July 11, 2021

Dear Chairman Hanson, Commissioner Wright, and Commissioner Baran,

My name is Pam Kohl. Thank you for providing this opportunity to comment on the topic of radiopharmaceutical extravasations. I am a metastatic breast cancer (MBC0 patient. I am involved with several MBC groups and as a result I am a very-well informed breast cancer advocate. I have written the NRC before and also submitted a comment for a recent petition to make the reporting of significant extravasations required just like any other misadministration that meets medical event reporting criteria.

Recently, I participated in a webinar on the topic of radiopharmaceutical extravasations, sponsored by AltusLearn. I provided the patient perspective. As part of this webinar, I was fortunate to work with several other presenters. Dr. David Townsend, the co-inventor of the PET/CT scanner, described the physics of how an extravasation negatively affects a camera image. I believed him. Dr. Jackson Kiser then showed how an extravasation absolutely affected his ability to interpret images. As a cancer patient, who relies on my PET/CT scans to help assess my treatments and guide my care, this was sobering to hear. Dr. Darrell Fisher, who used to be a member of the ACMUI, then precisely described the energy emissions of isotopes that are routinely used to assess my treatment. He made it perfectly clear that if these isotopes are extravasated, patients can receive very high radiation doses to their tissue. Dr. Marjan Boerma then discussed how ionizing radiation actually affects healthy tissue and how these effects can often take weeks or months to be discovered. The final two presenters were Nancy Warden and Stephen Harris, two nurses who gain venous access for a living. They are experts who are called when hospitals struggle with certain patients. I am one of those patients and it is not unusual for my clinical team to stick me several times as they try to gain access or before calling for help. Nancy and Stephen described their experiences with nuclear medicine patients and shared an example of a diagnostic and a therapeutic extravasation that harmed patients.

This experience made me think hard, especially when I continue to see comments from the medical societies that are very distressing. In a recent Health Imaging article, the American College of Radiology was quoted as saying that significant extravasations are “inconsequential.” I can assure you from the patient perspective, this position is not only wrong, but also insulting. This is the same group that publicly commented that there is nothing inherently harmful in a radiopharmaceutical administration. In this same Health Imaging article, the Society of Nuclear Medicine and Molecular Imaging assured the writer that significant extravasations are not a patient safety issue. How can the society representing nuclear medicine not understand the patient consequences of dumping radiation into the tissue? It makes me wonder if these clinicians truly understand the nature of the drugs they are using. Hopefully, none of these commenters are authorized users of radioactive material.

As I think about the countless nuclear medicine procedures I have experienced, I consider another point that Dr. Townsend made in the webinar. He described in great detail all the quality control efforts that are routinely performed to ensure the quality of nuclear medicine procedures. He noted that the one area of the imaging process that has the potential to have a very large impact on quality is the administration of the radiopharmaceutical, but that he was not aware of any routinely used quality assurance efforts for this process. He is right. In all my procedures, I was not aware of any monitoring of the quality of the administration.

And this leads me to the main reason I am addressing you today. Reflecting on the points from the webinar and all I know about this topic, I have assembled some questions. I think these questions should be sent to every authorized user and they should be required to respond. This will allow the NRC to better understand the issue.

1. What is the frequency of diagnostic and therapeutic radiopharmaceutical extravasations at your institution?
2. In determining these extravasation rates, does your institution actively monitor the administration process with a method that can know for sure if an extravasation happens or does your institution review images later to assess the quality of nuclear medicine administrations today?
3. If your institution actively monitors nuclear medicine administrations today,
a. what process is used to confirm that the administration was ideal or extravasated and are these processes different between diagnostic and therapeutic administrations?
b. when extravasation is identified, at what time in the administration process do you know of an extravasation is happening?
c. what steps are taken to mitigate the effects of a diagnostic extravasation? A therapeutic extravasation?

4. If your institution monitors nuclear medicine administrations today by reviewing images sometime after the procedure,
a. what percentage of diagnostic images (including all nuclear medicine procedures) capture the injection site in the imaging field of view?
b. does your institution image the injection site after therapeutic administrations?
c. when the injection site is not included in the field of view or imaging is not performed post therapeutic administration, how does your institution determine if the administration was extravasated?

5. At your institution, what specific tissue dose and skin dose thresholds are considered harmful (possibly leading to adverse tissue/skin reactions) to the patient? Are the clinicians aware of these limits?

6. What dosimetry method is used to measure the dose to tissue/skin at your institution? Does this method capture the biological clearance of extravasations? If so, how is this done?

7. If patients receive a tissue/skin dose higher than what your institution has determined will lead to adverse tissue/skin reactions,
a. are the extravasations and the estimated dose to tissue included in the patient's electronic health record?
b. is this information also shared with the patient and their referring physician?
c. how long are patients followed for the delayed radiation injury effects?
d. Are these reported to the FDA as adverse events or are they reported to Joint Commission as a sentinel event?

8. What percent of diagnostic extravasations at your institution require repeat imaging? What percent of therapeutic extravasations require repeat administration to ensure the target received the prescribed dose?
a. What is the process to determine whether or not the procedure should be repeated?

b. How are the costs of these repeat procedures addressed?
c. If the patient or a payer does not pay for the repeated procedure isn't there a financial disincentive for the institution to repeat the procedure?

9. What role does your institution's radiation safety committee play in nuclear medicine extravasations?

10. Does your institution employ a quality improvement process for radiopharmaceutical administrations? If so, please describe how this process works and can you share the trending information over the past 3-5 years?

11. Do reports of radiopharmaceutical extravasation go to the same executive in your institution as CT, chemotherapy, or general floor IV extravasations? If not, where do these reports go?

12. Does the organization that accredits your nuclear medicine program analyze radiopharmaceutical extravasations? What specifically is audited when it comes to radiopharmaceutical administrations?

Thank you for considering this request.

Sincerely,

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Cc: David Crowley, Chairman, Organization of Agreement States