to support the ACR in requesting that Congress mandate a national CT dose registry, which will give alerts to each facility daily for radiation dose outliers and proactively protect patients from radiation overdoses.

Key Words: Patient focused, patient safety, radiation dose and overdose, ACR CT dose registry, ACR accreditation

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Today, it is my pleasure to speak to you as president in the honored tradition of the ACR, to reflect and to challenge you. The year 2010, has been historic in medicine and radiology with major legislative changes in health care. While there is much to be learned about the future of radiology in this new era, there is a clear challenge, and there is an opportunity for all radiologists to demonstrate our great value in medicine. This has been a year of increased scrutiny of radiology and radiation oncology accidents involving radiation overexposure. These adverse events have captured the attention of the media, the lawyers, our patients, and most recently the US Food and Drug Administration (FDA); it has been an intense year. What do you and I need to do as ACR leaders? Can we just rely on the many years of extensive quality and safety programs that have been initiated by the ACR and just increase what we already do to address these issues? I would propose that we need to do more; we need to focus our attention on the patient’s safety, not just the quality

of the images. We should consider adding a new pillar to the ACR called “patient-focused radiology.”

Let me first ask you to remember the 5 pillars of the ACR, which represent the strengths of this society. The ACR is strong in advocacy for government relations, economics, education, clinical research, and quality and safety. How would having a new patient-focused pillar affect our work? How would it affect our visibility in the new federal health care environment, where patient-centered care is a major goal? During AMCLC, the ACR Council convened to consider actions on the threats and opportunities facing the ACR and all of radiology.

Why propose a new pillar? The quality and safety for which we are known will be terrifically important as we address radiation exposure. However, a sixth pillar for the ACR needs to be “patient focused.” For more than a century, diagnostic imaging has been a valuable tool in medicine. Everyone believed the risks were worth the benefits. We have reached new heights of quality in imaging, but at the same time we have dramatically increased the radiation dose to the US population, particularly from multidetector row CT and PET/CT scanning. We have focused on the quality of care; now we need to focus on the potential side effects of these advanced imaging techniques. We need to remember that performing and interpreting a patient’s examination is

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just one part of the service that we do for patients. Critical to that service is the safety of patients and the safety of the US population as a whole. Radiology has changed and is so integrated that just being a good radiologist with great medical knowledge in an isolated reading room is not enough. We need to be focused on the patient's care as first priority. Our logo has been "Quality Is Our Image"; I would propose that we change that logo to emphasize safety and specifically patient safety. I would recommend that the ACR change it to "Quality and Safety Is Our Image! We Do Patient-Focused Radiology!"

You may have seen the March 2010 *JACR* article "Flying in the Plane You Service: Patient-Centered Radiology" by Drs Swensen and Johnson [1] of the Mayo Clinic. They propose that radiology professionals should make each decision as if they were going to be on the next flight (as the patient). One of the top safety concerns of patients is minimizing radiation exposure. We need to emphasize our expertise in patient safety and make safety the message that our patients remember. We can help them get the right test. We can communicate those results to that patient either through the referring doctor or directly, as now required for mammography and as now requested by more and more patients whose outcomes have been compromised by failure of a critical transfer of information. Patient-focused imaging needs to start with radiation dose protection.

I believe radiation overexposure is a threat to our patients and to our specialty. In response to this threat, we need to emphasize radiation protection. It is an opportunity for the ACR and all radiologists to demonstrate our patient safety expertise and focus on patient-centered care. We need to take charge of radiation dose and demonstrate that radiology expertise is essential to safe imaging. The hospital or health system needs to understand that they just cannot safely outsource cheap radiology from teleradiology companies. They will not be protected from legal risks; their patients may not be protected from equipment errors, human errors, or systems errors without the departmental radiologists', radiation oncologists', and medical physicists' oversight of technologists, the rigorous review of protocols, frequent quality checks, and credentialing of all who do high-radiation dose procedures.

