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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

Document: NRC-2020-0141-DRAFT-0356

Comment on FR Doc # 2020-19903

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Organization: None

General Comment

See attached file(s)

Attachments

NRC Comment Letter - Phil Belt 11-15-20

Dear NRC Officials -

I am not a nuclear medicine practitioner, but I do have an interest in this topic.

Three years ago my father lost a multi-year battle with cancer. Along the way, he had many diagnostic tests. Several times, these led to a considered or actual change in therapy. Sometimes the changes helped, other times, they did not.

I hate to think that he might have gotten worse because his therapy was changed based on a flawed diagnostic test. Even worse, the flaw should have been known, but was not conveyed to him, our family, or his physician.

My expertise is in business, so I am not in a position to answer the specific questions the NRC has asked. I have worked in big pharma, and I have also worked in healthcare venture capital, funding companies that have solutions to real healthcare problems that affect many Americans. I do have a positive view of the way new technology and discoveries has made healthcare better for all.

I read the petition and find it thorough, compelling, and that it advocates a simple change that will shine light in an area that has been in the dark since 1980. This has to be a good thing for patients like my father.

I also read some of the public comments, including the one from Alan Packard, president of SNMMI. It seems he may be confused about conflict of interest. Yes, the petitioner's company has a tool that helps with the extravasation problem. He seems to think that invalidates the petition – but I disagree.

The validity of the petition is based on the data it presents and the science underpinning the data: that extravasations happen often, **they can happen less often**, and that some extravasations lead to incorrect patient management decisions and may expose the patient to a lot of radiation--much more than was intended for the procedure. The petition seems very well founded on these points.

Dr. Packard says diagnostic extravasations don't pose a safety problem and says no clinical data exists to support the claim extravasations pose a significant patient safety risk. He offers no data to support his statements. He seems not to have read the petition, because it cites a large number of peer-reviewed articles to support its claims, some of which were published in the SNMMI's own journals.

Perhaps he should acknowledge that the SNMMI is not a disinterested party--they too have a conflict of interest in this matter. SNMMI members are the ones making the errors, and they clearly do not want to tell anyone (patients, their doctors, or the NRC) about it.

If, as is potentially true in this case, technology has progressed such that it allows us to solve a problem and improve patient safety, we should embrace it, not deny it.

The SNMMI position statement that Dr. Packard submitted refers to ACMUI meeting discussions. The petition refers to some other ACMUI meeting discussions. So I read through the ACMUI minutes and got some interesting perspective on the topic.

In 2008 and 2009, it is clear from the discussion that the medical professionals on the committee do know how to deliver radiopharmaceuticals without extravasating. It is also clear that they do not bother to take this level of care when delivering diagnostics. I sure hope the people who injected my father did everything they could to get it right. His treatment, and his life, depended on those tests yielding accurate information. Shame on them if they cut corners or were in any way less diligent than if they had been delivering a treatment.

The 2017 discussion created the concept of passive patient intervention to explain extravasations. This is not very persuasive to me. If it is known how to deliver radiopharmaceuticals without extravasating (which is clearly is, based on the 2008 and 2009 minutes), then why would this group try to blame the patient when it happens? The 2019 discussion did not delve into the evidence they were tasked with evaluating. They simply reaffirmed the status quo--extravasations are exempted.

After reading these minutes, I wonder how much the NRC should rely on such advisers. They are clearly protecting their own self-interests, which is understandable. Perhaps this situation is analogous to the Federal Aviation Administration's over-reliance on Boeing related to the 737MAX safety concerns. Is the NRC relying too heavily on the ACMUI?

I do not believe that every problem should be solved with a new government regulation, but it is clear that the NRC has a role to play in protecting patient safety. It is also clear to me that:

- Extravasations happen frequently, **but they don't have to**. The petition says this, and the ACMUI minutes say this, too.
- The nuclear medicine practitioners have known for a long time that they happen frequently and they also have known how to avoid it. Rather than taking steps to fix the problem, it seems to me that the practitioners have actively worked, through their representatives on the ACMUI, to prevent the NRC from doing so.
- New information shows that some extravasations result in a very high radiation dose to the patient, even from diagnostics.
- The tools and techniques to virtually eliminate extravasations have been known for a long time, they just weren't used on all injections.
- The society's public statements and their members' public comments show they don't want the NRC to force them to fix this.

The NRC should take steps reduce the number of times patients experience extravasations and the potential harm that comes from them. Getting rid of the 1980 exemption will shine light where it is needed, and cause practitioners to stop ignoring extravasations. The result would be an unmitigated win for patients, their safety, and their care. The sooner the NRC does this, the better.

Thank you for your consideration of this important perspective.

Philip C. Belt
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