



Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices.

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Chapter 29 Preventing Patient Death or Serious Injury Associated With Radiation Exposure From Fluoroscopy and Computed Tomography: Brief Review (NEW)

Nancy Sullivan, BA.

Introduction

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Fluoroscopically- and computed tomography (CT)-guided diagnostic and interventional procedures are being performed with increasing frequency worldwide. From 1980 to 2007, annual performance of CT in the U.S. increased from 3 million¹ to 80 million.² With this rapid increase in the use of imaging techniques, there has been a concurrent increase in patient exposure to ionizing radiation.¹

Effects associated with radiation can be categorized as either deterministic or stochastic. Deterministic effects manifest themselves in a relatively short time after a high-intensity exposure to radiation (e.g., 1 or more sieverts).³ In 1994, approximately 50 radiation-induced burns were reported to the U.S. Food and Drug Administration (FDA). In 2000, a review of 73 reports of radiation-induced skin injuries⁴ identified fluoroscopically-guided procedures as the cause of 38 severe skin injuries (e.g., chronic ulceration); 18 requiring skin grafts.^{5,6} Radiation-induced burns have also been reported after extended radiation exposure during CT brain perfusion scans.⁷

Stochastic effects are increased risks of various conditions (e.g., cancer, heart disease) that manifest themselves over a longer time period. Recent estimates indicate that CT scans performed in the U.S. in 2007 will be related to approximately 29,000 future cancers; killing nearly 15,000. Almost one half of the projected cancers will be due to scans of the abdomen and pelvis.⁸ Experts indicate that more than 400 patients (across eight U.S. hospitals) who recently received “higher-than-expected” radiation doses while undergoing CT brain perfusion scans may now face long-term risks of cancer and brain damage.⁹

What Are the Practices for Reducing Ionizing Radiation Exposure?

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The core principle governing the use of ionizing radiation is ALARA (As Low As Reasonably Achievable). The goal of ALARA is to reduce both patient and technician exposure to ionizing radiation without compromising diagnostic or therapeutic efficacy. Several measures recommended by national organizations to reduce patient's exposure to ionizing radiation are discussed below.

Technical measures. The American College of Radiology (ACR), the Radiological Society of North America (RSNA), the American Association of Physicists in Medicine (AAPM), and the American Society of Radiologic Technologists (ASRT) are primary participating members in the Image Wisely campaign.¹⁰ On its Web site (imagerwisely.org), a list of technical mechanisms for dose reduction during CT include x-ray beam filtration, x-ray beam collimation, tube current modulation, peak kilovoltage optimization, improved detector efficiency, and noise-reduction algorithms.^{11,12} In 2010, task force members of the U.S.-based Conference of Radiation Control Program Directors (CRCPD)¹³ recommended technical methods during fluoroscopy:

- Minimize x-ray beam time
- Vary the site of the entrance port on the patient as clinically possible
- Optimize collimation

- Use the least amount of machine magnification possible
- Position the x-ray source and image receptor optimally
- Apply machine dose reduction features (e.g., last image hold feature, pulsed fluoroscopy)
- Maintain equipment in good repair and calibration

Appropriate utilization. Steps to improve use of diagnostic imaging by referring physicians include reexamining the need for more dose-intensive diagnostic imaging, which may affect the number of self-referrals.¹¹ As one of several U.S. physician groups participating in the Choosing Wisely Campaign, the ACR recently identified imaging exams that, although commonly used, might be unnecessary.¹⁴ To reduce unnecessary imaging, ACR recommended further physician-patient discussion before scheduling five specific imaging exams. The list includes imaging for uncomplicated headache absent specific risk factors for structural disease or injury and imaging for suspected pulmonary embolism without moderate or high pre-test probability of pulmonary embolism.¹⁵ The ACR recommendations were based on a review of professional guidelines and published evidence.

