Misrepresentation of Dosimetry

In response to Commissioner Baran's question about the pros and cons of a qualitative approach to medical event reporting of extravasations, subcommittee Chair Melissa Martin stated that methodology to characterize the dose from an extravasation is not yet available and the medical physics community may not have a methodology available to do so until summer 2023. She also confirmed that Commissioner Baran was correct when he asked if a driving factor for the ACMUI to suggest a more qualitative approach might be practical challenges of determining whether a particular dose threshold had been crossed. Just moments later, in response to a question from Commissioner Wright, Ms. Martin stated, "if an extravasation has occurred…, calculations certainly could be done to assess as best as possible the actual dose delivered." She continued, "the methodology is there. If a significant extravasation occurred the dose could be calculated."

ACMUI's advice is incoherent. On the one hand, they say it is not feasible to report extravasations as medical events because there isn't a dosimetric method and then they say that if a significant extravasation occurs today, dosimetry can certainly be performed to determine the dose delivered to tissue.

The real answer to Commissioner Baran's clarifying question is that there are no real practical challenges to determining if an extravasation has exceeded a dose threshold. Peer-reviewed published dosimetric methods exist today. Characterizing extravasations today is simple, free, and accurate. However, it is extremely uncommon for nuclear medicine providers to monitor for extravasations, to characterize and mitigate extravasations if they are detected, or to track extravasated patients, because there is currently no requirement to do so. The logistical difficulty ACMUI claims as a reason to continue exempting extravasations from medical event reporting requirements is not real.

Minimization of Potential Significance of Extravasations

Both Ms. Martin and Dr. Dilsizian minimized the potential significance of a radiopharmaceutical extravasation by comparing it to routine leakage when blood is drawn by a phlebotomist. In reality, these two situations and their consequences are not remotely analogous. Nuclear medicine extravasations are preventable errors in vascular access and the administration of a radiopharmaceutical. And while some extravasations may be quite small in activity, significant extravasations can result in serious damage to skin and tissue including necrosis and skin cancer, or compromised images resulting in the wrong course of treatment for critically ill patients. To compare a significant extravasation to slight bruising after a blood draw is inappropriate and insulting.

In response to Commissioner Baran's question about tissue versus skin damage and requiring patients to report their own symptoms, Dr. Dilsizian also suggested that radiation injury could be confused with allergy to a latex bandage (despite the fact that centers use cloth bandages for this very reason). Dr. Dilsizian failed to acknowledge that subdermal radiation injuries to the tissue may not be seen with the naked eye and may not manifest until weeks or months later, at which point the patient is unlikely to associate a symptom with the nuclear medicine procedure. Radiation injury to the skin or tissue is not comparable to superficial irritation caused by a latex allergy.

"Paradigm shift"

Chairman Hanson was exactly right to point out that it would be a paradigm shift for NRC to make medical event reporting criteria qualitative and focused on harm, rather than focused on dose criteria.

ACMUI is urging NRC to choose a regulatory option that requires harm as a criteria, contrary to NRC's stated policy. No other medical event requires harm, and such a standard would be unthinkable as it relates to nuclear reactor safeguards. Adopting such an option would place the burden on patients to discern the injury and source. It does not consider that some emissions will cause harm that is invisible to the naked eye. It would also require abandoning the stated purpose of medical event reporting – identifying problems in a medical facility's use of radioactive materials – in favor of a new standard that requires a patient to be injured to trigger transparency and corrective actions.

Conclusion

One ACMUI member is confused about the nature of the extravasation issue before the NRC. He asked, "What is the problem we are trying to solve?" He then launched into the questions of incidence and prevalence, as if there is a patient population living with a "disease" of extravasations. This is the wrong question. The correct question is, "Why should significant extravasations, which is clearly the result of a problem handling a medical isotope, remain unreported as medical events, now that we know they are preventable and that they routinely irradiate patient tissue with doses far exceeding reporting limits?"

We remain extremely concerned that advisers to the NRC continue to misrepresent information regarding extravasations. There is no justification for significant extravasations resulting in doses exceeding reporting criteria to continue to be exempt from reporting. We believe that an open dialogue and perhaps a live demonstration of a dosimetric calculation of an extravasation could bring clarity to the issue more quickly. We are available to have this conversation at any time. We thank the Commissioners for their interest and attention to this matter.