Patient protection from radiation overexposure requires oversight by radiologists, not just equipment companies. It is an opportunity to be the face of radiology. If we distance ourselves from taking responsibility for radiation dose, this is a risk to our position that we are experts. In fact, as experts in radiation protection, our safety focus will assure patients that we protect them from harm, and we can also protect them from scare tactics that would limit necessary imaging where it is needed for the best patient care. That is why there are

patient advocacy groups that lobby for imaging. They realize the need for patients to have access to imaging for lung cancer and critical diagnoses that affect their health and well-being. After the recent *New York Times* (*NYT*) series titled "Radiation Offers New Cures, and Ways to Do Harm" [2], public attention on radiation overexposure to patients has peaked with the FDA hearing in late February 2010. Fortunately, the ACR, Radiological Society of North America (RSNA), Society for Pediatric Radiology (SPR), and many other radiology organizations have been working on this issue for a long time. Marilyn Goske, MD, past president of the SPR, leads the Image Gently™ campaign [3-5]. She is clearly one of the faces of radiology. The ACR has a new Image Wisely™ campaign for adult radiation protection, co-chaired by Steve Amis, MD, and Jim Brink, MD. We need to make Image Wisely the face of radiology as well.

Not only the *New York Times* but even the *New England Journal of Medicine* (*NEJM*) has published articles on radiation exposure. In 2007, Brenner and Hall [6] published "Computed Tomography—An Increasing Source of Radiation Exposure," which discussed how CT has transformed medical imaging by providing 3-D views of organs or body regions of interest and high-speed CT from helical scans that do not require breath holding. Thus, many more studies are being done in children and especially in the ER, where speed is important for critical patients but also because workload pressures are so great.

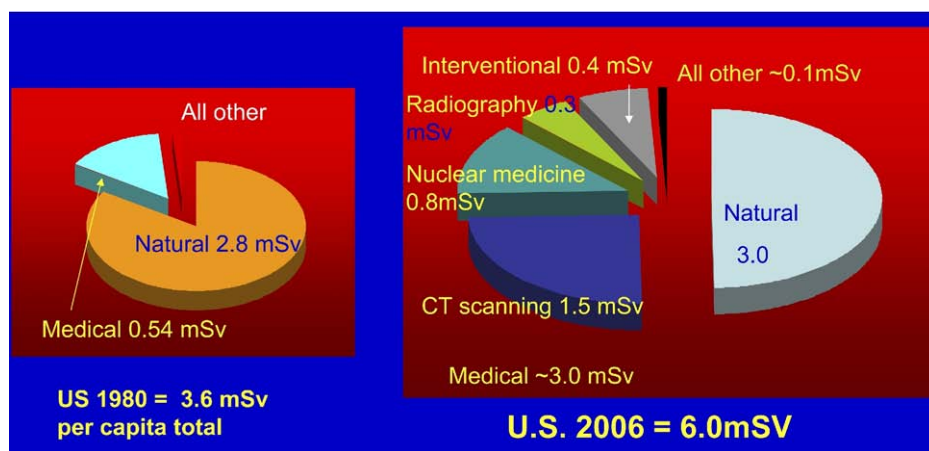
A more recent *NEJM* article in 2009 on radiation dose from medical imaging procedures emphasized the increasing effects on the US population [7].

So, what has changed to cause the increased radiation exposure? We have used advanced imaging techniques such as CT, interventional radiology, and PET scanning to revolutionize medicine. We make more rapid diagnoses with less invasive procedures. But more advanced medical imaging has increased the dose of radiation to the entire population. Now, 26% of procedures are advanced imaging techniques, and they account for 89% of radiation exposure.

