Theranostic Radiopharmaceuticals: A Universal Challenging Educational Paradigm in Nuclear Medicine

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T
he field of nuclear medicine traces its origin to the accidental discovery and naming of radioactivity by Henri Becquerel and Marie Curie in 1896 and 1905. In March 1936, Hamilton and Stone in California used “radiosodium,” the first artificially produced radioisotope, to treat 3 patients with leukemia and allied diseases. The same year, J.H. Lawrence at Berkeley initiated the therapeutic use of 32P for the treatment of leukemia and polycythemia vera. Saul Hertz’s success with radioiodine ablation of hyperthyroid patients between 1937 and 1942 paved the way for a seamless transition to Samuel Seidlin’s investigations with radioactive iodine (131I) in thyroid cancer. Nuclear medicine first became recognized as a potential medical specialty in 1946 when Seidlin reported on the success of radioactive iodine in treating a patient with advanced thyroid cancer.

By the 1950s, the clinical use of radioactive isotopes in medicine had become widespread as researchers increased their understanding of detecting radioactivity and using radionuclides and the rectilinear scanner to monitor biochemical processes. By 1960, the use of radioiodine in the examination of thyroid disease had become a prominent subject (1,2).

More than a half century ago (1971), the American Medical Association acknowledged nuclear medicine as an official medical specialty (3). Many countries around the globe followed suit and recognized nuclear medicine as a full-blown specialty through their health-care system regulatory agencies and by forming nuclear medicine societies and associations.

The educational requirements, organization, and practice of nuclear medicine vary from one country to another and are largely dictated by the regulatory framework in place in each country. Nuclear medicine is an advanced diagnostic and therapeutic medical and scientific field and a combination and convergence of many different disciplines. As such, it must be handled by well-educated and trained professionals such as radiochemists, nuclear physicists, radiopharmacists, engineers, technologists, physicians, and other health-care professionals.

THERANOSTIC RADIOPHARMACEUTICALS

The concept of theranostics refers to the integration of therapeutic and diagnostics in a single management approach allowing image-guided therapy and defining of treatment outcome at an early stage. The word theranostics, the new buzzword in medicine, was first coined in 1998 by John Funkhouser (a U.S. consultant), in a press release from the company Cardiovascular Diagnostics, to describe a material that combines the modalities of therapy and diagnostic imaging and was used in the early 2000s by the same John Funkhouser (then chief executive officer of PharmaNetics) to define the vision for his company as a blend of therapeutics and diagnostics.

Over the past 2 decades, one of the most significant outcomes of the human genome project in nuclear medicine has been the development of new theranostic radiopharmaceuticals that are based on patients’ disease genotypes and phenotypes and that are labeled with radionuclides. Through their exquisite sensitivity and specificity, these nuclear theranostics, in combination with sophisticated high-performance digital hybrid imagers (SPECT/CT, PET/CT, and PET/MRI), have started to play a major role in precision medicine by significantly improving patient disease management, particularly in oncology (4).

As exciting as it sounds, the clinical implementation of theranostic radiopharmaceuticals in nuclear medicine faces significant challenges. The practice of a fully integrated diagnostic and therapeutic nuclear medicine specialty requires an in-depth knowledge of many different fields of medicine, radiochemistry, radiopharmacy, dosimetry, radiopharmacology, and complex imaging equipment, along with an in-depth understanding of diseases and their management, health-care systems, and health-care economics. This type of complex knowledge, experience, and expertise represents both unique
opportunities and significant challenges for medical schools, imaging centers, and nuclear medicine centers across the globe.

EDUCATIONAL CHALLENGES AND OPPORTUNITIES

Over the past 2 decades, numerous clinical trials with theranostic radiopharmaceuticals have been performed, confirming their potential in the management of certain types of cancer. The documented success of these trials conducted first in Europe and Australia and more recently in the United States and the rest of the world has driven significant interest by health-care professionals, particularly in oncology, and by patients, who are requesting access to these unique and specific precision medicine therapies.

The significant increased demand for these types of therapy across the globe and their medical use have been and remain quite challenging in many aspects. Their manufacturing, transportation, distribution, availability, and medical use are still in their infancy and require stringent regulatory frameworks. Fundamental to their appropriate and safe medical applications are the education-and-training, experience, and expertise requirements of the health-care professionals who will be interpreting the images and the administration of these theranostic radiopharmaceuticals.

THERANOSTIC EDUCATION ACROSS THE GLOBE

At the 2018 completion of a project on access to and availability of radiopharmaceuticals, the global initiative committee of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) launched an initiative aimed at assessing the educational and training resources available on theranostics.