The ACR also suggests that regularly posting individual physician ordering patterns, whether appropriate or inappropriate, may positively influence physician ordering behavior through peer pressure. This practice may be especially helpful for non-physicians (e.g., physician assistants, nurse practitioners) who may be ordering imaging studies, and whose ordering patterns are likely to reflect the behavior of their supervising physicians.¹⁶ The ACR also sponsors registries (e.g., Dose Index Registry), which provide participating facilities with feedback on their radiation-exposure levels in comparison with nationwide levels and those from other institutions.¹⁷ Prior and recent successes have been reported in providing physician feedback and the psychology underlying it.¹⁸⁻²⁰

Education and training. Referring physicians must be thoroughly educated on radiation safety in order to routinely consider this factor when ordering imaging examinations. Technologists should be trained to ensure that proper procedures and techniques are followed to prevent the need for repeated imaging due to suboptimal image quality. Technologists can also notify a radiologist when a duplicate questionable examination is ordered. Substituting less dose-intensive modalities (e.g., MRI, ultrasound and radiography in lieu of CT) should also be considered.¹⁶ According to the CRCPD, training of fluoroscopist and staff on the biological effects of ionizing radiation is one of three components of a comprehensive radiation dose management program. Two remaining components are monitoring and tracking of fluoroscopic dose and patient follow-up.

Algorithms and protocols. CT-related strategies targeted to Imaging Physicians by the Image Wisely campaign include use of adaptive iterative reconstruction and development of protocols that maximize diagnostic yield while minimizing dose. A few preliminary studies have suggested for example that more limited CT of the lower abdomen and pelvis (versus standard practice to perform CT of the entire abdomen and pelvis) should be performed to evaluate conditions such as suspected appendicitis.²¹⁻²³ Adjustment of CT protocols to reduce radiation exposure according to factors such as body mass is also a recommended strategy.²⁴

How Have These Practices Been Implemented?

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Studies focusing on radiation exposure reduction measures during fluoroscopy and CT were mostly conducted at single institutions at a university hospital setting. The largest study examined efforts among 15 imaging centers involved in a Mid-west consortium.

Fluoroscopy. Lee et al. evaluated the effectiveness of a quality assurance (QA) protocol to reduce radiation exposure during fluoro urodynamics.²⁵ Prior to implementation, this institution identified many unnecessary images that did not contribute to the diagnostic value of a patient's study. In this study, fluoroscopic imaging helped to visualize the anatomy of the lower urinary tract in 97 patients diagnosed with urinary incontinence, urinary retention, and other conditions. The QA protocol, limiting fluoroscopy to 4-5 static images, was distributed to all physicians, nurses, and radiology technicians involved in the procedure. The importance of radiation safety was emphasized to all staff involved in the procedure. This QA protocol was limited to anteroposterior views in the sitting position so generalizability of this protocol may be limited.

Ngo et al.²⁰ evaluated cases of unilateral ureteroscopy for stone disease. First steps to

implementation included working with operating room (OR) personnel to track fluoroscopy time as an additional step in their post-procedural documentation. This process was not widely publicized and “required minimal changes to existing OR staff workflow.”

The multicomponent QA protocol evaluated in Greene et al.²⁶ started with a detailed review of prior imaging, which was later placed in front of the scrubbed surgeon on a high-definition monitor during the entire case. In addition, while previous radiation-reducing measures were performed without regard for respiratory motion, the fluoroscopy-reducing protocol included C-arm activation timed with the patient's respiration. Key to implementation was participation of a designated fluoroscopy technician “acquainted with the protocol goals and completely familiarized with the fluoroscopy machine usage and relevant urological anatomy.”

Lakkireddy²⁷ reported use of four high-dose [lithium](#) fluoride thermoluminescent dosimeters, a direct method to measure patient exposure. As a relatively new technique, atrial fibrillation (AF) catheter ablation involves a steep learning curve. Staff physicians, the primary operators during the procedure, were described as having experience performing more than 400 AF ablations. Three of the four studies described above stated adherence to the ALARA principle as an external influencer.

Computed tomography. Implementation tools used in one study²⁸ included the use of “real” and “distractor” stickers to blind study radiologists to the location of the region of tenderness. Staff participating in the study was also blinded to clinical information, including the patient's original radiology reports. Broder et al. indicated that targeted CT strategies that focus on scan length optimization may be inappropriate under certain conditions such as the need to visualize an entire structure (e.g., aorta) or “when diffuse abdominal processes are strongly considered” (e.g., bowel obstruction). Changes in clinical practice in one study¹ included the integration of computed tomography angiography (CTA) as part of routine imaging in monitoring patients for development of vasospasm

The first step in implementing an imaging algorithm in another study was providing an imaging protocol to the ED staff.²⁹ A collaborative approach between imaging services (including radiology and nuclear medicine) and the ED staff followed soon after. If ED staff requested a CTPA [computed tomographic pulmonary angiography] for a patient with a normal chest radiograph, an action that violated the protocol, a radiologist would followup with the ED by phone or email to discuss the request. Implementing this patient safety practice has encouraged the ED at this institution to implement additional radiation reduction measures for other diagnoses (e.g., renal colic).

