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Submitter Information

Name: John Witkowski
Address:
5400 Laurel Springs Parkway
Suite 405
Suwanee, GA, 30024
Email: john.witkowski@uppi.org

General Comment

Docket: NRC-2020-0141
Reporting Nuclear Medicine Injection Extravasations as Medical Events

I believe the Nuclear Regulatory Commission (NRC) should consider rulemaking concerning Nuclear Medicine injection extravasation as a Medical Event and make a change based on new and emerging radiopharmaceuticals, diagnostic and theranostic, as to regulatory oversight.

In 1980, the NRC decided to exclude extravasations, then referred to as misadministrations, as a medical event. The ACMUI Subcommittee on Extravasation in 2019 reviewed the 1980 NRC decision and concluded that extravasations were a practice-of-medicine concern, not a medical event, and beyond the regulatory scope of NRC oversight. Meaning that in 40 years there was no need to change the 1980 decision despite 40 years in the development of radiopharmaceuticals for single photon emission computed tomography (SPECT), positron emission tomography (PET) and radiotherapeutic, or theranostic use applications.

In the 40 years, a first-in-case alpha particle radiotherapeutic for prostatic bone cancer Radium 223 dichloride (Xofigo), and another approved radiotheranostic labeled Lutetium 177 Dotatate (Lutathera), a beta particle emitter, have entered frequent medical use. Several new PET products employing the radionuclides: Gallium 68 and Copper 64 have also entered the diagnostic PET imaging as tumor tracers.The products mentioned are delivered to the patient via venous injection. And other new alpha and beta emitting radionuclides, such as Actinium 225, Thorium 227, pure alpha emitters, Rhenium 188, a beta emitter and Tin 117m with gamma and xray emissions will see approval as injectable theranostics in

the future. Going forward, nuclear imaging and radionuclide therapy will expand in new and emerging isotopes that need consideration for licensing, medical use and potentially medical event reporting due to extravasation.

ACMUI in its discussion of extravasation mentioned "unintended permanent functional damage". This is an interesting concept since particulate radiations such as alpha and beta radionuclides (and some diagnostic imaging isotopes, perhaps, nanoparticles) might deliver radiation exposures beyond the injection site if extravasated. Several images presented in the documents submitted to the NRC by Lucerno Dynamics appear to show uptake in the upper arm and axial area, on the injection side, that has to be explained as lymphatic drainage. The use of alpha and beta emitters with high LET could pose significant exposure to lymph and axillary lymph nodes, in addition to the local injection site, caused by extravasation. Further, Lutathera requires an amino acid infusion before, during and after the injection of the Lu 177 to protect the kidneys from radiation exposure during the administration of the radiotherapeutic. Should Lu 177 be extravasated and the absorption of the dose be prolonged via lymphatic removal of some of the patient dose lost to the tissues of the injection site, then is this potentially an unintended permanent functional damage to the kidney? Some might say this is conjecture, but if I were a patient for such therapy, or any therapy or large activity diagnostic imaging dose, then it would be of concern to know if the intended amount to be injected was delivered, and not extravasated.

Noted, too, is the lack of scientific literature following the effects, acute or latent, to a patient that had an extravasated radiopharmaceutical injection. I find the slim amount of reviews not surprising since for 40 years extravasation was not a reportable medical event -thus a lack of emphasis to the cause and effect. As a nuclear medicine technologist since 1973, I was well aware of misadministrations then which included extravasations (prior to 1980). Having extravasation as a reportable event did increase training and awareness to prevent occurrence. A vessel could collapse, a hematoma can form and patient motion can enlarge the venous entry point, or dislodge the needle slightly to cause an extravastion. It happens.

I find it a false objection to say that the Lucerno Dynamics claim has no clinical data to support it and thus is being made for the company's enrichment. Cannot a company have a concern for patient safety, image quality or the delivery of the intended diagnostic or therapeutic dose?

With the continued development of new and emerging radionuclides having high LET, as therapeutics, or capable of delivering localized radiation absorbed doses due to high radioactivity, the NRC needs to reassess its position on extravasation as a medical event either for certain therapeutic radionuclides or imaging procedures. Oversight and review will be needed in the future, if not today.

Sincerely,
John Witkowski
President UPPI, LLC.