The collective annual population dose from medicine has increased 7 times between 1980 and 2006. Let's look at this in more detail in regard to the actual source of radiation [8]. The radiation dose just from medical imaging procedures is up from 15% of yearly radiation exposure in 1980 to now 50% of all yearly radiation exposure in the US (Figure 1) [9]. As a result, the yearly radiation dose has nearly doubled to the population in 26 years. As experts in radiology, we need to do more to decrease the dose per patient and the dose to the population.

As you know, there is controversy about whether there is a clear threshold for radiation-induced cancer, and is

Fig 1. Sources of radiation exposure to the US population [9].



there a cancer risk from CT? The Hiroshima data has been used to suggest that there is no threshold because patients at 50 years after that explosion are developing cancers. But are these cancers directly related to the exposure, and is that a rational comparison, since it was a very high dose of radiation in a short time? We know that one CT sequence results in a dose of about 10 mSv, which is clearly below the accepted threshold of 50 mSv that has been shown to cause a small increase in cancer risk (Figure 2) [6]. You see here that a standard 3-phase liver CT scan is already above the 50-mSv threshold. Due to patients' having multiple CT scans, about 5% have an even higher radiation dose. These patients typically have chronic diseases followed with CT or PET/CT. They need our help with tracking their dose, and we need to move to lower dose CT techniques or develop alternative imaging pathways such as ultrasound or MRI.

As experts in radiation dose, we need to carefully study what we are doing. Is it a good idea to screen whole populations rather than target at-risk groups? New uses of CT are increasing, which improves confidence in diagnosis. They are clearly easy to interpret and fast to do. We need to be very careful about screening so that we produce rock-hard evidence of effectiveness in screening

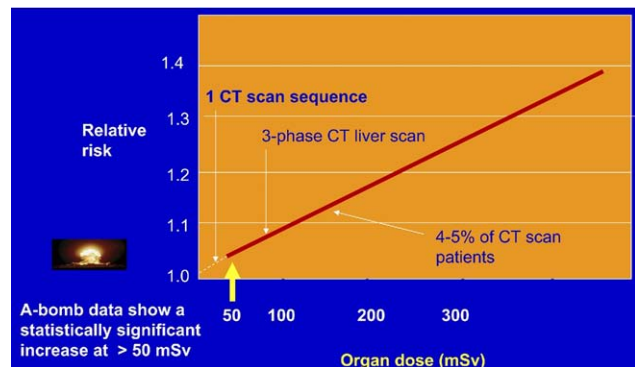


Fig 2. Risk from one abdominal CT scan [6].

research. Screening needs to be proven to significantly change patient outcome and show the radiation dose is worth the benefit for the population and not just for one patient.

We know that the age of the patient is clearly related to the risks of radiation. Brenner, *NEJM* November 29, 2007 (Figure 3) [10-13], showed that the risk of radiation-induced cancer is much lower over 35 years and much higher the younger the patient. We need to focus our efforts most strongly as the Image Gently campaign is doing to protect children and everyone less than 35 years of age.

If we take just CT scans of the abdomen and pelvis, CT use is growing at 10% per year (Figure 4) [14]. ERs are overwhelmed, so diagnostic CT is used to speed up the triage of patients and satisfy federal Emergency Medical Treatment and Active Labor Act regulations. The ER doctors argue that the normal CT “assures” that the patient is stable thus allowing rapid discharge of patients

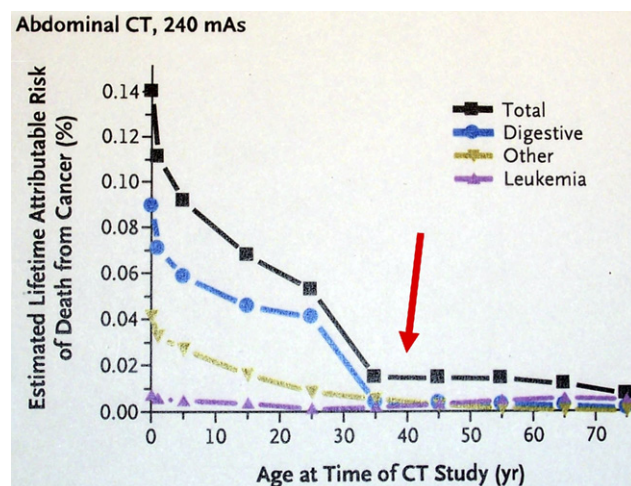


Fig 3. Is there a cancer risk from CT? Organ dose vs relative risk [10-13].

