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Reporting Nuclear Medicine Injection Extravasations as Medical Events

Comment On: NRC-2020-0141-0004
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

public comment NRC

These comments are in reference to: Docket ID NRC-2020-0141

As a nuclear medicine physician and also section chief and medical director of molecular imaging for 4 hospitals and 2 outpatient imaging centers. I read approximately 5500 exams each year. I am board certified by the American Board of Radiology and received additional special competency from the ABR in nuclear medicine. I previously received board certification in internal medicine from the American Board of Internal Medicine and am currently board eligible. I have been practicing for 23 years.

V. Request for Public Comment

I have reviewed the NRC request for public comment and the petition. I understand from section V. that these public comments should take into consideration the Medical Use Policy Statement and how this Statement may relate to radiopharmaceutical extravasations. While reading section V, I noted that the NRC stated that the NRC will not intrude into medical judgements affecting patients. Medical judgement in context of the NRC and regulations is referring to the physician and patient care determination. Extravasations are in no way related to medical judgement – the NRC is certainly not intruding. No nuclear medicine professional would ever suggest that patients should experience an extravasation as part of their medical care. Additionally, I have reviewed ACMUI meeting minutes on this topic and there are comments suggesting extravasation is a medical practice issue and the NRC should not be involved in the extravasation topic. I disagree with this perspective. If a center is routinely extravasating patients, NRC should be involved. And from my review of the supporting information in the August 3, 2000 Federal Register, the NRC has stated that they are responsible for ensuring the accurate administration of radioactive materials and for the radiation protection of patients. It would seem to me that the NRC has already determined that the extravasation of radioactive material is directly related to the NRC Medical Use Policy Statement.

Injection Quality Monitoring

The extravasation topic is also directly related to the NRC's interest in encouraging licensees to use quality assurance tools to ensure administrations are conducted as I intended them to be delivered. Our centers like most in the United States spend a considerable amount of time ensuring we provide the right dose to the right patient at the right time and right activity level. Interestingly, those efforts for most centers stop at the point of administration. It has only been in the past few years that centers can access technology that helps assess whether the administration was actually delivered into the patient's vascular system as the nuclear medicine physician intended.

1. How frequently does radiopharmaceutical extravasation occur? We have published our extravasation rate. When we first evaluated our performance several years ago, we found that we extravasated at our main clinic ~ 13% of the time. Before monitoring our rate, we did not have a good idea of how we were performing; we thought we were better than we really were. In fact, our team was dismayed at our initial results and we immediately used the latest technology and the DMAIC quality improvement process to improve. Within 4 months of starting our extravasation learning journey, we improved our rate to 2.9%. Several years later we are now extravasating less than 2.0% of the time. Our goal is less than 1%. Our satellite

centers are now examining their extravasation rates. They are also in the mid-teens and several sites are implementing improvement processes and we are seeing similar improvement as we saw in our main center. I would also suggest that most centers that know they are extravasating are unlikely to report it in a public setting. From our experience as part of that large study, from our own facilities, and from talking to other centers, I believe the average rate is more than the published rate of 15.5%.

