

Addressing Radiation Overexposure

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Recent reports about excessive medical radiation have prompted significant media attention and visibility within the health care industry. Most recently, this has led government agencies, including the Food and Drug Administration, to move forward with attempts to address the issue.

The FDA Initiative

Through the *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*, the U. S. Food and Drug Administration (FDA) advocates universal adoption of radiation protection principles, aimed at minimizing risks associated with ionizing radiation exposure. The initiative specifically targets utilization of computed tomography (CT), fluoroscopy and nuclear medicine — the greatest contributors to total radiation exposure within the U.S.

In a collaborative effort, the FDA plans to work with other government and health care organizations to:

1. Promote safe use of medical imaging devices;
2. Support informed clinical decision making; and
3. Increase patient awareness.

At [National Imaging Associates \(NIA\)](#), we applaud this initiative and compliment the FDA for investing time and energy in addressing an industry issue that carries such important patient safety implications. We strongly support the FDA's call for greater awareness and collaboration across various government and health care entities, and we acknowledge the value of the government's involvement. The credibility and visibility of the FDA's involvement likely will make a significant impact on this long-standing issue.

Additionally, we agree that the best way to protect consumers against unnecessary radiation exposure is to implement a system of checks and balances that mitigate this risk. In fact, the FDA-led initiative is largely consistent with the tenets of NIA's own radiation exposure safeguards that have been protecting the best interests of our customers and their members for many years.

Informed Decisions

One of the safeguards included in the FDA's initiative is the promotion of a personal health record system that would allow patients to track their own medical imaging history. This is especially important because radiation exposure is cumulative, with each medical imaging scan increasing a patient's lifetime risks, and it is an approach entirely consistent with NIA's philosophy and consumer engagement practices.

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By encouraging consumers to take an active role in their health care, we can foster healthy patient-physician dialogue and informed decision-making that allows a balancing of the medical benefits with the risks of future imaging studies. NIA was an industry pioneer in this area — both in terms of consumer engagement and in terms of tracking cumulative radiation exposure for the 19 million Americans under our care by assessing and tracking utilization through claims data. This information is accessed when reviewing providers request authorization of imaging studies. While clinical necessity is still the barometer for authorization, this additional information allows us to work with providers and consumers to ensure informed decision-making. More transparency is absolutely a step in the right direction, and we applaud the FDA for this approach.

Additional safeguards in the FDA's initiative include development of a radiation dose registry that would pool data from many imaging facilities across the country as well as targeted requirements for CT and fluoroscopic device manufacturers to incorporate important safeguards into the design of their equipment. There also are proposed requirements that devices display, record, and report real-time dose metrics, offer an alert for users when the dose exceeds a pre-set threshold, and provide an automatic default to lower-dose options, when available. In proposing this multi-pronged initiative, the FDA has recognized that significant advances in medical imaging equipment allow for technology-based safeguards and overall reductions in radiation dosages. Ideally, as these new technological advancements become available, providers should strive to stay current with these advances to minimize their patients' radiation exposure.

Right Exam, Right Time

In addition to the continued pursuit of these safeguards, it is important that we acknowledge — and address — a far more dangerous threat to patient safety from radiation overexposure. This overexposure comes from the clinically inappropriate use of advanced diagnostic imaging that occurs every day. Our nation's collective rush to scan, often even in the absence of strong clinical evidence, must be addressed.

There is no question that when used appropriately, diagnostic imaging delivers tremendous benefit and value. However, there is no safe or justifiable amount of radiation from a clinically unnecessary test. And with multiple independent studies concluding that as many as one of every three imaging procedures is clinically inappropriate, this must be part of the radiation safety dialogue.

If an exam is clinically unnecessary, it doesn't matter how little radiation the test carries or how well-calibrated the equipment is. It is our collective responsibility to inject greater clinical decision support and responsibility into how advanced imaging tests are ordered. This is at the very heart of our pre-procedure review process, applying evidence-based guidelines to safeguard the clinical appropriateness of each examination and the optimal outcomes for each individual patient.

After all, informed decision-making does not just stop with the consumer. And no amount of radiation exposure is safer than zero.

Moving Forward ... Together

Again, we applaud the FDA for their leadership and progress in addressing the issue of radiation overexposure and for heightening public awareness on the importance of practical solutions that protect the public's best interests. Collaborative efforts, like the initiative recently announced by the FDA, are a step in the right direction for ensuring that every patient receives the right scan, at the right time. At the end of the day, that is what matters most.

Here at NIA, we will remain actively involved in these discussions and will continue to contribute our insights and recommended solutions as we work to address this industry-wide patient safety issue.

For more information, or to learn more about NIA, call 1-877-NIA-9762.

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