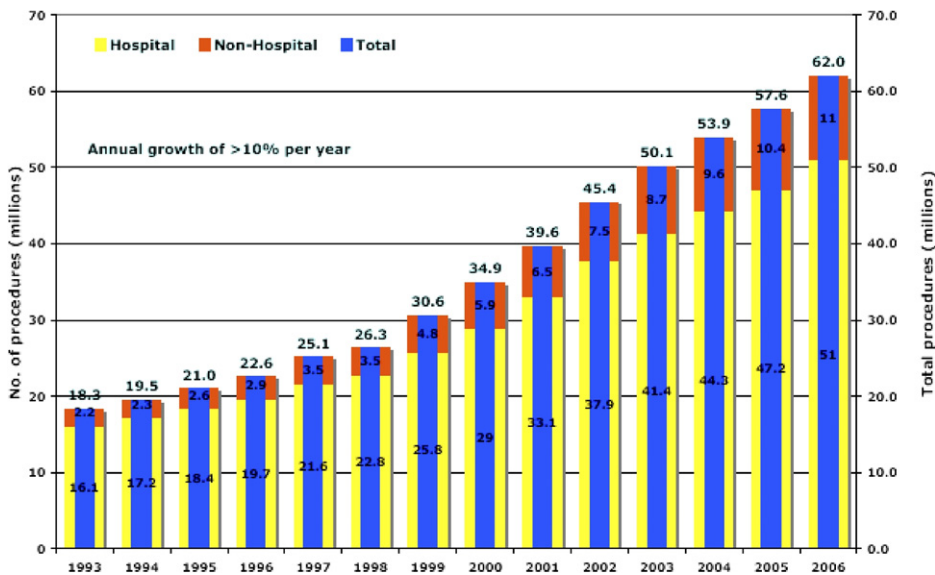


Fig 4. CT procedures have grown on average at 10% per year from 1993 to 2006 [14].

regardless of whether the CT is appropriate; we need to work more closely with these colleagues to help them where a decision support system may be very valuable. We also see that the use of CT changes with age. Fortunately, the majority are done to patients above 35 years of age (Figure 5) [14]. The younger patients at most risk are the children with chronic diseases and repeated CT scans as they accumulate significant doses over time.

What radiation accidents have been identified? In the *New York Times* series titled “Radiation Overdoses Point Up Dangers of CT Scans,” they reported that CT brain perfusion scans at several California hospitals were associated with hair loss in some patients [15]. This was the first clue to recognition of the error in these new higher dose CT protocols. In this technique, better analysis of

blood flow to the brain required higher doses but were inadvertently set at 8 times the expected CT dose. The *New York Times* also reported radiation therapy overdoses at a New York hospital that occurred with new high-dose intensity-modulated radiation therapy, or IMRT. It reported that a computer error occurred in the transfer of the treatment plan, and that caused the collimator to stay open continuously for head and neck therapy rather than intermittently. This dose was lethal but according to the *New York Times* was not recognized when it occurred. Because of legal implications, these radiation accidents are handled locally, and no system is in place to report publicly or anonymously to a databank. Patient safety could be dramatically improved throughout the medical systems of care in radiology and

Fig 5. CT abdominal and pelvic examination distribution by age in 2003 [14].

