Reducing Radiation Exposure In Diagnostic Imaging

Since 2008, awareness about the dangers associated with radiation exposure in medical or diagnostic imaging has increased. This article focuses on the need for a change in regulations to reduce this exposure.

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Since 2008 publicity and public awareness have increased about the dangers associated with medical or diagnostic imaging[1]. In particular, the increased publicity stemmed from dramatic news stories in California about serious damage inflicted on over 200 patients[2], especially a twenty-three month old child[3]. From these initial incidents, follow-up investigation showed the risk of exposure to radiation was a very broad issue and not limited to a technician, specific imaging equipment, or even a few institutions. Consequently, Federal agencies have begun introducing changes in their processes, including the FDA[4] and NIH[5].

Concern has been growing for some time regarding radiation exposure. This concern is due in part to a doubling in radiation exposure from diagnostic or medical imaging in the population since the 1980s as more imaging has been used throughout the healthcare system. Specifically, the increase from medical imaging is a result of several trends. The *LA Times*[6] reports that it is due in part to economic incentives for doctors and hospitals to order more tests and from a concern about malpractice lawsuits if they don't order imaging tests. The result, according to the same article, is over 70 million CT scans are done each year, which is three times the number done in 1995. Of great concern is the medical justification, or need, for all these diagnostic tests, where each one has a significant amount of radiation exposure for patients.

There is not universal agreement about the effects of low-dose radiation exposure, but it is a concern given the increase in imaging procedures. For example, Brenner and Hall[7] suggest that based upon the survivors in Japan, who were exposed to atomic bombs, the risks of radiation-induced cancer significantly increases from even low doses of radiation. Those doses would be equivalent to two or three CTs, which many U.S. patients receive in one hospitalization. The certainty of the risks is clearer for children, who represent about 7% of CTs in 2006[8].

The FDA suggests that one element of the radiation exposure problem is the vast variance in radiation exposure among the equipment that is used in the same test across many facilities. In one study Smith-Bindman, et al.[9] report that there is a mean 13-fold variation in the amount of radiation dose for the same kind of diagnostic imaging across the participating institutions. This suggests that the dose of radiation is not standardized even for the same procedure among clinicians and facilities, although many professional organizations have developed these benchmarks (e.g. American College of Radiology [ACR] and National Council on Radiation Protection and Measurements [NCRP]). It appears that in practice, the alerts and dosing are not standardized sufficiently to protect patients from unnecessary radiation doses. In light of this the ACR and the Radiological Society of North America (RSNA) are initiating a program called Image Wisely to increase awareness of ways to reduce radiation dose in adult imaging procedures.[10]

Furthermore, the FDA suggests that there are several aspects of the ordering physician's information technology that needs to be improved. For example, typically the physician does not have information about the patient's history of radiation exposure or medical imaging. This is because these data for radiation exposure are not typically kept in electronic medical records (EMRs) and because procedures can be done in multiple facilities that do not share the radiology information or outcomes across EMRs. The FDA warns that "due to insufficient information, physicians may unnecessarily order imaging procedures that have already been conducted."[11] This duplicate or questionable ordering is a part of the broader problem of over-exposure of radiation.

The key to changing the use of unnecessary medical imaging tests rests with the ordering physician. With all the volumes of research on efficaciousness of various imaging tests, it is important to provide decision support at the point of care that will easily provide the proper guidance

for the physician to order the most appropriate procedure. Some studies suggest that 30% to40% of all imaging procedures are inappropriate.[12] Various professional organizations, foremost among them is the ACR, have developed and disseminated imaging referral criteria, called "appropriateness criteria" or "appropriate use criteria," associated with a number of medical conditions. However, use of criteria to ensure appropriate medical imaging exams has not yet been broadly adopted by the practicing medical community.[13] This is true even if healthcare providers use a Computerized Provider Order Entry (CPOE) system because the implementation of the healthcare IT varies greatly in its success for providing the information when the physician needs it to determine efficiently the best course of action for a particular patient.[14]

The federal government according to the FDA's 2010 announcement will address the radiation exposure issue through several regulatory mechanisms regarding the imaging devices. The FDA intends to introduce additional safeguard requirements into the manufacturer's device labeling and training to reduce the risk of radiation exposure for patients. By focusing on the manufacturers it means that all of the imaging equipment will have similar safeguards and that all manuals and training will provide clear instructions about the risk and prevention needed for unnecessary radiation exposure. Through the Centers for Medicare and Medicaid Services (CMS) new safety regulations for diagnostic imaging will be made part of the accreditation for imaging facilities and hospitals. This will make sure the users of the equipment are following practices that protect patients.

The FDA will also collaborate with the professional community to establish better reference guides for the proper radiation exposure for the use of CT, nuclear medicine, and tomography. These reference levels will be collected both locally and nationally via a registry. Part of goal would be to develop the proper radiation levels for the various exams and to have as a goal the reduction of the levels as part of benchmarking or best practices from the registry. The other device requirement sought by the FDA is to make sure that the equipment records the radiation exposure for each patient, preferably in an EMR in order to accumulate more information about the history of exposure for each patient to determine the possible risk and benefit to additional radiation doses.

The greatest change in reducing radiation exposure for patients may come from improving the process of ordering exams by the physician to include decision support from evidence-based medicine. This means the exam is the right exam for the patient giving support for the general level of radiation exposure that is medically necessary. Since the decision support tool could also supply information about the history for the patient's radiation exposure, then physician could take those data into consideration as well for the most comprehensive decision-making to choose the most efficacious exam while balancing the riskiness of the exam. Since the growth of high dose radiation exams, many patients are inappropriately exposed to the radiation when little or no benefit from the exam. One estimate of 29,000 future cancers would be related to CT scans done in 2007.[15]

Given these estimates, it is generally agreed that we must try to restrain the use of radiation in diagnostic imaging to be used only when the risk is outweighed by the benefit for the patient. If an alternative diagnostic method will provide the information, it should be used. Paralleling the Image Wisely campaign[16], there are several things that patients can routinely ask:

Why do I need this exam (based upon what evidence)?
How will having this exam improve my health care?
Are there alternatives that do not use radiation which are equally as good?
Is this facility accredited?
Is the radiation dose "As Low As Reasonably Achievable" (ALARA)?

