August 30, 2021

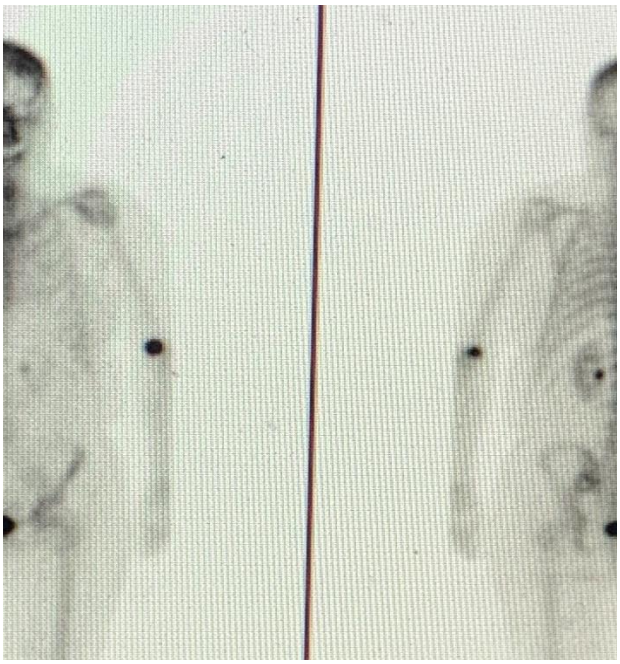
Dear Chairman Hanson, Commissioner Wright, Commissioner Baran, and Ms. Jamerson,

On July 11, 2021, I sent you comments intended for an upcoming NRC ACMUI meeting on radiopharmaceutical extravasations. As you may recall, I expressed the patient perspective regarding the effects of radiopharmaceutical extravasations. I shared my disappointment in the attitudes of clinicians to these medical errors and also questioned their understanding of the radioactive drugs they are using. I also challenged the NRC to survey authorized users with questions that would shed light on the real issue.

Unfortunately, later that month, I was extravasated myself during a nuclear medicine procedure. I would like to explain what happened and then comment on the recent meeting material that the NRC medical staff and the ACMUI posted online in advance of the postponed July 15 meeting that is now scheduled for September 2.

As I mentioned in my previous letter, I am a metastatic breast cancer patient. As a result, I also am a regular nuclear medicine patient. During my latest round of imaging, I was extravasated during a bone scan procedure. During the injection of 22.5 mCi of 99mTc MDP, I felt an unusual sensation. I noticed it because it felt different from previous injections I have had. I immediately suspected that I had been extravasated, only because I know a lot about this issue. I would guess that most patients would not have suspected extravasation, since they don't even know what an extravasation is. I asked my technologist and suggested she had just extravasated me. Even though I am well-versed in this issue, I didn't quite know what to do. Neither did my technologist, which surprised me. My care is provided by a leading academic center in the United States. Finally, I asked the technologist how do I know that the injection is in my vein? After examining the site closely, she noticed a slight swelling and decided to image my arm right then. She removed my IV and we went to a camera and imaged the arm and sure enough I was extravasated. She then imaged my other arm and saw activity indicating some of the MDP had made it into circulation.

As I mentioned, patient advocacy is my vocation. But I admit that I did not consider what to do next. I should have asked the technologist to try and mitigate the amount of absorbed dose my tissue would receive. But I didn't. As a result, no additional flushing with saline was done to disperse the radioactivity. No warm compress was provided to try and increase blood flow. No massage was done. I was not told to raise my arm or move my arm to try and increase vascular flow. Even though I had attended the May 2021 webinar when vascular access experts explained mitigation, I did nothing. More disappointing to me was that the technologist did nothing. She just wrapped up the procedure and I waited several hours for my imaging. The following day, I had another imaging procedure. I requested a vascular access expert use an ultrasound device to guide the access procedure. Same arm, different vein. No extravasation. The image from that procedure was flawless, but as you can see, my bone scan was not flawless. I have attached cropped versions of my images for your consideration.



What was the absorbed dose to my arm tissue? Why did mitigation not happen? Why did I not receive any instructions on what to look for in the days or weeks to come. I know that the energy emissions from 99mTc will not likely reach my skin, so I shouldn't expect to see skin damage, but what is happening to my tissue? When I reviewed the questions I asked you in my previous correspondence, I can now answer some of them about the center that performs my nuclear medicine procedures.

- My center does not actively monitor injections. As a patient, I had to suggest that I had been extravasated.
- My center takes no steps to mitigate the radiation dose when they extravasate.
- My center obviously does not know what threshold should be worrying, since they didn't bother to perform dosimetry to assess my absorbed dose and compare it to a threshold.
- While the extravasation was noted on my radiology report, perhaps because I brought it to the attention of the technologist, there is no estimation of the dose to my tissue from the extravasation in my medical record.
- I am requesting that my oncologist ask for a nuclear medicine physician to compare my July extravasated bone scan image quality to my April not extravasated bone scan image to see if they think I should repeat the procedure.
- I was not followed by anyone in nuclear medicine to see if I have had any adverse tissue reactions.

