The Nuclear Medicine Technologist's Role in Theranostics: SNMMI-TS Advocacy's Vision

Dmitry D. Beyder, MPA, CNMT[1], Cheryl L. Rickley, CNMT, FSNMMI-TS[2], Tricia L. Peters, CNMT, PET, RT(CT)[3], Jeremy L. Iman, CNMT, PET CRA, CT[4], and Christina M. Arenas, JD, MPH[5]

[1]*Barnes-Jewish Hospital/Mallinckrodt Institute of Radiology, St. Louis, Missouri;* [2]*TTG Imaging Solutions, Pittsburgh, Pennsylvania;* [3]*Ridley-Tree Cancer Center at Sansum Clinic, Santa Barbara, California;* [4]*UNC REX Healthcare, Raleigh, North Carolina; and* [5]*Society of Nuclear Medicine and Molecular Imaging, Reston, Virginia*

With the approval of ^{177}Lu PSMA-617, theranostics' presence in nuclear medicine is expanding beyond thyroid cancer and neuroendocrine tumors to higher-incidence diseases. This April (2022), *The Journal of Nuclear Medicine* published an ahead-of-print article, "Joint EANM, SNMMI and IAEA Enabling Guide: How to Set Up a Theranostics Centre" (*1*). The guide provided valuable information to enable interested stakeholders to safely initiate and operate theranostics centers. The article defined the theranostics concept as "using the same target for both imaging and therapy." That is also how we define the theranostics concept as Nuclear Medicine Technologists (NMTs) and SNMMI-Technologist Section (SNMMI-TS) Advocacy governance.

SNMMI-TS Advocacy Committee would now like to expand on that article to answer the following questions and cast a level of opinion on: What training does an NMT need to participate and complete theranostics? What does the SNMMI-TS Advocacy Committee feel are important initiatives to have NMTs fully engaged in theranostics today and in the long-term?

We hope the following article will serve as a springboard for theranostics considerations from the perspective of the NMT.

NMT THERANOSTICS TRAINING

What training does a nuclear medicine technologist need to have to administer and safely treat patients with theranostics?

The SNMMI-TS Advocacy Committee supports best practices in evidence-based science that promote the highest quality in patient care and safety by supporting standards for education and training for NMTs as defined by the Joint Review Committee on Educational Programs in Nuclear Medicine (JRCNMT). Currently, the NMT is initially trained to get into the field by way of college, graduate school, or certificate curriculum, to gain their certification. After obtaining certification, the NMT must participate in continuing education annually to maintain their NMTCB (Nuclear Medicine Technology Certification Board) or ARRT (The American Registry of Radiologic Technologists) certification. That education is thorough and encompasses radionuclide therapy, including the handling of radiopharmaceuticals, adjunctive medications to support clinical nuclear medicine, and patient care management through capturing patient vitals, monitoring, and observing patients before and after procedures.

Most accredited programs are at the baccalaureate level, and some are converting to a master's level due to the complexity of the field and the volume of material that must be taught to perform nuclear medicine technology. Educational programs require extensive didactic education in the fundamentals of nuclear medicine, radiation biology, radiopharmaceuticals, and radiation physics. Additionally, clinical competency requirements must be successfully completed under the direct supervision of a qualified and certified practicing NMT. It would be extremely challenging to meet all these educational requirements via an apprenticeship model. As a point of reference in 2021, Arizona enacted a law (*2*) that would allow some junior college programs to offer baccalaureate degrees due to the academic rigor and the number of required hours that a student must take (120 h). Nuclear Medicine Technology was one such program, and as such students who graduate from a Nuclear Medicine associate's program in Arizona are now awarded a baccalaureate degree.

Although current NMT training is inclusive of most of the components that go into the theranostics *therapy* component of patient care, more training and competency would be helpful to be more competent to access patients' chest vascular ports, lead pre- and postpatient therapy management, and administer therapy-related adjunctive medications such as amino acids.

Why is radiation safety training so important, particularly in the context of theranostics?

With new technology and evolving radiotherapeutic therapies, it is important for medical professionals to continue

Received Jun. 25, 2022; revision accepted Jul. 13, 2022.
For correspondence or reprints, contact Dmitry D. Beyder (dbeyder@gmail.com).
Published online Jul. 26, 2022.