Recognizing the issues before the FDA and the radiology community, Sage HMS has recently enhanced its RadWise® clinical decision support system for imaging to track radiation exposure and accumulate the totals over time (both an estimate for each procedure and an actual radiation dose if available) for each patient. By tracking the estimated radiation dose for a particular exam and the actual, significant differences can alert both physicians and patients to equipment issues or facility issues. The manner of investigation that followed the publicity in California would become the operational norm and simplify tracking radiation. Furthermore, these radiation exposure doses can be sent to an EMR, if automated, or to the patient's health record, if requested.

The reduction of radiation exposure will take some time as currently facilities and providers do not have any policies to aid them in deciding how to use the history effectively in making imaging decisions. There is also little in the medical literature that aids in determining how this information fits into the clinical decision. This sets up the proverbially paradox. We must collect the data first to assist with policy development and better clinical decisions, but providers fear litigation and liability from knowing more about patients' radiation exposure. However, as the FDA, ACR, NCRP, and others have declared, our society must begin to move in a direction where we treat radiation exposure from medical imaging as a public health issue.[17] Much more needs to be disclosed about the possible risk associated with low dose radiation exposure.

There are some in the medical community that have worried that the emphasis on radiation exposure will cause unnecessary alarm in patients. However, there has been another trend in health care that suggests better informa-

tion is the expectation of patients worldwide. Patients have been growing more comfortable with the availability of health information about disease, treatment options, and choices there will be a greater demand from patients for transparency and patient input into the care plan. Some have suggested that these types of information may make patient decisions truly "personalized." That is, not only using information about the unique genetic makeup of a patient to determine treatment options, but to encourage the patient to "bring their voices into the decision making."[18] There is a growing appreciation that patients have their own unique perspectives, which make healthcare decisions relevant and meaningful. In fact providing information to patients about the risks of imaging will give the patient the ability to make informed decisions about very complex issues in their own care.

Unlike the exposure of workers in health care and the nuclear industry, which can be regulated, the exposure of patients cannot be restricted, largely because of the inherent difficulty in balancing the immediate clinical need for these procedures, which is frequently substantial, against the risks of cancer that would not be evident for years, if at all.[19] If strict regulation is not possible due to the complexity of the imaging decision making, then it would seem the patient must rely on the expertise of their physician.

However, research suggests that physicians who order the imaging tests may not have adequate familiarity with radiation exposure to have the sole responsibility for these decisions. For example in one study by Lee, et al.[20] among U.S. health care providers using CT in patients with abdominal and flank pain, only 9% of emergency department physicians reported even being aware that CT was associated with an increased risk of cancer. This lack of awareness of radiation exposure among ordering physicians does not appear to be limited to the United States as in a German study by Heyer in 2007[21], concluded that "correct estimation of the radiation exposure or effective dose (ED) of radiological chest examinations, especially that of CT examinations with a high ED, poses substantial difficulties for non-radiologists regardless of the length of professional experience and field of clinical training." Therefore much more needs to be done to make sure that the ordering professionals are aware of the radiation exposure risks, that the equipment and EMR systems report the radiation exposure for possible accumulation over time, and that decision support guides the clinical appropriateness of the imaging orders including the estimates of the radiation exposure.

As the public becomes more aware of the issues, there will be greater demand for this type of patient-centered focus in what information is collected and how health care is improved. However, the task is significant as the practice of medicine must reverse the trends of the last two decades of increasing use of radiation without consideration of the risks or benefits. This trend, for example, is shown in the use of CTs in emergency departments increased from 1998-2007 three-fold with no commensurate increase in the prevalence in life-threatening diagnoses.[22]

Hillman and Goldsmith[23] suggest that we must change the culture of medical practice to encourage more thoughtful use of imaging to help ensure that future patients will benefit from continued imaging innovation. Such a shift begins with the training of medical students to consider when to request imaging and then how to use clinical decision support to consider what procedures are appropriate. The goal is to get physicians to move toward the use of imaging as a part of their thoughtful diagnosis based upon taking the patient's history and the physical exam rather than a reliance on imaging as the beginning point of diagnosis.

In early October 2010, California became the first state in the U.S. to require the reporting of CT scans that exceed by 20% the amount of radiation intended for the patient.[24] Given the public awareness in California of the risks of radiation exposure, this should not be a surprise. With all these efforts from manufacturers, regulators, and especially Healthcare Information Technology (HIT) vendors to provide imaging decision support at the point of care — the national goal of radiation reduction from diagnostic imaging can be achieved. It will require support, however, from the public, who recognize that lowering radiation exposure is an important public health issue, and from providers, who understand both the risks and the benefits of diagnostic imaging.

ABOUT THE AUTHOR

Prior to Dr. Gray's broad background in health care management, she was a Director of Research with more than 45 publications and presentations. Her management experience traverses all segments of the health care industry, including managed care, self-insured employers, long-term care, hospital systems, Medicaid and Medicare, and specialty care. A recognized leader in health care quality and efficiency improvements, in 1997 Dr. Gray founded Sage Health Management Solutions, Inc. with a vision to develop web-based technology to improve the diagnostic process using evidence-based clinical decision support. Dr. Gray is considered an innovator and force for change in the national health care industry.

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