Use of prospective gating was a core element of radiation reduction measures in two studies.^{30,31} Other measures used in one study³⁰ included limiting scan length, minimizing tube current or voltage according to body physique, use of small bowtie filters, and tube current modulation during cardiac cycle. A collaborative effort amongst three sites was involved in protocol development in one study.³¹ LaBounty states that two measures (prospective ECG gating and 100-kV tube voltage imaging) were only used in 92% and 67% of patients, suggesting that additional radiation reductions would have been possible if protocol compliance had been higher. Lack of awareness, uncertainty regarding appropriate implementation, and concern about the quality of studies that assessed reduction techniques were also described as barriers to implementing multiple radiation reduction techniques in everyday practice. The generalizability of implementing a similar initiative at less experienced sites may be limited because the patient population involved in this study underwent cardiac computed tomography angiography (CCTA) at three large-volume, experienced centers.

One large urban medical center benefitted from adding a decision support (DS) system to its existing radiology order entry (ROE) system.³² Before DS integration, referring physicians completed a ROE form to initiate a CT exam. After introduction of the DS component, a second form was populated providing physician feedback on appropriateness of the exam (1-9 appropriateness score), alternate procedures to consider, and options to proceed or cancel the request. Appropriateness scores, based on ACR Appropriateness Criteria scores and “locally developed indication and procedure pairs,” are continuously reviewed and modified.

Locally derived evidence-based imaging guidelines were the basis for a DS tool at another multispecialty integrated health care network.³³ Rapid implementation of the DS tool was attributed to pressure from local commercial payers and an institutional culture already vested in evidence-based medicine (including evidence-based imaging protocols) and lean health care management

methodology.³⁴ An audit of imaging requests to determine outcome for orders initially denied by the DS system was described as a potential screening method to determine whether providers had “gamed” (developed ways to order inappropriate studies) the system.

Lastly, Raff et al. described implementation efforts at 15 hospital imaging centers participating in the Advanced Cardiovascular Imaging Consortium in Michigan. Hospital imaging centers were located in both small community hospitals and large academic medical centers (1,000+ beds). Best practice recommendations were developed based on data (including radiation dose and image quality metrics) from CCTA scanning of 620 patients acquired during a 13-month control period. During an 8-month intervention period, recommendations created by a team consisting of a physician program director, a consulting radiologic technician, and a licensed medical physicist were distributed to participating sites at scheduled consortium meetings, during on-site visits by coordinating center staff and through personal communication.

This Best-Practice Model for Scan Acquisition includes directives on topics such as medical history, administration of beta blockers and [nitroglycerin](#), and protocol parameters (e.g., field of view, tube current modulation). Scanner manufacturers were involved in training on scanner-specific techniques. Responsibility for on-site implementation was designated to a physician and radiology technologist. Raff et al. reported that the greatest reduction in dose occurred at low-volume sites (≤ 30 scans per month).

What Have We Learned About These Practices?

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We limited our research to studies implementing initiatives to reduce patient's radiation exposure from fluoroscopy and computed tomography in the United States from 2005 to the present. Study designs of the 12 included studies were randomized controlled, non-randomized comparison, prospective double-blind observational, retrospective cohort, pre-post observational, and a time-series analysis.

Fluoroscopy. Two studies evaluated the effectiveness of single component initiatives to reduce radiation exposure during diagnosis of urologic conditions. Several benefits were reported from implementation of a QA protocol to limit fluoroscopy to 4-5 static images (unless clinically warranted).²⁵ Significant decreases at the 0.001 level were reported post-implementation for mean fluoroscopy time (40.9 to 11.7 seconds per procedure), mean dose area product (energy absorbed across the entire x-ray beam)(518.90 to 150.28 mGy), and mean air kerma (the energy absorbed by ionizing radiation in a unit mass of air)(15.48 to 4.25 mGy). Increased physician and staff awareness of radiation safety were also listed as benefits. Lee (2011) indicated that significant reductions in outcomes did not change the treatment or diagnosis in 100% of the fluoro urodynamics.