DOI: 10.2967/jnmt.122.264565

to develop a comprehensive knowledge and understanding of radiation biology and safety. The misuse, overuse, or inappropriate handling of radiologic technology can be detrimental to both the patient and the NMT. Improper use of equipment can result in faulty images, which in turn can lead to a misdiagnosis or false interpretation of patient conditions. To prepare knowledgeable, competent, and qualified professionals, the educational content and course competencies are expanding and becoming increasingly complex. Currently, SNMMI is in the process of publishing the sixth edition of the *Nuclear Medicine Technology Competency-Based Curriculum Guide* that outlines the radiation safety knowledge, skills, and experience necessary for NMTs and students to complete a JRCNMT-certified program and be ready for the evolving theranostics field. The curriculum guide develops a competency-based education model that is necessary for students to demonstrate understanding of theranostics radiation safety. NMTs must be able to demonstrate and understand the safe handling of radiopharmaceuticals, practice aseptic technique, and understand the selection and use of proper radiation shielding devices.

The SNMMI is currently working on theranostics-based badges that will be purchasable in 2023. The Molecular & Therapy Task force is heading the efforts to develop the theranostics badges, which includes Xofigo, Lutathera, Azedra, and more. The plan is also to have the badges be CEU (continuing education units) based for NMT formal training. These badges do not take the place of certification but are more so a way to promote the field and the work NMTs do.

Radiation safety training plays an integral aspect of administering theranostics to ensure safety to the occupational workers, NMT, and patient. The NMT must understand the radiation emission of the isotopes used in theranostics to select the correct means of following ALARA (as low as reasonably achievable). Selecting the correct shielding, means of delivery, and proper distance from the patient are all considerations that come from proper training. In some theranostics administrations, proper preparation is key to minimize residual radioactivity exposure and contamination, that is, prepping the bathroom on Lutathera administrations. For the NMT and ancillary staff, training from the vendor-specifics to the therapy and the knowledge acquired during school training are essential to ensuring the safety of all involved. In regard to Lutathera and even high-dose ^{131}I administrations, knowing how to handle emesis during and after administration is also essential in conducting successful radiotherapy.

THE THERANOSTICS CARE TEAM

Now is the time most critical to make sure that the nursing and NMT groups work together to ensure that we have enough health-care providers to serve the growing population of patients who are going to require theranostics treatments. The list of available theranostics today includes thyroid cancer, neuroendocrine tumors, and prostate cancer, and this list will grow significantly with time, as other imaging therapy radionuclide packages come to market. Just recently, an analysis from McKinsey and co. found a potential shortage of 200,000–450,000 nurses not available for patient care in the short-term (*3*). The same analysis mentioned that by 2025, there could be a shortage of nurses of half a million throughout the United States.

Today, our nursing partners play a pivotal collaborative role in the provision of theranostics therapy, where much of the patient management and appropriate adjunctive medications for therapy are administered by nurses. The shortfall of nurses puts a larger strain on our health-care system and the provision of theranostics, as nurses may not be available to support the NMTs and authorized users to provide patients with this incredibly important therapy. Therefore, the SNMMI-TS Advocacy Committee feels that a focus on NMT training and further evaluation and possible expansion of the NMT curriculum to include all components of theranostics are crucial. Furthermore, developing a collaborative training process with the nursing professionals is essential to make sure that theranostics will have enough health-care personnel to provide this essential patient therapy and that NMTs can safely and effectively participate in all components of theranostics care delivery.

Another important member of the nuclear medicine care team is the Nuclear Medicine Advanced Associate (NMAA). The NMAA is a master's level and board-certified professional who serves as a physician extender or midlevel provider with specialization in all areas of nuclear medicine. The NMAA performs duties and responsibilities in a manner consistent with our mission, values, guiding principles, and American Heart Association/NMTCB service standards within the scope of an NMAA practice (*4*). In the theranostics setting (as in diagnostics), NMAAs work under the supervision of a licensed physician and serve as an adjunct between the physician and other health-care professionals (including NMTs) to enhance patient care.