Table 1. ACR actions on radiation safety

1. Accreditation programs
2. Practice guidelines and technical standards
3. Appropriateness Criteria®
4. ACRIN® 2005: digital mammography lowers radiation dose
5. ACR Task Force on Radiation Dose in Medicine 2007
6. ACR National Radiology Data Registry: Dose Index Registry
7. www.RadiologyInfo.org
8. Image Gently
9. Image Wisely
10. CT summit April 2010
11. CARE (HR 3652)

Note: CARE = Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009.

radiation oncology if dose registries with alert systems back to the institution were provided by ACR.

It's not all about equipment error; human factors are involved as well, although we have much to learn in this regard. In 2008, in Mad River, California, a 2-year-old boy received 151 scans over 65 minutes until his father complained that they were scanning too long. After the study, the child developed delayed facial burns. It is not clear exactly why it happened, but the technologist was fired [15]. However, we should have a better proactive system to protect patients. The ACR can be a major part of the solution if credentialing of technologists is required within the ACR accreditation program. When patients need imaging, federal regulations should require the imaging center to be accredited, the imaging personnel to be credentialed, and the protocols sized to the patient to ensure quality. The patient dose should be tracked for that patient as well as that facility, and alerts should notify the facility at the time of the problem.

So what is the ACR doing to reduce radiation dose? The February 2010 *ACR Bulletin* has a summary of one of these adverse events which explains what the ACR is doing to protect patients now and how to not expose patients and radiologists to radiation risks [16].

The ACR has engaged in many projects that affect radiation safety issues over many years (Table 1). We can be proud of our extensive quality and safety actions, and I will touch on each of these actions. I want to note first the ACR digital mammography research led by Etta Pisano, MD, that was reported in 2005 in the *New England Journal of Medicine* [17]. This ACRIN®-funded project showed that digital mammography lowers the radiation dose in addition to proving its accuracy. I also note that Dr Amis was asked to testify at the FDA hearings in February this year on the actions that the ACR is

taking and is recommending for the future [18]. He focused on training of all users of CT and fluoroscopy based on his leadership of the 2007 "American College of Radiology White Paper on Radiation Dose in Medicine" [19].

Since 1987, ACR accreditation programs have been working to raise the standards of mammography. Mandatory accreditation of mammography occurred with the Mammography Quality Standards Act (MQSA) of 1992. The ACR is the only deemed accreditor with this expertise. ACR accreditation of CT and radiation oncology is still voluntary. However, by 2012, Medicare has mandated [20] Medicare Improvements for Patients and Providers Act (MIPPA) 2008 accreditation for advanced imaging, including CT, MRI, and nuclear medicine, for all outpatient imaging centers. ACR is requesting federally mandated accreditation of all "advanced imaging" and radiation oncology accreditation, whether inpatient or outpatient.

ACR accreditation programs are of the highest quality, with both self-assessment and independent external expert audits. They assess qualifications of personnel, policies, procedures, equipment and quality assurance activities. Very importantly, they require audit of images from both clinical patients and phantoms, which unfortunately is not done by the Joint Commission, which is also deemed to accredit these imaging facilities. For the ACR, patient safety and patient care are the priority, not just checking if all documents are present.

Practice guidelines and technical standards have been debated by every ACR Council for many years. These are drafted by expert panels from multidisciplinary backgrounds.

The ACR has increasingly developed collaborative standards drafted with multispecialty medical groups and radiology subspecialty organizations so that we raise the standard of care for all imaging, regardless of whether it is done by radiologists or nonradiologists. These are reviewed and commented on by the entire ACR membership and voted by the ACR Council at the annual meeting.

The ACR began developing Appropriateness Criteria® in the 1990s to eliminate inappropriate imaging, and there are now over 800 guidelines using age and symptoms as well as the relative radiation risk. So, how can a decision support system use the Appropriateness Criteria? At Massachusetts General Hospital [21], the ACR appropriateness guidelines have been incorporated into a computerized order entry program where requesting doctors must enter patient information prior to ordering a scan. If they get a yellow light, the need for that study is questionable, or another test is better. They get a red light if a scan isn't recommended. While the red light can be overridden, it requires calling a radiologist, who

explains the reason for not doing the test. While overutilization can occur, the trends are followed and later evaluated for doctors who are outliers. Since this program was introduced, from 2004 to 2009, the rate of growth in outpatient scans fell 12% to 1% per year, while outpatient visits grew 5% over the same period.