Similarly to the explosion and lack of preparedness of the imaging community vis-a-vis the Internet revolution of the 1990s and early 21st century, nuclear medicine communities around the globe are witnessing the explosion of theranostic radiopharmaceuticals and scrambling to provide their health-care professionals with appropriate education, training, and expertise. There is an urgent need to develop the knowledge and expertise to practice theranostics.

The aim of this white paper is to summarize current educational and training initiatives for theranostic physicians by the nuclear medicine communities that were part of the global initiative committee of the SNMMI on theranostics between 2018 and 2022.

Australian and New Zealand Society of Nuclear Medicine

For more than a decade, Australia and New Zealand have been at the forefront of clinical trials in theranostics.

All nuclear medicine specialists in Australia are qualified physicians or radiologists. Trainees have to complete basic physician training and examinations before entry into the nuclear medicine advanced training program, which consists of 2 core years and 1 elective or fellowship year. Radiology trainees also have to pass radiology examinations before entering the nuclear medicine advanced training program, which consists of 2 core years. During advanced training in nuclear medicine, the minimum required exposure to concepts on radionuclide therapy is the use of radioactive therapy in benign and malignant thyroid conditions. Because novel radionuclide therapies such as peptide receptor radionuclide therapy and peptide receptor radioligand therapy are not approved in Australia, there are only a limited number of sites that perform these in a compassionate-access scheme or via clinical trials, to which advanced trainees have limited exposure during their core training years. The requirements for advanced training in nuclear medicine are overseen by the committee for joint college training, which has representatives from the Royal Australasian College of Physicians and the Royal Australian and New Zealand College of Radiologists. Theranostic recommendations will be specifically included in the curriculum update for nuclear medicine.

In 2020, the Australasian Association of Nuclear Medicine Specialists published a position statement on the practice of theranostics in Australia (5). This statement represents a consensus of recommendations regarding the provision of safe, high-quality delivery and administration of nuclear theranostic therapies. The rapidly evolving field of theranostics, the need for an in-depth understanding of the medical and scientific aspects of these new diagnostic and therapeutic radiopharmaceuticals, patients’ disease genotype and phenotype, and the goals of and the need for a medical multidisciplinary approach to treat patients served as the main parameters to establish the guidelines.

Asia Oceania Federation of Nuclear Medicine and Biology

With a population of more than 5 billion people and nearly 40 countries under its umbrella, the nuclear medicine communities in Asia have probably the biggest challenge of all in delivering high-quality basic and specialized nuclear medicine education, training, and practice to professionals. In addition to physician training, the federation acknowledges that there is a clear need for education and theranostic training of radiochemists, physicists, technologists, and nursing staff.

The federation endeavors to establish centers of excellence in theranostics and to educate and train nuclear medicine staff in collaboration with regional associations and societies and the International Atomic Energy Agency (IAEA), particularly in underserved countries.

The Asia Oceania School of Nuclear Medicine, the Asia Oceania Journal of Nuclear Medicine and Biology, and the congresses and events of the federation bridge the gap between clinical practice and formal education and create networking and learning opportunities through exchanges within Asia and Oceania.

Arab Society of Nuclear Medicine and Molecular Imaging

The Arab Society of Nuclear Medicine is a young organization. It was inaugurated during a meeting of the project called ARASIA (Cooperative Agreement for Arab States in Asia for Research, Development and Training Related to Nuclear Science and Technology). The meeting, which was held in Vienna in 2014, was titled “Strengthening Nuclear Medicine Applications through Education and Training to Help Fighting Noncommunicable Diseases in the Arab Asian Member States.” The main objective of the society is to educate health-care and medical professionals about the remarkable growth of nuclear medicine in diagnostic imaging and therapeutics. It also aims to strengthen regional and international cooperation between nuclear medicine and molecular imaging professionals, groups, and societies active in the field.

British Nuclear Medicine Society

The British Nuclear Medicine Society is concerned with clinical practice, education, and research and development in nuclear medicine within the United Kingdom. Except for some endocrinologists treating benign thyroid disease and rheumatologists using radionuclide synovectomy, the only 2 specialties that can receive a nuclear medicine license in Great Britain are clinical oncologists and nuclear medicine physicians. Clinical oncologists normally limit themselves to just 1–2 cancer types; also, they have no training in the diagnostics of theranostics. The only practitioners who can acquire licenses for all radionuclide therapies and understand
the relevant molecular imaging are nuclear medicine physicians.
Training for nuclear medicine physicians and clinical oncologists is
6 y after general internal medical training (itself 3 y after inter-
training). Because the number of training posts in the United King-
dom is limited, the number of trained people in the United King-
dom who are giving radionuclide therapy beyond $^{131}$I for thyroid
cancer is low (probably less than 100 for a country of 60 million).

