The Joint Commission
Sentinel Event Alert

A complimentary publication of
The Joint Commission

Issue 47, August 24, 2011
Revised: February 2019 (in red)

Radiation risks of diagnostic imaging and fluoroscopy

Diagnostic radiation, which includes fluoroscopy, is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a patient receives repeated doses, harm can also occur as the cumulative effect of those multiple doses over time.[1,2,3] Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation.[4] The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.[1,5,6,7] X-rays are officially classified as a carcinogen by the World Health Organization's International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.[1]

Over the past two decades, the U.S. population's total exposure to ionizing radiation has nearly doubled.[8] Diagnostic imaging and fluoroscopy services can be provided in hospitals, imaging centers, physician and dental offices, and practitioners can order tests and procedures that involve exposure to radiation, with no knowledge of when the patient was last irradiated or how much radiation the patient had previously received. From the 74 million CT (computerized tomography) scans performed in the U.S. during 2017, it has been estimated that 29,000 future cancers and 14,500 future deaths could develop due to radiation (cancer incidence = 0.04 percent).[9] Another study estimates the incidence of cancer related to CT radiation at 0.02 to 0.04 percent.[10] While these studies' conclusions rely upon some currently unverified scientific assumptions – namely, a linear relationship between radiation dose and risk even at very low exposures – they do highlight the need to maintain radiation doses as low as reasonably achievable when obtaining needed diagnostic information and performing fluoroscopic procedures.

While experts disagree on the extent of the risks of cancer from diagnostic imaging, there is agreement that care should be taken to weigh the medical necessity of a given level of radiation exposure against the risks, and that steps should be taken to eliminate avoidable exposure to radiation.[7] Patients most prone to harm from diagnostic radiation are children and young adults;[11] pregnant women;[12] individuals with medical conditions sensitive to radiation, such as diabetes mellitus and hyperthyroidism;[6] and individuals receiving multiple doses over time.[2] The diagnostic procedures most commonly associated with avoidable radiation doses are CT, nuclear medicine and fluoroscopy.[13]

As a result of the risks and potential dangers associated with ionizing radiation, the Centers for Medicare & Medicaid Services (CMS) began requiring the accreditation of facilities providing advanced imaging services (CT, magnetic resonance imaging (MRI), positron emission tomography (PET), nuclear medicine) in non-hospital, freestanding settings, in 2012. Additional standards changes were made in 2015 to further address risks related to these imaging modalities. And as of January 1, 2019, several new and revised Joint Commission requirements focused on risks related to fluoroscopy became effective.

Addressing contributing factors to eliminate avoidable radiation exposures

There are actions that organizations can take to minimize radiation exposures. First, staff should be aware of the contributing factors to, and activities that can help eliminate, avoidable radiation exposures, which include:

- A comprehensive patient safety program, including education of practitioners and staff about managing radiation exposures and optimizing radiation doses when providing ionizing radiation.
- Awareness of the potential dangers from excessive radiation exposures among organizational leadership, hospital staff and patients.
- Awareness among physicians and other clinicians about the levels of radiation typically used and related risks.[1,6,14,15]
- Training on how to use complex new technology.[4]
- Guidance in the appropriate use of potentially dangerous procedures and equipment.[16]
- Adequately trained and competent staff and practitioners.
- Knowledge regarding typical radiation doses and dose ranges.
- Clear protocols that identify the maximum dose for each type of study.
- Consulting with a qualified medical physicist when designing or altering scan protocols.
- Communication among clinicians, medical physicists, technologists and staff.
- Safety, operational and functional checks of the imaging equipment before initial use and periodically thereafter.

Actions suggested by The Joint Commission

Health care organizations can reduce risks due to avoidable ionizing radiation by raising awareness[17] among staff and patients of the increased risks associated with cumulative radiation doses and by providing the right test and the right dose through effective processes, safe technology and a culture of safety.