While most of you know we have an ACR National Radiology Data Registry [22], it is primarily voluntary and does not presently act to protect patients and their doctors from adverse events of radiation overexposure. The entire National Radiology Data Registry includes the National Mammography Database, which is the only one now required. The Dose Index Registry is a new pilot. It should be mandated and would be an effective method to identify problems and notify facilities in a proactive fashion. The other databases are all voluntary, but they are very valuable as they could generate huge banks of data for the ACR to use in the proof of efficacy in multiple areas of radiology. The ACR is requesting that Congress mandate a national CT dose registry.

Another valuable patient resource of ACR and RSNA collaboration is the Web site www.RadiologyInfo.org, which is the result of many years of focus on patient safety. This excellent resource delivers images and videos for public education on radiation exposure in x-ray examinations and does address radiation dose.

The Image Gently campaign originated in the Society for Pediatric Radiology, and by 2008, 41 organizations that had joined the alliance. This campaign began following the worrisome February 2001 *American Journal of Roentgenology* publications of Patterson, Donnelly, and Frush [23]. These authors found that outside CT scans at 3 major children's hospitals showed pediatric helical CT protocols were not adjusted for the examination type or the age of the child. These children were exposed to an unnecessarily high radiation dose during body CT since the same dose was used whether an adult or a child was scanned. Within 5 years, a survey of SPR practices showed that their education actually changed behavior to weight-based imaging and that radiation dose parameters decreased [24]. The ACR has been a proud sponsor of Image Gently that continues to spread nationally and internationally with work by ACR leaders Don Frush and Kimberly Applegate. Every radiologist can take the pledge to image gently by going to the Web site www.pedrad.org and clicking on "Image Gently." Image Gently brings the face of radiology home. It is clearly aimed at pediatric radiologists or any radiologist scanning children, and it reassures parents that we care.

The ACR-RSNA Task Force on Adult Radiation Protection is planning to launch the Image Wisely campaign. Is it time for radiation oncology to develop a "Treat Carefully" campaign?

Still pending in Congress is the Consistency, Accu-

Table 2. What has come of the ACR recommendations [26]?

All ACR quality and safety documents have dose estimates
Appropriateness Criteria [®] have relative radiation dose levels
ACR technical standard 2008 for management of radiation in fluoroscopic procedures
ACR accreditation chairs recommend 1 technologist have advanced specific registry in CT or nuclear medicine
ACR patient safety online self-assessment module released
ACR CT accreditation adopted pass/fail criteria for maximal radiation dose
JACR has published 15 articles on radiation dose issues
Safety link on ACR home page and RadiologyInfo.org home
ACR guideline 2008 for imaging pregnant or potentially pregnant adolescents and women with ionizing radiation
Image Gently for CT and Step Lightly were launched
Image Wisely planned
ACR added questions on radiation dose to in-training examination
AAPM-RSNA-ACR education for radiology residents at rsna.org

Note: AAPM = American Association of Physicists in Medicine; RSNA = Radiological Society of North America.

racy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009 (CARE), HR 3652 [25]. This was one of the key recommendations of the ACR Task Force on Radiation Dose. It would require new minimum federal education and credentialing standards for radiology and radiation oncology technologists and all personnel performing the technical components of medical imaging and radiation therapy. There is no doubt that we could reduce the risk of radiation exposure if every person administering radiation is required to be trained in radiation risks and protection for our patients' safety. Credentialing for every health care provider who does conscious sedation is now mandated to protect the patients from the risks of sedation. If that is required to prepare for the worst-case scenario of sedation overdose, shouldn't training also be done for high-dose radiation procedures, which can also cause major adverse events and the worst case is lethal?

