From: Amir H. Khandani
To: RulemakingComments Resource
Subject: [External_Sender] Comments on Reporting Nuclear Medicine Injection
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1. Are there any benefits, not related to medical techniques, to monitoring and reporting certain extravasations as medical events? What would be the burden associated with monitoring for and reporting certain extravasations as medical events?
Answer: No, there would not be a benefit.

Extravasation of radiotracers in an uncommon event and rarely associated with serious complications. This is based on my experience of almost 30 years in nuclear medicine and published data in renowned journals. In the largest publication summarizing the reported cases of extravasation in diagnostic and therapeutic nuclear medicine procedures published in the European Journal of Nuclear Medicine and Molecular imaging (EJNMMI), in 2017, van der Pol et al reported results of thirty-seven publications. There were 3016 cases of diagnostic radiopharmaceutical extravasation, of which only three cases reported symptoms after extravasation. Eight publications reported 10 cases of therapeutic tracer extravasation. The most severe symptom was ulceration. None of the cases had any lasting effect on the patients.

In our current practice at the University of North Carolina Medical Center where I serve as Division Chief of Molecular Imaging and Therapeutics, we use intravenous catheter for all diagnostic and therapeutic radiotracer injections. We flush each catheter before injection with a large volume of normal saline while palpating the cannulated vein to ensure proper flow. We also observe the cannulated site throughout the injection and thereafter and release the patient only knowing that the injection was done properly. For all therapeutic injections, either a physician or a combination of a pharmacist or nurse and a technologist must sign off on the proper placement of intravenous catheter. In difficult cases, we obtain help from our phlebotomy team for placement of catheter.

I personally have never observed and do not know of any serious side effect such as local tissue damage at the injection site. Our patients very frequently see the referring physicians in the days to 1-2 weeks following the nuclear medicine diagnostic or therapeutic procedure – a time frame in which any tissue damage associated with extravasation would have taken place. Referring physicians and their teams observe these patients very closely and carefully. As such, any side effect associated with extravasation would not go undetected. I have never been contacted by referring physicians or patients regarding side effects resulting from extravasation. Classifying extravasation as medical even would mean that it must be communicated to the patient. Many patients who already have to cope with cancer or other serious diseases would have to deal with this additional piece of information, no matter how trivial it might be.

Additionally, I am concerned that that any manipulation such as placing sensors at the injection site to measure radioactivity may lead to increased pressure on the veins

and disturb and slow the flow of radiotracer in all patients, leading to actually increased radiation exposure at the injection site. In the case of FDG, I am also concerned that such manipulation could cause muscle uptake and limit the diagnostic value of PET images. One should also note that measuring radioactivity at the injection site in a way that one could accurately assess the radiation exposure of the surrounding tissue is not trivial and needs sophisticated and reliable engineering, and the algorithm calculating radiation exposure has to be publicly available. To the best of my knowledge, currently published data do not indicate that such a device is available. Before any such device could be used in humans, a multi-center trial with a well-defined gold standard would be needed to establish safety and accuracy of such a device.

In our practice, reports of nuclear medicine imaging studies are often needed for medical decision-making on the same or next day. The nuclear medicine therapies are almost always part of a complex multi-disciplinary treatment regimen - or as mono-therapy, the last resort in an advanced cancer stage. Therefore, any delay in performing nuclear medicine imaging or therapy procedures should be very thoughtful and balanced against potentially harmful consequences. Any such delay would in most cases directly affect the patient's care.

Finally, assessing, documenting, and reporting each nuclear medicine diagnostic or therapeutic injection for extravasation would be associated with tremendous cost. I expect this to require hiring of two additional technologists in our practice of 3 sites of operation and about 50 daily injections. This in addition to the cost associated due to involvement of radiation safety and purchasing the equipment and parts needed for each patient. In a time of limited resources in healthcare, any additional cost must be comprehensively thought through. Funds should be directed to train technologists for best practices and other measure to improve quality of injection of radiotracers.

2. If the NRC were to require that licensees report certain extravasations as medical events (recorded in NMED), what reporting criteria should be used to provide the NRC data that can be used to identify problems, monitor trends, and ensure that the licensee takes corrective action(s)? N/A

3. If the NRC requires reporting of extravasations that meet medical event reporting criteria, should a distinction be made between reporting extravasations of diagnostic and therapeutic radiopharmaceuticals? If so, why? If not, why not? N/A.

Thank you for reviewing my comments.

Best,
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