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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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Comment on FR Doc # 2018-23521

Submitter Information

Name: Robert Wagner

General Comment

See attached comments

Attachments

Letter to NRC - Comment on AU training_0001

LOYOLA
UNIVERSITY
HEALTH SYSTEM

January 28, 2019

Dear Ms. Ma,

I am delighted to provide my comments with respect to training for authorized users (AU's) as requested.

I am a physician single boarded in Nuclear Medicine by the ABNM and have been in practice at an academic medical center for nearly 30 years. During those 30 years, there have been many changes in my practice. New radiopharmaceuticals have been tested and introduced to the market. Many of these have succeeded while others have failed. The successful products stand on their own, demonstrate clinical benefits that are recognized by the referring physicians, are competitively priced and delivered by health care professionals that are well trained in the prescribing, handling, administration, and radiation safety issues that are integral to the practice of the specialty. I believe that some of the products that failed could have been successful if managed differently. I do not believe that any of them failed because of the lack of trained authorized users or their desire to accept them into their practice. Their failure can often be attributed to other causes.

The recent closure of many NM residency programs is likely a result of many factors. It is difficult for a small hospital to economically justify a full time nuclear physician as the case load may be relatively small. In those institutions a radiologist will often perform the diagnostic component of the NM practice. Therapeutic NM in those smaller hospitals may be done in a limited fashion by one of those radiologists if they have the proper training and experience. Alternatively, a radiation oncologist may accept those duties. In any event, therapy with radiopharmaceuticals at small hospitals is generally limited to a well-defined population and is relatively low in volume and complexity.

Some of the recently introduced agents are clinically more complex in their technical administration and clinical management than what has been used in the past. These therapies often require inclusion and exclusion criteria that are more in depth, a schedule of administration, knowledge of the disease process and the current clinical management, periodic blood tests, and the ability to set time aside and meet with the patient, referring physician and the multidisciplinary team. Such workflow is time consuming and represents a significant change in the way that many AU radiologists currently practice. In fact, such scheduling is more analogous to cycles of chemotherapy provided by an oncologist than traditional radiology professionals. In short, the newer therapies are complex and require a greater level of work by many members of the care team. If there is a lack of interest in those

therapies being performed, perhaps it is due to the significantly greater clinical effort without appropriate reimbursement for that effort. The problem may not be that there are too few AU's to perform the service, but that it is no longer economically viable to offer it.

Decreasing the training requirements may indeed increase the number of AU's, but this is a short term fix that will compound into greater problems over time. The assumption being made is that the required knowledge of radiation safety and radiation biology today is similar to the training requirements of decades ago. In fact, the complexity and variety of radiopharmaceutical therapy is significantly greater today. If anything, the use of different radiopharmaceuticals, alpha and beta emitters should increase the training requirements to plan therapy and practice safely. I have heard someone state that administration of an alpha emitter radiopharmaceutical is simpler and safer because there is less concern necessary for contamination. This represents a stunning lack of concern for radiation safety. Further, there is no assurance that the added number of AU's will actually embrace the newer and complex therapies that are likely to emerge.

The creation of "specialty AU's" is an interesting idea although it too will present with problems that will be difficult to deal with later. A non-AU specialist (urologist or oncologist) may wish to begin using one of the radiopharmaceuticals for treatment of bone pain. The frequency of use is an important factor. It is well recognized that a certain number of cases should be maintained on a regular basis to maintain proficiency. Therapy with radionuclides and the safety of their use is no exception. Lowering the bar of education to create more AU's that are specifically trained will create more "casual" users. This may increase the use of the radiopharmaceutical, but at the price of safety and possible medical events or contamination.

The use of radiation in therapy is also not simply the administration of a fixed dose of treatment. In addition to patient considerations, there should be a discussion of radiation safety with the patient and family, consideration of potential contamination within the patient's home, and in some cases restrictions to travel and the general public. Fears of radiation have driven patients to spend post therapy time in hotel rooms; a practice that should be strongly discouraged up front.

Established professions for AU certifications already exist. They are well trained in the fundamentals of radiation, radiation biology, safety and patient care. It is these individuals that embrace and are most familiar with the handling, use and safety. Their broad experience is useful in making individualized judgements in care in specific situations that may not be considered by the casual user. Further, as "specialty AU's" desire to learn additional skills, what will be the pathway for that education? Will they need to complete the entire curriculum of training or will it be some abbreviated form? Who will determine that training and that pathway? Creation of a multitude of "specialty AU's" trained a la carte also creates training problems that will need to be dealt with later.

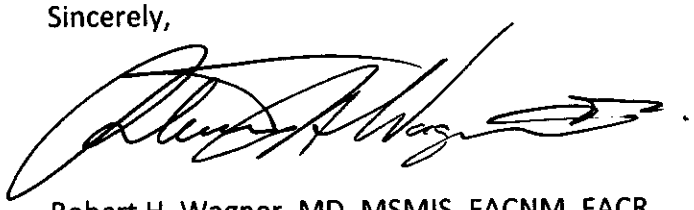
In summary, it can be expected that a number of new targeted radiopharmaceutical therapies will be introduced over the next decade. The majority of these therapies will be performed at

larger institutions that already have AU's present. The barrier is not the number of AU's, but the time required to safely prepare, administer and follow through the patients care with colleagues of other specialties. This paradigm shift in practice will require recognition of the additional effort and time invested. Increasing the number of AU's through limited training creates a cadre of more casual users who may be more focused on a single disease process, but less likely to see the big picture of radionuclide therapy and practice.

I urge you to maintain the existing training and certification requirements and focus on the underlying requirements of a changing practice rather than take the short term gains of decreasing training or creating a separate "specialty AU" class of providers.

Thank you for this opportunity to comment.

Sincerely,



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