SNMMI-TS ADVOCACY THERANOSTICS FUTURE PLANS

Engagement with the U.S. Nuclear Regulatory Commission (NRC) and The Joint Commission (TJC)

It is immensely important to SNMMI-TS and the nuclear medicine community that our regulators are aware of what theranostics is. For this reason, in the fall of 2021, the SNMMI-TS Advocacy Committee met with the U.S. Nuclear Regulatory Commission staff to refine language on the NRC webpage of what "nuclear medicine is and is not." On that same page, we proposed that the NRC include the following, under common nuclear medicine procedures: "Theranostics for targeted radioactive imaging and therapy for various cancers and diseases. Theranostics uses targeted imaging to tailor patient treatment."

Additionally, the SNMMI-TS Advocacy Committee embarked on a multiyear effort to oppose the further dilution of the training and experience (T&E) requirements for

unsealed byproduct materials (10 CFR part 35). In 2020, NRC staff recommended that the Commission pursue regulatory changes to the T&E requirements for radiopharmaceuticals, moving to using solely board certification for determining and obtaining authorized user status. Specifically, NRC staff indicated they planned to modify the board certification criteria to allow for additional medical specialty boards, beyond nuclear medicine and radiation oncology, to qualify for meeting the T&E requirements. In practice, this would necessitate weakening the already robust, yet flexible, board recognition criteria. Thankfully in January 2022, the Commission disapproved of their staff's recommendations, preserving the T&E status quo (*5*).

In the last year, NRC has been busy supporting novel positron emission tomography (PET) diagnostic radiopharmaceuticals and will play a direct role in creating regulations involving proposed rules on ^{82}Rb generators and other new emerging medical technologies (EMTs). The Commission approved of their staff proceeding with rulemaking in January 2022 due to the anticipated increase in the number of EMTs licensed by the NRC (*6*). As the use of medical applications of radioisotopes continues to increase and new advancements in medical technologies are expected, we anticipate that the NRC will continue to be busy in this segment of radiopharmaceuticals. Proactively, to address these challenges, the NRC staff recommended updating part 35 to establish generally applicable, performance-based requirements for EMTs that would focus on the essential, safety-related elements necessary to ensure radiation safety for workers, patients, and the general public. The revised regulation would also include performance-based requirements for ^{82}Rb generators, gamma stereotactic radiosurgery units, and ^{90}Y microspheres (*7*).

In the staff's rule-making plan (*7*), "'radiotheranostics' that merge molecular-targeted diagnostic imaging agents with molecular-targeted radiopharmaceutical therapy" is an example of new EMTs that currently would require licensing under 10 CFR 35.1000. SNMMI and the SNMMI-TS Advocacy will engage in providing comment to the proposed rule, along with participating in stakeholder calls, during the 90-d comment period in March 2023.

The support of not only the NRC, but also the Joint Commission (TJC), a national accrediting body, is essential in having NMTs fully participate in the delivery of theranostics. There are currently regulations within the NRC that allow the NMT to perform all actions of therapeutic radiopharmaceutical administration under the guidance of the authorized user (*8*). The SNMMI-TS Scope of Practice and Performance Standards (SOP) updated in 2022, as written, allows the NMT to perform and participate in all elements of theranostics care delivery (*9*). The SNMMI-TS Advocacy Committee understands and further welcomes guidance or rulemaking on the various NMT roles in radiopharmaceutical therapies, in order for the technologist to be properly supported, licensed, and prepared to safely deliver all components of such therapies. Adjustment of policies and standards are common when you evaluate the history of NRC and TJC, and over the next 3–5 y it is reasonable to see these changes happen with the support and collaboration between these and other appropriate accrediting and governing groups.

State and Local Collaboration

SNMMI-TS Advocacy plays a significant role to ensure that state rules and health-care facility policies allow NMTs to practice to their standardized scope, practice standards, and training. This oversight is pivotal in NMTs playing a fully encompassing role in theranostics therapy. The SNMMI-Technologist Advocacy Group Committee (TAG) has been effectively collaborating throughout most of the states in the United States (in addition to the District of Columbia and Puerto Rico) to ensure that NMTs are properly licensed to deliver all components of nuclear medicine in their published SOP. Although this is an ongoing effort, today almost 80% of our states license NMTs to practice to their training in their respective states. As NMT roles expand with theranostics, licensure will need to keep up with curriculum and scope of practice changes. These changes will need to evolve and be incorporated into state regulations to have NMTs participate and lead in all aspects of theranostics therapy. This is a tall task and one that will require consistent work by the TAG and state governments, working together. The Advocacy Committee will continue to use the SNMMI Model Practice Act (MPA) to equip states with legislative support and a thorough understanding of the NMT scope, so proper licensure and regulation are in place to support the evolving skills needed to provide safe handling and administration of radiopharmaceuticals used for theranostics. Furthermore, the SNMMI-TS Advocacy Committee is currently considering creating one MPA for the field by collaborating with organizations such as the Conference of Radiation Control Program Directors (CRCPD) and the Organization of Agreement States (OAS).

