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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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General Comment

Why extensive training and education is required to administer radionuclide therapies:

To provide high quality and responsible care, a physician must master the nature of this type of therapy and understand its mechanisms of action: systemic delivery of ionizing radiation and conferring targeted damage at a cellular level from a non-sealed radioactive source. A relatively short and incomplete list of requirements to reach such competency includes in-depth understanding of physics, instrumentation, and radiobiology pertaining to radiopharmaceuticals: interaction of radiation with matter, nature and energy of radioactive emissions, radionuclide properties, radioactivity units, physical half-life calculations, bystander and cross-fire effects, and dosimetry. Radiation protection, largely a non-issue when it comes to diagnostic applications, is clearly a patient, personnel, and public safety issue in the context of radio-therapeutics. Considerations regarding the supply chain, since radiopharmaceuticals do not have a durable shelf life, judicious ordering radiopharmaceutical to avoid wasted doses, a state of the art hot lab with necessary equipment including shielding material, hoods, and dose calibrators, and finally appropriate waste management with radiation safety surveys and concrete standard operating procedures in place for cases of spillage and emergencies are among other fundamental necessities. Even more specific to theranostics, advanced skills in nuclear hybrid imaging interpretation, thorough understanding of biological half-life of specific therapeutic radiopharmaceuticals, target expression, target volume, and target heterogeneity prior to delivering therapeutic radionuclides are all among imperative aspects of a comprehensive training. Above and beyond, training needs to embed radionuclide diagnostics and therapeutics in a solid understanding of physiology, tumor biology, oncology, and multidisciplinary patient management. Can all of this be accomplished without

training?

Management of side effects of treatment, which do exist, as well as integration and coordination of care all require real expertise not pseudo-training. It is absurd and grotesque to assume that this expertise can be acquired in 80 (= 2 weeks) or even 700 hours (= 4 months). This expert-level competency requires years of solid training. Would anyone send a family member to any treatment delivered by someone who had 2 weeks of training? Limited authorized user licenses would be akin to providing privileges to non-oncologists to administer cytotoxic chemotherapies or immunotherapies after a 2-week course or to a non-surgeon to perform complex laparoscopic surgery after 4 months of surgery training.

The NRC has abdicated its role as a protection agency for patients. Its policy in the past and current rulemaking considerations have been overreaching the commissions purview and defeat the very purpose of its existence which is protecting public health and safety!