Right test

1. In order to reduce the exposure of the patient to ionizing radiation, use other imaging techniques, such as ultrasound or MRI, whenever these tests will produce the required diagnostic information at a similar quality level.[17]
2. Create and implement processes that enable radiologists to provide guidance to and dialogue with referring physicians regarding the appropriate use of diagnostic imaging using the American College of Radiology's *Appropriateness Criteria*®.[17]

See relevant Joint Commission requirements: LD.03.10.01; HR.01.05.03

Right dose

3. Adhere to ALARA guidelines as required by the Nuclear Regulatory Commission. The ALARA acronym stands for "as low as reasonably achievable" – making sure doses are as low as possible while achieving the purposes of the study.[18] Adhere to the *Image Wisely*®, *Image Gently*® and *Step Lightly*® guidelines when providing imaging radiation to children and adults.[11,19,20,22]
4. Provide physicians and technologists with reference doses based on anatomy, purpose of the study, and patient size. Establish appropriate dose ranges for high-volume and high-dose diagnostic imaging studies.
5. Radiologists should assure that the proper dosing protocol is in use for the patient being treated.
6. Institute a process for the review of all radiation dosing protocols either annually or every two years to ensure that protocols adhere to the latest evidence.
7. Investigate patterns of radiation exposures that fall outside of identified thresholds for appropriate doses. Identify opportunities for process improvement. Track radiation doses from exams repeated due to insufficient image quality or lack of availability of previous studies to identify the causes. Address and resolve these problems through education and other measures.[4]
8. Record the dosage or exposure as part of the study's summary report of findings.

See relevant Joint Commission requirements: LD.03.10.01; PC.01.02.15, PC.01.03.01

Effective processes

9. Create and implement policies and procedures delineating those responsible for approving changes to password-protected diagnostic imaging protocols and for monitoring new developments in diagnostic imaging and fluoroscopy. Provide for oversight of these policies and procedures and related activities, including control of the password, by a multidisciplinary group with expertise in radiation (such as a radiation safety committee), including a medical physicist.[4]
10. Develop and implement policies and procedures that delineate physical protective risk reduction measures to be taken by staff delivering radiation to patients, including appropriate lead shielding for both patients and employees and radiation-protection training for all technologists.[4,21]

11. Designate an individual to serve as radiation safety officer. Ensure that the role has the needed leadership support to intervene when unsafe practices related to the provision of ionizing radiation are noted. The radiation safety officer should participate on the organization's patient safety committee.
12. Ensure all practitioners (including physicians) and technologists who either prescribe, supervise, or operate equipment used to perform patient exams or procedures that involve radiation exposures receive dosing education and are trained on the specific make and model of equipment being used.[4,17,21] Institute a process for annual education, review and competency testing.

See relevant Joint Commission requirements: HR.01.02.01, HR.01.02.05, HR.01.04.01, HR.01.05.03, HR.02.02.01, LD.04.01.05, MS.03.01.01, MS.03.01.03, MS.06.01.03

Safe technology

13. Perform an organization-wide audit/survey of imaging equipment that have the potential of emitting high amounts of radiation. Implement a system for centralized quality and safety performance monitoring of this inventoried equipment under the supervision of a medical physicist, radiation safety officer, or your organization's multidisciplinary group with radiation expertise or both. (This equipment may no longer solely be within the province of the radiology department and may be located within a variety of hospital or clinical departments, including the cardiac catheterization suite and the OR. In the ambulatory setting, this equipment may be found in physician or dental offices.)
14. Have a medical physicist test all imaging equipment initially and at least annually for CT, NM, PET, and fluoroscopic units to assure proper installation and calibration, and to review scanning protocols and doses.[4] Such tests should be conducted in accordance with Joint Commission requirements and/or applicable state and federal laws and regulations. Where no such regulations exist, tests should be conducted in accordance with the applicable standards as promulgated by the American Association of Physicists in Medicine.
15. Ensure that recommended quality control, testing (including daily functional tests) and preventive maintenance activities are performed in accordance with manufacturer's guidelines. The health care organization, in consultation with the medical physicist, should identify these activities, their frequencies, and who will perform them.
16. Invest in technologies that optimize or reduce dose.[4,19,22,23]

See relevant Joint Commission requirements: EC.02.02.01, EC.02.04.01, EC.02.04.03, EC.04.01.01-EC.04.01.05, EC.02.04.01, EC.02.04.03, LD.04.01.05

Safety culture

17. Use the following Joint Commission standards to support the use of safe and effective diagnostic radiation and fluoroscopic imaging: LD.03.01.01, LD.03.04.01, LD.03.05.01, LD.03.06.01, LD.04.01.05. The concepts in these standards promote a safety culture, which is necessary for the safe use of diagnostic radiation. A safety culture is expressed in the beliefs, attitudes and values of an organization's employees regarding the pursuit of safety. It is present in the organization's structures, practices, controls, and policies, which are used to achieve greater safety. For more information about safety culture, see *Sentinel Event Alert* Issue 57: The essential role of leadership in developing a safety culture.

