LUCERNO DYNAMICS

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Findings: Unintentional exposure poses risk to nuclear medicine patients

Radiopharmaceutical injections that miss the vein can result in localized tissue radiation doses that significantly exceed recommended limits

Nuclear Regulatory Commission (NRC) is re-evaluating a 41-year-old loophole that allows incidents to remain hidden from patients

CARY, NC – Lucerno Dynamics, a North Carolina-based medical technology company, today highlighted a peer-reviewed publication in the radiation safety journal Health Physics demonstrating that extravasations of routinely-used radiopharmaceuticals can cause unintended irradiation to patient tissue that "exceed well-established radiation protection and regulatory limits." An extravasation occurs when all or part of the administered radiopharmaceutical misses the intended vein and absorbs in the tissue.

The paper's authors analyzed 26 extravasation cases involving common diagnostic radiopharmaceuticals and found patients received unintentional radiation exceeding federal dose limits by up to twenty-two times. Their findings demonstrate the importance of injection quality monitoring during nuclear medicine procedures and performing dosimetry and clinical follow-up when extravasations occur. Because radiation injury symptoms can take many months to present, patients and treating physicians should be notified when the extravasation tissue dose exceeds recognized dose limits so that patients can be followed clinically.

Dr. Darrell Fisher, senior author of the paper, recent president of the Health Physics Society, and former patient advocate on the U.S. Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI), said "We found that extravasations of commonly used diagnostic radiopharmaceuticals occur more frequently than many realize. When they do happen, the infiltration of radioactive material into arm tissue and patient-specific biological retention result in tissue doses that may be high enough to warrant concern. The novel scientific approach detailed in this paper suggests a straightforward way for clinicians to characterize local radiation dose to guide follow-up response. "

Dr. David Townsend, co-author of the study and co-inventor of the PET-CT scanner, said "Nuclear medicine imaging plays an essential and increasing role in the diagnosis and assessment of major diseases. When radiopharmaceuticals are properly administered, patients experience minimal radiation

exposure and there is absolutely no question that the benefits of imaging far outweigh any risk to the patient. However, to be truly beneficial to the patient, the imaging procedure should be of the highest quality, from the injection of the radiopharmaceutical to the acquisition of the scan. When the radiopharmaceutical extravasates into the patient's tissue instead of being cleanly injected into the vein, image quality and quantification can be compromised. In addition, as our publication demonstrates, such an extravasation can also lead to a very high local radioactive dose to the patient. For these reasons, extravasation rates should be kept to the absolute minimum."

The paper's findings are particularly relevant as the NRC is currently considering medical event reporting of extravasations. The NRC currently requires nuclear medicine providers to report medical events that result in unintended irradiation of patient's tissue by a dose equivalent greater than 0.5 Sievert. However, since 1980, a loophole in this rule has exempted extravasations from reporting requirements--even when patients received doses that would be otherwise reportable.

The NRC loophole is based on their mistaken belief from over four decades ago that extravasations are "virtually impossible to avoid." For the past two years, Lucerno Dynamics has presented scientific and clinical evidence to the NRC and the ACMUI that providers can drastically reduce the occurrence of extravasations with dedicated monitoring and feedback to the technologists. This evidence included positive results from the largest quality improvement project ever conducted for nuclear medicine injections as well as case studies where the patient tissue was unintentionally irradiated with doses far in excess of NRC's 0.5 Sievert reporting threshold. A petition for rulemaking filed by Lucerno Dynamics and accepted for docketing by NRC has garnered letters of support from the Organization of Agreement States (OAS), lawmakers, physicians, medical physicists, experts, patients, and patient advocates.

OAS (NRC's regulatory partner in 39 states) publicly commented that in 1980, when the current rule was created, "there was a smaller scope of radioisotopes in use, practice and techniques were still in early development, the consequences were not fully understood, and medical practitioners told the NRC that extravasations were nearly impossible to avoid. Four decades later, it is clear that the rationale for this exemption is no longer appropriate. Overnight, the NRC could make a policy decision to drastically improve the health, safety and clinical outcomes for hundreds of thousands of patients a year."

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