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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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Submitter Information

Name: Ramsey Kilani
Address:
Raleigh, NC, 27609
Email: ramsey@gliaventgroup.com
Phone: 9193589964

General Comment

I'm a Radiologist. The existing NRC dose threshold for reportable events exists in a broad sense for the safety and well-being of the public, and patients undergoing nuclear medical procedures should not be excluded from this protection based on an antiquated understanding of the real prevalence, consequence, and preventability of these extravasations. In published studies, nuclear medicine extravasation rates far exceed the norms in the rest of medical imaging and in nearly all other settings in medical care requiring IV administrations. This is likely because there is no monitoring, reporting, or accountability surrounding these injections. Generally, when quality measures are tracked in the modern healthcare era, they tend to improve over time due to corrective interventions, and systems and procedures are established to deal with the events that do occur in order to minimize patient impact.
Transparent reporting provides a comprehensive understanding of these events, enabling healthcare professionals to refine their practices, enhance patient care, and minimize the likelihood of future occurrences. Iterative improvement in patient care related to vascular access is the standard for the rest of medical imaging (CT, etc.) and healthcare more broadly, which results in extravasation rates that are much lower than those reported in the literature in nuclear medicine departments. Further, the potential argument that reporting these events is too operationally and clinically onerous, or administratively burdensome, flies in the face of medical ethics as well as the NRC's mandate to protect the public.
It is widely agreed upon that that not all extravasations are clinically significant, however, some of them are. This includes those occurring in both diagnostic procedures and the growing field of radiopharmaceutical therapy. Furthermore, many extravasations, including clinically significant ones, have the potential to go undetected at the time of injection due to the small volume of liquid injected and the fact that these drugs aren't vesicants that produce acute effects. This window for detection also corresponds to the window in which treatments can be applied to lessen the potential for radiation-related injury in the subacute to chronic timeframe due to the dose effects of a radionuclide persisting in a small volume of tissue in the arm compared to the distributed and rapidly cleared total body dose when properly

injected intravenously. In the modern era of nuclear medicine, with the use of higher dose agents trending upward, extravasation rates must come down for patient safety. The only way to reliably achieve this is to make extravasations above the dose threshold reportable, which requires monitoring, detection, and dosimetry calculation. The current policy, which places the responsibility of detecting and reporting the events on the patient, is unrealistic and borders on disgraceful in its spirit.

The proposed rule not only reinforces a commitment to patient safety but also fosters an environment of accountability, patient safety, quality assurance, and continuous improvement within the stakeholder medical community. This transparency encourages departments to maintain the highest standards of care and promptly address any deviations from established protocols. Additionally, by collating data on nuclear medicine extravasations, healthcare organizations can identify trends, develop targeted interventions, and continuously improve guidelines and training procedures.