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Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

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General Comment

See attached file(s)

Attachments

Perrin NRC comment

Comments submitted in respect to Petition for Rulemaking (Docket No. PRM-35-22).

I am an employee of Lucerno Dynamics, the petitioner. Thank you for considering my comments related to the NRC's policy on reporting certain nuclear medicine injection extravasations as medical events. The NRC is in an unenviable position in that it must rationalize the contradictory guidance which it has received from its committee of advisors. The commission has been informed that extravasations are nearly impossible to avoid. At the same time, it is suggested that special care is taken for injections of therapeutic radiopharmaceuticals thereby resulting in lower rates of extravasation.

The commission's task is further complicated because these claims are presented anecdotally, without supporting evidence. Particularly when compared to other fields of medicine, the efforts of the nuclear medicine community to understand and explain this issue are unconvincing.

I would encourage the commission to review, for example, literature from practitioners who administer chemotherapy. The C3NSI group, consisting of nurses in several National Cancer Institute (NCI)-designated cancer centers, studied nursing-sensitive indicators associated with extravasations and established a benchmark for their rate of incidence [1]. A total of 739,812 infusions were evaluated at 19 cancer centers. Incidence for all extravasation events was 0.09%. The study included administrations via peripheral intravenous (IV) access devices (commonly used in nuclear medicine) as well as central venous access devices (CVAD). Incidence for peripheral IVs alone was estimated to be 0.18% of administered doses. One might reasonably presume that there is a broad overlap among the patients who receive chemotherapy infusions and those who receive radiopharmaceutical infusions. The quality of nuclear medicine procedures should be measured against similar benchmarks.

A second publication [2] presents a broad review of the literature related to chemotherapy extravasations and the recommendations of international professional societies. Of relevance in this article is "Table 3 - Overall summary of guidelines for prevention of chemotherapy extravasation", which identifies 19 steps that should be taken by the practitioner to ensure proper administration. Nearly all of these steps could be applied to the administration of radiopharmaceuticals. In addition, the article notes that "*any local incidence of extravasation should be reported. While documentation may differ among institutions, certain items remain essential and should be documented for every incident. In addition to date and time and patient's name, name of the drug, characteristics of the solution infused, the IV access used, description of the extravasation area, signs and symptoms and management should always be documented.*" The nuclear medicine community should not consider such guidelines to be either onerous or without precedent.

The commission might also review related efforts to reduce extravasations of computerized tomography (CT) contrast dye [3]. The Society of Abdominal Radiology and American College of Radiology co-developed a "practice quality improvement project" to study extravasations that occur during CT exams. For 454,497 contrast-enhanced CT exams, 1,085 (0.24%) extravasation events were reported.

The ACMUI has suggested [4], based on a literature review written by van der Pol [5], that the extravasation rate for radiopharmaceuticals is already as low as 0.1% This is a misrepresentation of the publication, which does not attempt to assess the frequency of extravasations but does conclude with the statement, "Extravasation of diagnostic radiopharmaceuticals is common." The article did identify 3016 cases of extravasation in the literature and noted that of these, 3 patients (0.1%) had been followed for subsequent injury. A thoughtful review of this data might lead to the concern that in known

cases of extravasation, only 0.1% of patients were followed, and that for the remaining population, dosimetry and patient follow-up were not performed.

Today there is evidence that, using well-developed competency validation processes, policies and procedures, extravasations resulting from peripheral IV infusions can be minimized. With education, training, and appropriate incentives, the nuclear medicine community can match the benchmarks established by their peers.

Respectfully submitted,

Steve Perrin

References

(1) Jackson-Rose, J., et al. (2017). "Chemotherapy extravasation: establishing a national benchmark for incidence among cancer centers." Clin J Oncol Nurs **21**(4): 438-445

(2) Kreidieh, F. Y., et al. (2016). "Overview, prevention and management of chemotherapy extravasation." World J Clin Oncol **10**(7): 87-97.

(3) Dykes, T. M., et al. (2015). "Intravenous contrast extravasation during CT: a national data registry and practice quality improvement initiative." J Am Coll Radiol **12**(2): 183-191.

(4) NRC Commissioners – ACMUI Meeting, November 18, 2020

(5) van der Pol, J., et al. (2017). "Consequences of radiopharmaceutical extravasation and therapeutic interventions: a systematic review." Eur J Nucl Med Mol Imaging **44**(7): 1234-1243.