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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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Submitter Information

Name: Daniel Scanga
Organization: Society of Nuclear Medicine & Molecular Imaging

General Comment

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As a nuclear medicine physician, practicing at Mecklenburg Radiology Associates in Charlotte, NC, I believe no additional rulemaking is needed to require reporting of certain nuclear medicine injection extravasations as medical events. This issue of extravasations has been addressed by the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) several times in recent years. Most recently, in 2019 ACMUI Subcommittee on Extravasation reviewed the 1980 NRC decision to exclude extravasations from being considered a misadministration (medical event). They concluded that extravasations are a practice-of-medicine issue and thus beyond the scope, appropriately, of NRC regulatory oversight.

The Subcommittee reconfirmed that the exclusion of extravasation from medical-event reporting was appropriate for both diagnostic and therapeutic procedures. However, one of its recommendations was for extravasations to be considered a type of passive "patient intervention" and that extravasations that lead to "unintended permanent functional damage" be reportable as a Medical Event under 10 CFR 35.3045(b). This is not inconsistent with the NRC's policy from 1980 and therefore such policy is still current. The scientific literature also confirms this. A systematic review performed by van der Pol, et al. concluded that, although extravasation of diagnostic radiopharmaceuticals is not uncommon, of more than 3,000 reported cases of extravasation of diagnostic radiopharmaceuticals, only 3 cases (<0.1%) resulted in patient symptoms that required follow-up. More specifically, none of the reported cases of

extravasation of Tc-99m, I-123, F-18, or Ga-68-labeled tracers required intervention; the only cases where patient symptoms were reported were for the less-often-used tracers Tl-201 and I-131 Iodocholesterol.

This systematic review also mentioned that extravasation of therapeutic radiopharmaceuticals is a more significant event that can potentially induce severe soft-tissue reactions. In this context, it is important to point out that extravasation of chemotherapeutic agents is an on-going concern in medical oncology and that there are well-established procedures for management of extravasated radiotherapeutic agents, similar to those in place for extravasated chemotherapeutic agents.

I have been practicing in Charlotte, NC since 2005. The departments of Nuclear Medicine for which I serve as the Medical Director perform up to 300 intravenous diagnostic radiopharmaceutical injections per week. This accounts for no more than half of all diagnostic injections in Mecklenburg County alone.

Diagnostic dose extravasation occurs approximately once per month in my experience, and is easily recognizable by both the technologist and radiologist. Assessing image quality implicitly includes deciding whether sufficient dose was delivered to make a diagnostic image. Therefore monitoring for extravasation is done on every study. Diagnostic doses are usually very small in volume. An extravasated dose typically gets absorbed rapidly enough and in sufficient quantity to produce an image of adequate diagnostic quality. In the rare cases where the image is uninterpretable due to insufficient activity, our certified Nuclear Medicine Technologists and Board-Certified Radiologists are trained to recognize the deficiency and arrange for a new IV site with a new dose. This only happens about twice per year at our institution. Our technologists routinely attempt to establish reliable antecubital IV access before resorting to more tenuous distal sites, so our rate of extravasation is already low. The form and quantity of radioactivity in diagnostic injections have never been conclusively shown to cause physical damage or subsequent skin cancer. We have never seen a case of physical harm at the injection site due to diagnostic dose extravasation in our institution.

Additional real-time monitoring is unlikely to lower the rate further because we already follow best practices for IV access. Therefore, NRC regulatory action requiring monitoring and review of extravasation would not significantly improve patient radiological health and safety at our institution.

In our practice, the burden of the Proposed Rule would be substantial, for essentially no benefit. At least 12 novel devices would need to be purchased and used on those 300 injections per week. The Lucerno Dynamics Lara product, by the manufacturer's own estimation, would add 90 seconds to each injection. That would be 7.5 additional person-hours per week for data collection, not to mention as-yet unknown time spent maintaining and updating the documentation and reporting. The device can only detect an infiltration, but it cannot prevent one from occurring. Again, all this effort and cost would go toward finding a very small number of diagnostically relevant extravasations, which would be detected during routine image review already.

If the NRC requires r