Ngo et al. reported a statistically significant reduction in mean fluoroscopy time (2.74-2.08, $p = 0.002$) for unilateral ureteroscopy after physician feedback.²⁰ Baseline data were collected over a 9-month period. A continuous downward trend in mean fluoroscopy time was reported over three consecutive years (263 cases) after surgeons received quarterly reports that showed their mean fluoroscopy time and mean times of their peers. Multivariate analysis indicated that a surgeon's receiving feedback was an independent factor predicting decreased fluoroscopy time ($p = 0.0004$).

Two studies evaluated the effectiveness of comprehensive radiation safety programs. In 2010, Greene et al. compared 30 ureteroscopy cases pre- and post-implementation of a QA protocol. This multicomponent protocol consisted of use of a laser-guided C-arm, use of a designated fluoroscopy technician, and substitution of visual for fluoroscopic cues during ureteroscopy. Results included a significant reduction in mean fluoroscopy exposure from 86.1 seconds to 15.5 seconds ($p < 0.001$).²⁶ Greene et al. stated “this represents an 82% reduction in fluoroscopy time and consequently a proportional reduction in radiation exposure.”

A comprehensive radiation-reducing program examined by Lakkireddy et al. included (1) verbal reinforcement of previous fluoroscopy times; (2) effective collimation; (3) minimizing source-intensifier distance; and (4) effective lead shield use.²⁷ These techniques were implemented during catheter ablation of atrial fibrillation, a procedure that requires extensive fluoroscopy time with 15-20% of patients needing a second procedure. Patients were randomized to either Group I (unexposed to program) or Group II (exposed to program). Significant improvements were reported in Group II for lower dose area product (234 ± 120 vs. 548 ± 363 Gy cm^2 , $p = 0.03$) and mean patient peak skin dose (0.40 ± 0.08 vs. 0.12 ± 0.03 Gy, $p < 0.001$). Using five cancer

deaths/mSv [millisievert] for assessing excess cancer risk, additional lifetime cancer risk was reported as significantly lower in Group II patients (0.08 vs. 0.2%, $p < 0.001$).

Computed tomography. Broder et al. examined 93 emergency department (ED) patients who had abdominal tenderness; 51 (55%) patients had abnormal CT results. Implementation of two hypothetical z-axis restricted CT-reduced strategies, based on the region of tenderness, resulted in reductions in mean radiation exposure by 70% (Strategy 1; 95% confidence interval [CI] 60% to 78%) and 38% (Strategy 2; 95% CI 29% to 48%). The primary endpoint was the frequency of complete inclusion of the acute pathologic region (detected on the complete CT scan) within the scope of the two hypothetical z axis-restricted CT scans. Current standard practice indicates a CT scan of the entire abdomen and pelvis. Abdominal pathology was completely included in limited CTs in 17% to 36% of patients; completely or partially included in 84% to 92% of patients. However, in 12 cases (eight from Strategy 1), the pathology detected at CT lay completely outside the marked region of tenderness (see harms below).

Two studies examined use of algorithms to reduce radiation exposure from CT. Loftus et al. examined use of an imaging algorithm to reduce radiation exposure in 60 patients with aneurysmal subarachnoid hemorrhage (435 CT examinations).¹ This imaging algorithm describes the most appropriate time points at which to detect vasospasm with CTA and CT perfusion imaging. Post-implementation results included a 12.1% decrease in cumulative radiation exposure ($p > 0.05$), a 25.6% reduction in mean number of CT examinations performed per patient, and a 32.1% decrease in the number of CT perfusion examinations per patient. Stein et al.²⁹ implemented an imaging algorithm in which stable ED patients with a clinical suspicion of pulmonary embolism underwent chest radiography followed by V/Q scanning (negative chest radiograph) or CTPA (positive). Data indicates that when comparing CTPA to V/Q scanning, the total effective dose from CTPA is almost five times greater; the dose to the female breast 20 to 40 times greater.^{35,36} After one year, results included a statistically significant 20% reduction in mean effective dose (8.0 mSv to 6.4 mSv; $p < 0.0001$); a 32% reduction in mean effective dose in women younger than 40 years. From 2006 to 2007, no significant difference in the false-negative rate (range, 0.8-1.2%) between CTPA and V/Q scanning occurred and CTPA usage in ED patients with suspected PE declined from 64.6% to 39.4%.