What has come of ACR white paper radiation dose recommendations (Table 2) [26]? We can be very pleased that so many of the recommendations of the ACR Task Force on Radiation Dose in Medicine have already been

accomplished. All ACR quality and safety documents have dose estimates. For all Appropriateness Criteria, there are now relative radiation dose levels to help both referring doctors and radiologists. For radiologists, the ACR patient safety online self-assessment module has been released, ACR CT accreditation has adopted pass/fail criteria for maximum radiation dose, and *JACR* has published 15 articles on radiation dose issues. There is now a safety link on the home page of both the [ACR.org](http://www.acr.org) and [RadiologyInfo.org](http://www.RadiologyInfo.org) home, and a new ACR guideline for imaging pregnant or potentially pregnant adolescents and women with ionizing radiation 2008. In addition, Image Gently for CT and Step Lightly have launched. Image Wisely is planned, and the ACR technical standard for management of the use of radiation in fluoroscopic procedures was written in 2008.

For radiology residents, the ACR added questions on radiation dose to the in-training exam. The ACR has collaborated with the medical physicists (American Association of Physicists in Medicine [AAPM]) and RSNA to create education on radiation dose protection for radiology residents on the RSNA Web site.

For technologists, the ACR technical standard for management of the use of radiation in fluoroscopic procedures was adopted in 2008. In addition, the ACR accreditation chairs recommended at least one technologist be required to have an advanced specific registry in CT or nuclear medicine.

So, what can a radiologist do to reduce radiation dose in CT? If a CT is medically necessary, then the radiologist can “right size” the protocol [27]. They can set the dose by body area and weight for children and by clinical question for everyone. The radiologist can reduce the mA, or tube current, directly in order to decrease the dose. If the radiologist doubles the pitch, radiation dose can be reduced by half because this allows a shorter time for the CT to scan the patient and so will decrease the dose. If only contrast CT can be done, which is frequently done for children, this is half the dose. If a CT is not medically necessary, the dose is zero if you do no CT.

For cardiac CT scans, you can drop to 20% of the usual dose by imaging only during specific parts of the cardiac cycle [28]. You can limit repeat CT scans. It is exciting to me to see monthly advances in reducing radiation dose in many peer-reviewed journals already occurring [29]. But lowering the dose is not enough. We need to push Congress to require the ACR Dose Index Registry so the ACR collects aggregate site data and gives feedback, including alerts on dose outliers.

What can yet be done with regulations that would reduce radiation exposure? Mandatory accreditation of all advanced imaging facilities, mandatory accreditation of radiation oncology, Dose Index Registry mandated for all advanced imaging, uniform state regulation of CT

protocol reviews, CARE act credentialing standards for nonradiologists requesting to do fluoroscopy (MDs, nurse practitioners, etc).

What are the challenges to ACR and radiology nationally? First, these include radiation protection of patients, so that we are recognized by patients as experts. We need to be the face of radiology! Secondly, communication directly to patients: radiation risks and benefits, medical errors: take charge of radiation protection. Thirdly, we need to develop standardized reports to patients and providers that include dose records in each report and summary dose data in each patient record. We need to adopt the ACR Dose Index Registry that will give alerts to each facility daily for radiation dose outliers.

What else can the ACR do now to become more patient focused and safety centered? The College can develop clinical imaging pathways with multispecialty experts. It can develop guidelines that define best practices for safety, not just imaging. The ACR can develop credentialing of everyone performing or supervising radiation. It can emphasize decision support systems beyond just Appropriateness Criteria. The ACR can focus on developing evidence-based proof of imaging pathways. And most importantly, the ACR should invest in and strongly embrace databases to prove the safety and efficacy of our imaging. We owe it to our patients and to their safety.

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