Unfortunately, I am experiencing adverse tissue reactions. In the days and weeks that followed this extravasation, the injection site has been painful. In fact, the pain woke me up at night. Even worse, extreme fatigue is one side effect of my current treatment for my cancer and now my sleep has been affected by a preventable misadministration of a radioactive drug. And I still don't know how much damage that isotope has caused to my arm tissue. I understand it could be weeks or months or even longer for that to show up and frankly, I have more important things to worry about.

Since I was registered for the upcoming NRC/ACMUI meeting, I received notification that the September 2 meeting material was available online. Now, my disappointment with clinicians and the ACMUI regarding extravasations extends also to your organization.

On April 1, 2021, the NRC medical staff submitted a report on their preliminary findings to the ACMUI subcommittee on extravasations. I have several concerns from a patient perspective.

The NRC staff states that the purpose of the regulation is "to reduce unnecessary radiation exposure to patients" and that the purpose of medical event reporting is "to identify the causes of events in order to correct them, prevent their recurrence, and allow the NRC to notify other licensees of the events so they too can avoid them." They go on to say that "Medical events may not necessarily cause patient harm, but the NRC requires their reporting because they have the potential to cause harm and they may indicate a potential problem with how a medical facility administers radioactive materials or radiation from radioactive materials." Yet, the rest of the report appears focused on finding excuses why the NRC should allow the community to continue to avoid addressing extravasations. Let me be clear what a patient thinks:

- A center that routinely extravasates is more likely to have significant extravasation than a center that rarely extravasates at all. It is important that patients are aware of which centers extravasate frequently and which centers rarely extravasate.
- Extravasations are not routinely caused by patients – the NRC should know this by now! We are the same patients who undergo chemotherapy and contrast CT injections. Those nurses or technologists have to undergo infusion training. They have to be observed gaining access by trained vascular access experts. They have to prove their skills again to trained vascular access professionals annually. Technologists do not. Nor do they have to report when they make a mistake. Extravasations are caused by technologists who do not use the latest technology, do not employ the proper technique, and who do not have the requisite training. Ultra sound guided techniques are available and should certainly be used when radiopharmaceuticals are involved. Stop blaming me for my extravasation. Stop blaming patients
- Standardized uptake values do matter. My oncologist waits for my SUV measurements to help guide my treatment. Incorrect quantification is unacceptable when it can be eliminated. Nuclear medicine physicians can talk all they want about the variability of these values (some caused by extravasations), but patients, medical oncologists, and radiation oncologists use these quantitative values. I think Cardiologists use quantification, too.
- Doses greater than 0.5 Sv or absorbed doses of more than 0.5 Gy, need to be reported. My tissue and my skin should not be getting any dose more than what it gets when my administration is done properly. The NRC has already determined that 0.5 Sv is the right reporting threshold. It may not cause harm, but it does indicate a potential problem. If a center is constantly extravasating and irradiating patient tissue with 1-2 Sv then something is wrong at that center. And the higher the absorbed dose the greater the chance a patient can develop cancer down the line. Furthermore, I would not want my imaging procedure to be done there.
- I have met with the Chairman of the OAS. The OAS is not skeptical about extravasations; they know that extravasations should be reported and want the NRC to eliminate the reporting exemption, period. Please ask the OAS board to confirm.

Many of the options that your staff listed for the consideration of the ACMUI scare me. It is hard to believe that the staff would even list a *no action* option or a *permanent functional damage* option. Other options mention excluding diagnostics, worrying about regulatory burden of a center that routinely extravasates with doses greater than 0.5 Sv, not performing dosimetry on extravasations like mine, asking patients to be responsible for self-reporting when most of them have no idea what has happened to them, asking physicians to subjectively assess extravasations (have you seen the clinicians' comments to the petition?), suggesting extravasation doses less than 10 Gy be ignored, or mentioning financial burden when centers already spend lots of money to provide quality in all other aspects of the procedure are just a few examples that make it clear that your staff is not following the medical policy statement.

I have read the ACMUI positions for the past few years and even back to 2008 and 2009. I have read the clinician comments to the NRC. The community is not going to voluntarily address this issue. A regulatory option is needed. Let me suggest the option patients care about. We want an option that will ensure our technologists are trained to the same level as chemotherapy infusion nurses and also trained on mitigation steps in case they extravasate. We want an option where our administrations are monitored. We want an option that lets us know immediately if we have been extravasated. We want the option that makes centers perform dosimetry on extravasations, so we know how bad the extravasation was and whether or not we should reimage and whether or not we will have a tissue reaction later. We want an option that makes centers check on us and not send us home without instructions on what to do if symptoms develop. We want an option that drives centers to stop extravasating.

It is extremely disturbing for a patient to see an organization whose goal is to prevent unintentional irradiation of patients, allowing extravasations to continue. This issue is so simple to patients. We do not want to be extravasated. But when it happens, we want to know. Centers that routinely extravasate and ones that routinely extravasate really large amounts of radioactivity need to stop. This is the role of the NRC. I hope my message gets delivered to your staff. Thank you so much for considering my request.

Sincerely,

Pam Kohl