A new initiative starting in 2021 increased the number of train-
ing posts, which enables a trainee radiologist with internal medi-
cine boards and 1 year of nuclear medicine training to take a
further 1-y course to gain experience in diagnostic and therapeutic
aspects of theranostics.

Canadian Association of Nuclear Medicine

The Canadian Association of Nuclear Medicine strives for
excellence in the practice of diagnostic and therapeutic nuclear
medicine by promoting the continued professional competence of
nuclear medicine specialists, establishing guidelines for clinical
practice, and encouraging biomedical research. In Canada, the
Royal College of Physicians and Surgeons of Canada provides
education and certification of competency through Royal College
accreditation and examination of nuclear medicine residencies.
Because of the provincial bases of health-care delivery, there are
regional differences in practice. The Royal College provides the
underlying continuity and standards. Radioisotope therapy has
been an objective of training in this process. The rapid evolution
of the field of theranostics has challenged this objective, as there
are regional differences in access for patients and therefore in the
training required. The needs for education, training, experience,
and expertise in diagnostic and therapeutic theranostics are cur-
cently under assessment by the Royal College specialty committee
for nuclear medicine. The process has been somewhat further
complicated by the fact that the Royal College system of training
and assessment is undergoing a relatively radical evolution to a
competency-based system. The first residents in this new model
have just entered training.

European Association of Nuclear Medicine

The European Association of Nuclear Medicine is promoting
the theranostic idea in education by its European School of Multi-
modality Imaging and Therapy and has initiated official events
during its annual congress or dedicated focus meetings (6).

As the national countries and their health-care and accreditation
programs are responsible for adequate education and training of
residents, harmonization of the legal basis and curricula for educa-
tion toward radionuclide therapeutic applications is a big challenge
in Europe. The activities of the European School of Multimodality
Imaging and Therapy endeavor to provide a common basis with
goals and state-of-the-art educational content.

The European Association of Nuclear Medicine certifies experts in
radiopharmaceutical sciences, including both diagnostic and thera-
petic applications, after completion of a postgraduate diploma
course and many years of hands-on training within nuclear medi-
cine institutions.

The European Union of Medical Specialists supports the free
movement of European medical specialists while ensuring the high-
est quality of medical care for European citizens, and standardization
of training is therefore a prerequisite. The European Union of Medi-
cal Specialists program covers the many aspects involved in the use
and safe administration of nuclear theranostics (7).

IAEA

In October 2019, the IAEA published a training curriculum for
nuclear medicine physicians (8). The IAEA recognizes that therano-
static radiopharmaceuticals for the diagnosis and treatment of disease are
an important but not exclusive part of the large family of thera-
nostic concepts and compounds. The diagnostic and therapeutic
use of radioactive iodine is the most common theranostic applica-
tion globally in nuclear medicine, both in hyperthyroidism and in well-differentiated thyroid cancer. For the purpose of the
training discussed in this publication, it is better to limit the scope
of the theranostic radiopharmaceuticals to nuclear diagnostic and
therapeutic oncology applications, particularly in view of their
complexity. The major barriers to the development of theranostic
programs in low- and middle-income countries are related to the
complexity of the procedures, including logistic, financial, and reg-
ulatory aspects.

Without a doubt, innovation in research and development is a
-driving force of theranostics. New radiopharmaceuticals, applica-
tions, and medical evidence are produced at a fast pace and need
not be propagated. New standards of best practice should not be
emphasized only as a part of training programs but also in an
effort to keep the medical community abreast of developments to
optimize patient care and professional growth. We are facing
major educational gaps, essentially in the therapeutic field. Pro-
fessionals involved in theranostics should acquire additional hard
and soft skills to properly manage patients and deal with complex ther-
nostic applications. There is a need to include not only radioiod-
dine therapies but also more complex theranostic applications as
part of the curriculum and to harmonize the training requirements
globally.

In addition, the establishment of a clear legal framework and
policies should be emphasized and differentiated from those of
external-beam radiotherapy. The IAEA’s recommendation is to
add, as a minimum, 1 full year of theranostic education and train-
ing to the curriculum for nuclear medicine physicians (8).

The global initiative committee should reach an agreement
recommending and promoting a harmonized approach to the edu-
cation and training of professionals who use and administer ther-
nostic radiopharmaceuticals. The committee should also consider
facilitating the establishment of accreditation and regulatory frame-
works for the use of nuclear theranostics.