Like the evolution of the NMT SOP, health-care facilities themselves will also need to adjust their practices and determine what components of care they can transition from licensed nurses to NMTs. Hospitals have policies in place for patient monitoring, patient management, and medication administration. These are policies that will need to be evaluated, reevaluated, and updated to allow NMTs to provide full care to radiopharmaceutical *therapy* patients. Some of this training will be done by continuing education units (CEU), on the job training, and supplementary material from certification boards and badging options described earlier. The relationship and collaboration between nurses and NMTs are essential to make sure that the technologists can learn and practice in the safest and most patient-responsible way. The action of training Radiology Technologists from other health-care providers like nurses has historically been successful in various scopes in thousands of hospitals and clinics throughout the United States, and the transition to NMTs performing all aspects of theranostics therapy under

proper guidance and policy management will be no different. With expected severe nursing shortages, the sharing and training is of utmost importance now, to ensure that access to theranostics for patients is not compromised. The Advocacy Committee plans to continue to engage with hospitals and other health-care facilities to further the field of nuclear medicine and NMTs to support the continued growth of theranostics. This continued work and attention to licensure and regulation should allow the NMT to stay front-and-center in theranostics delivery and further create pathways for new NMTs to get into the field and be available to support our patients as the demand grows.

Incorporation of Theranostics into the Scope of Practice

Immediate recommended actions of the SNMMI-TS Advocacy Committee include the continuous evaluation of the SNMMI-TS NMT SOP, to be amended and revised to cover all components of therapy. Some considerations that the advocacy team are considering are adding the term *theranostics* to the *Technologist Qualified to Perform Nuclear Medicine Procedures* section (*9*).

1. Under the supervision of an authorized user, the nuclear medicine technologist is responsible for the safe use of ionizing and nonionizing radiation and molecular imaging for diagnostic, therapeutic, [*theranostics*,] and research purposes.
2. A certified nuclear medicine technologist is qualified to perform general nuclear medicine procedures, nuclear medicine therapy, [*theranostics*,] nuclear cardiology procedures, nuclear breast procedures, PET procedures, and CT attenuation correction and localization, and administer radioactive, adjunctive, and imaging medication at entry-level.

Adding *theranostics* into the SOP achieves the goal of exposing the NMT profession and scope to the rapidly emerging field and places the practice standards and scope at the forefront of the NMT's ability to have a fully inclusive role in this therapy delivery. As NMT curricula expand and training increases to fully encompass all components of the delivery of theranostics by the NMT, the SOP will continue to expand and become more specific to each element.

The Advocacy Committee is also looking to amend the MPA for nuclear medicine technology and to add the *theranostics* definition to the document to start exposing states to the NMT role in these therapies. As NMT education and training expand, so will the MPA, referencing all tasks that the NMT should be allowed to conduct while providing theranostics therapy care to patients.

CONCLUSION

The NMT profession is evolving at a rapid pace. How will current nuclear medicine technologists prepare for these new roles? Because of their position, their education, and the respect they have earned, NMTs are well-positioned to take an active lead in theranostics growth and advancement.

NMTs need to initiate the conversation for policy and process changes locally, with their clinic leaders and the local governments, so they can start building a stake in this exciting emerging therapy available to our patients in the United States. NMTs leading and being fully contributing members to the interdisciplinary theranostics teams may require some NMTs to step out of their comfort zone and gain more training, but this effort will not only allow the NMT scope and profession to expand but also lead to a significant improvement in patient access for these integral therapies.

The work by SNMMI and SNMMI-TS over the next several years will be to continue to build on and further launch a comprehensive theranostics awareness campaign to highlight its importance as a professional growth pathway and encourage NMTs to be front-line health-care providers in the delivery of all radiopharmaceutical therapies. These steps forward will require collaborative work among health-care professionals and various departments in health care and will ultimately help patients have better access to the care that they require to live better and longer lives.

DISCLOSURE

No potential conflict of interest relevant to this article was reported.

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