2. I was under the impression that medical event reporting was not necessarily associated with patient harm, but rather associated with a potential problem in handling radioactive materials. Nevertheless, I am aware of patient harm. We have documented a case of a diagnostic extravasation that led our tumor board to reach the wrong conclusion in determining the best treatment for a patient. Fortunately, we repeated the imaging procedure (radiating the patient again) and realized the extravasation had led us to the wrong treatment recommendation. This case has been published. We are in the process of publishing several other similar cases. Additionally, we have begun to perform dosimetry on our significant infiltrations. Nearly all of them result in doses that exceed well-known thresholds for when patients will experience deterministic effects. As you know, these effects will likely become evident in 2-3 years. That is why it is absolutely important that we tell patients and their physicians when they have received a very high dose to their tissue.
3. We do monitor the quality of each of our PET/CT injections. Additionally, at one satellite center we are now monitoring all bone scans because we have determined extravasated MDP injections can also result in extremely high doses to tissue. We are now also monitoring our Lutathera infusions for extravasations. We are in the process of introducing injection monitoring into our remaining satellite nuclear medicine centers. We used to monitor for extravasations by including the injection site in the field of view. This is not ideal for the image for a variety of reasons. Then we participated in the largest quality improvement project ever conducted on nuclear medicine injections and were introduced to a technology that we have adopted. The technology helps us assess the presence of excess radiotracer at the injection site. The technology also provides additional information which are Radiation Safety Officer can use to calculate dose to tissue. Most importantly, the technology gathers information about each injection that we use to help determine factors associated with extravasations. That information is what we use to address our issues as part of our quality improvement processes and has been very helpful in reducing the frequency of extravasations.
4. Monitoring extravasations and reviewing results absolutely leads to improved radiopharmaceutical administration techniques. Our technologists never had feedback before we began monitoring. Now, all of the technologists use the information to improve their technique to provide better care for our patients. Additionally, the quality improvement project we participated in with other centers proved extravasations could be improved by following a DMAIC approach.
5. We have been working on the extravasation issue for several years. In that process, I have presented at many meetings and held many discussions with other centers. I am 100% sure that requiring centers to report significant extravasations and making this is public will improve patient radiological health and safety. Centers will no longer continue to extravasate patients at their current rate. They will want to drive the frequency down to avoid having to report to NRC when they have exceeded the reporting threshold. Additionally, they will not want to tell patients or their physicians what has happened, so they will drive improvements. Some centers

will likely try and continue to ignore this issue, and I think NRC needs to audit centers to assess how they are ensuring they are not extravasating patients.

Medical Event Classification and Reporting Criteria

1. I believe there are many benefits beyond improved medical techniques that will result from monitoring and reporting significant extravasations as medical events. First, the patients will have peace of mind that their injection was done properly, and they can trust the results of their image. Just recently we had a patient come in during COVID. She previously traveled to a major cancer center in Texas for treatment and PET/CT images. She expressed her concern before her radiopharmaceutical injection that in the cancer center they have had difficulties finding her veins. She was so relieved when our technologist showed her the technology we use to help us assess the injection quality. She loved seeing her time-activity curve after the injection and even made sure she told me how satisfied she was with the process. Another benefit is the confidence I have in reading images when I know the injection was not extravasated. Another benefit is improved quantification of the images, which treating physicians often use to guide treatment and assess tumor response or cardio performance. We do not believe there is any real burden for monitoring injections. The process adds about 60 seconds to the technologist job and 20 seconds to the patient experience. The cost of monitoring is inconsequential to the harm and inconvenience caused by an extravasation.
2. Centers should report extravasations that exceed 0.5 Sv dose equivalent, just like we are required to do for other medical events. Monitoring the rate of reported extravasations over the number of cases performed is our number one metric as a center and the number one metric for each technologist. Additionally, when patients experience a reportable extravasation, we notify them and their referring physician, perform dosimetry, repeat the imaging if needed, and include the patient in our follow-up process similarly to how we handle FGI patients. We do not take corrective action for each individual event. Rather, we track all extravasations to look for factors that will lead to extravasations. That helps us design improvement steps and is why we are continuing to reduce our frequency of extravasations. This quality assurance step is what will help us drive extravasation to zero in the future. Centers that are constantly trying to improve this process do not need any regulatory action. Centers that routinely extravasate and that are not making improvement require regulatory action since they are harming patients.
3. There should be no difference in reporting of diagnostic or therapeutic extravasations that exceed 0.5 Sv dose equivalent. The unit of measure, Sv, already considers the energy of the radiopharmaceutical. Why is NRC even asking this question? It does not matter if a a 1.0 or 5.0 Sv extravasation is caused by a therapeutic or diagnostic….it is still providing a potentially harmful dose that exceeds the reporting requirement.

Please feel free to contact me if you have any questions about my comments.