In addition, The Joint Commission:

18. Endorses the creation of a national registry to track radiation doses as the start of a process to identify optimal and reference doses.[1,7,16]
19. Encourages manufacturers to incorporate dosage safeguards into equipment and to capture dose information in the patient's electronic medical record and national dose registry.[13]
20. Supports stricter regulations designed to eliminate avoidable radiation exposures and monitor the appropriateness of self-referred imaging studies (referral of a patient to a facility in which the referring physician has a financial interest).[16]

References

[1] Amis, Jr. ES, et al: American College of Radiology white paper on radiation dose in medicine. *Journal of the American College of Radiology*, 2007; 4:272-284
[2] Holmberg O, et al: Current issues and actions in radiation protection of patients. *European Journal of Radiology*, 2010, doi:10.1016/j.efrad.2010.06.033
[3] Smith-Bindman R, et al: Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Archives of Internal Medicine*, 2009; 169(22):2078-2086
[4] ECRI Institute: CT radiation dose, *Health Devices*, April 2010; 110-125
[5] Koenig TR, et al: Radiation injury to the skin caused by fluoroscopic procedures: lessons on radiation

management. Annual Meeting of the Radiological Society of America, 2000
[6] Koenig TR, et al: Skin injuries from fluoroscopically guided procedures. *American Journal of Roentgenology*, 2001; 177:3-11
[7] U.S. Food and Drug Administration, White Paper: Initiative to reduce unnecessary radiation exposure for medical imaging, Feb. 16, 2010
[8] National Council on Radiation Protection and Measurements: Ionizing radiation exposure of the population of the United States (2009). NCRP Report No. 160, Bethesda, Md., 142-146
[9] Organisation for Economic Co-operation and Development: Health at a Glance 2017, OECD Indicators. OECD Publishing Paris, 2017
[10] Radiological Society of North America: Exposure to ionizing radiation and estimate of secondary cancers in the era of high speed CT scanning. Presentation to 96th Scientific Assembly and Annual Meeting, Dec. 1, 2010
[11] Firestine, K: CT dose reduction in pediatric patients. *Radiology Management*, March/April 2011
[12] Diagnostic ionizing radiation and pregnancy. Is there a concern? *Pennsylvania Patient Safety Advisory*, March 2008; 5(1):3-15
[13] U.S. Food and Drug Administration: FDA unveils initiative to reduce unnecessary radiation exposure from medical imaging. FDA news release, Feb. 9, 2010
[14] Kim C, et al: Radiation safety among cardiology fellows. *American Journal of Cardiology*, 2010; 106:125-128
[15] Richardson L: Radiation exposure and diagnostic imaging. *Journal of the American Academy of Nurse Practitioners*, April 2010; 22(4):178–185
[16] Baerlocker MO, et al: Radiation safety: have we let the public down? *Journal of the American College of Radiology*, August 2010; 7(8):557-558
[17] American College of Radiology: *2017 ACR Appropriateness Criteria*
[18] United States Nuclear Regulatory Commission: ALARA
[19] The Image Gently Alliance: *Image Gently*®, and Pause & Pulse: Image Gently in Fluoroscopy
[20] Harolds J: Some recent steps taking by private organizations and the federal government to increase the safety of medical imaging. *Clinical Nuclear Medicine*, July 2010; 35(7):510-511
[21] Watson DS: Radiation safety. *Association of periOperative Registered Nurses Journal*, August 2010; 92(2):233-235
[22] American College of Radiology: *Image Wisely*®
[23] Medical Imaging and Technology Alliance: Nation's CT manufacturers unveil new industry-wide medical radiation patient safety features, MITA news release, Feb. 25, 2010

Resources

The Joint Commission: Standards FAQs on radiation overdose

American College of Radiology: 2018 ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures

---

Patient Safety Advisory Group

The Patient Safety Advisory Group informs The Joint Commission on patient safety issues and, with other sources, advises on topics and content for *Sentinel Event Alert*.