Two studies evaluated the effectiveness of clinical DS systems to reduce unnecessary CT imaging.^{32,33} Siström et al.³² reported results after integrating a new DS component to a computerized ROE system at a large, integrated, multispecialty group practice. Significant decreases were demonstrated in absolute growth (311 vs. 37; $p < 0.001$) and growth rate (3% vs. 0.25%; $p < 0.001$) of CT exams per quarter from 2004 to 2007. The authors reported that the number of CT exams was “essentially flat” despite an increase in outpatient visits by almost 70,000 over the same period. One retrospective cohort study evaluated use of an evidence-based clinical DS tool to reduce outpatient imaging use rates for several high-volume imaging procedures.³³ Two years after implementation, Blackmore et al. reported data from a single commercial payer indicating a clinically and statistically significant decrease (-26%) in use of sinus CT for suspected sinusitis (relative risk [RR], 0.73; 95% CI 0.65 to 0.82; $p < 0.001$). Secondary analysis indicated that use of the DS tool was also associated with a decrease in overall volume of sinus CT studies, regardless of diagnosis.

The three remaining studies implemented several radiation reduction measures in cardiac computed tomography angiography (CCTA);^{30,31,37} prospective gating was implemented in two studies. Prospective gating was a core element in initiatives implemented in one study ($n = 623$) by Choi et al.³⁰ Results included a statistically significant difference in radiation dose between the prospective ($n = 384$) and retrospective ($n = 239$) gating groups (2.0 vs. 9.6 mSv; $p < 0.0001$). In addition, median radiation doses per month decreased from 6.2 to 2.1 mSv over time due to increased usage of prospective gating. One multisite study ($n = 449$) examined effectiveness of a standardized BMI [body mass index]-based and heart rate-based protocol. Post-implementation, LaBounty (2010) reported median radiation dose had decreased from 2.6 mSv (interquartile range 2.0 to 4.2) to 1.3 mSv (interquartile range 0.8 to 1.9) due to use of the standardized protocol ($p < 0.001$). Statistically significant reductions ($p < 0.001$ level) were also reported for prospective (versus retrospective) electrocardiographic gating (-82%), reducing tube voltage (-41% for 100 vs. 120 kV [kilovolts]), lowering tube current (-25% per -100 mA), and reducing overall scan length (-6% per -1 cm). LaBounty also reported no differences between groups in the frequency of interpretable studies on a per patient (96.4% vs. 95.5%; $p = 0.66$) or per artery (99.1% vs. 98.5%; $p = 0.26$) basis.³¹

Lastly, Raff et al. (2009)³⁸ reported improvements from dose reduction strategies from a consortium of 15 imaging centers (n = 4,862). Radiation reduction measures involved implementation of a best-practice model including techniques to minimize scan range, heart rate reduction, electrocardiographic-gated tube current modulation, and reducing tube voltage in suitable patients. Compared with the control period, patients' estimated median radiation dose in the follow-up period was reduced by 53.3% (dose-length product decreased from 1493 mGy × cm [IQR 855-1823 mGy × cm] to 697 mGy × cm [IQR, 407-1163 mGy × cm]; p<0.001. A statistically significant reduction in effective dose was also reported (21 mSv (IQR, 12-26 mSv) to 10 mSv (IQR, 6-16 mSv) (P<0.001)). No significant changes were reported in median image quality assessment (control vs. follow-up period) or proportion of diagnostic-quality scans.

Harms. Harms from a PSP were reported in one study when implementation of CT-reduced strategies resulted in erroneous findings of no pathology in 12 patients.²⁸ Three patients required emergency treatment resulting in a laparoscopic appendectomy, stent placement, and admittance for pyelonephritis.

Conclusions and Comment

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A range of radiation-reduction measures have been successfully implemented by U.S. institutions to lower risk of deterministic and stochastic injuries. Significant improvements were reported for imaging time, number of images, and radiation dose (mostly measured by indirect methods)—measures that hypothetically correspond to reduction in patient exposure. Benefits also included increased physician and staff awareness of radiation safety and no impact on diagnostic interpretability.

Several studies provided moderately detailed descriptions of implementation but minimal information on the influence of context on outcomes. Two studies included a discussion of generalizability. One study described the expansion of radiation reduction measures for other diagnoses. Two studies described reliance on national and local evidence-based guidelines to assist in developing decision support systems.

Direct costs were not reported in these studies. However, initiatives were described as inexpensive, easy to implement, and requiring minimal changes to current workflow. One study described implementation of a comprehensive QA protocol with simple radiation-reducing techniques as adding no technical difficulty. A summary table is following ([Table 1](#)).



[Table 1, Chapter 29](#)

Summary table.

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