Japanese Society of Nuclear Medicine

In Japan, nuclear medicine is a subspecialty of radiology, radiation
oncology, or internal medicine. The Japanese Society of Nuclear Med-
icine certifies physicians to practice nuclear medicine through a board
examination. To be eligible, applicants must have 5 y of education,
training, and experience in nuclear medicine that follows the Japanese
Society of Nuclear Medicine–prescribed curriculum in a training pro-
cram certified by the Japanese Society of Nuclear Medicine. The
nuclear medicine certificate is renewed every 5 y on the basis of a
mandated educational and training maintenance of certification.

There is currently no specific educational or training program in
theranostics. Radionuclide therapy is practiced by institutions
without a standardized framework. This is related in part to the
diverse background of nuclear medicine specialists and in part to
the absence of designated radionuclide therapy beds in hospitals.

Korean Society of Nuclear Medicine

In South Korea, a physician board-certified in nuclear medicine and
licensed as a radiation worker by the regulating agency may practice
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theranostics. The 4-y nuclear medicine residency program requires trainees to participate in a specific number of radionuclide therapies. Radiiodine therapy has been widely used in Korea since its first administration in 1959, and there are no perceivable gaps in training for conventional radionuclide therapy. However, training does not adequately cover novel theranostics, largely because of limited clinical applications to date. Currently, $^{223}\text{Ra}$-dichloride and $^{177}\text{Lu}$-DOTA-TATE are approved for use, and $^{177}\text{Lu}$-PSMA radiopharmaceuticals are available through expanded-access programs. Anticipating a substantial increase in the number of theranostic procedures, the Korean Society of Nuclear Medicine is currently updating and increasing its educational programs.

South African Society of Nuclear Medicine

In South Africa, nuclear medicine is an independent specialty. Resident training requires a skill set that includes a broad range of knowledge and experience in radiobiology and physics, as well as dosimetry and radiation protection knowledge. Training program requirements include successful participation in and performance of radionuclide therapies.

The training programs are coordinated by the various academic institutions in the country, and summative examinations are administered by the College of Nuclear Physicians (part of the College of Medicine of South Africa). There is a minimum number of therapy cases that need to be performed and observed by residents (at least 180 cases).

The South African Society of Nuclear Medicine provides training opportunities in terms of master classes and webinars with local and international experts to enhance the training and application of theranostics in southern Africa. With the rapidly evolving field of theranostics, nuclear medicine training in South Africa will need to be optimized for these new oncologic therapies.

Society of Nuclear Medicine, India

The Society of Nuclear Medicine, India, aims to promote, encourage, and assist the development and advancement of nuclear medicine as a specialty. In India, nuclear medicine theranostics (9) are being practiced primarily in the public-sector hospitals that are affiliated with academic institutions and in only a few private-sector hospitals. Although formal guidelines do not exist for the development and regulation of theranostic programs in India, individual centers have developed their own sets of protocols for the use of theranostic radiopharmaceuticals.

The present training for nuclear medicine physicians in India requires a 3-y period of residency after completion of medical school. This period includes rigorous, cross-over training in both diagnostic and therapeutic nuclear medicine and in allied specialties such as radiology and radiation oncology. Similarly, nuclear medicine physicists and technologists also receive training in diagnostic and therapeutic nuclear medicine. The current challenges include limited exposure to and practice of dosimetry, despite extensive permeation of the radionuclide therapies. This limitation results primarily from the lack of skilled and dedicated specialists in performing radionuclide dosimetry. Adopting an integrative and all-inclusive approach can help build a comprehensive and uniform theranostic program that will be beneficial not only to the Indian populace but also to the global nuclear medicine fraternity.

SNMMI

The requirements of the accreditation council for graduate medical education for graduate medical trainees in nuclear medicine, published in July 2022, include several statements on procedural competencies involving radiopharmaceutical therapies, including the following statement, “When appropriate, thyroid studies must include measurements of iodine uptake and dosimetry calculations for radio-iodine therapy” (10). Although no other specific radiopharmaceutical therapies are directly mentioned in this document, probably because of the rapidly evolving state of radiopharmaceutical therapy availability and practices, the document does state that there should be an understanding of the “therapeutic administration of other unsealed radiopharmaceuticals for malignant and benign diseases...[as well as] scheduling and performing post-therapy follow-up” among the many other tasks involved in patient care. The document also states that faculty members must have appropriate qualifications in their field—that is, be certified by a governing board or possess qualifications that are acceptable to the review committee—but it does not state what those qualifications must be.

The SNMMI has been actively involved in radiopharmaceutical therapies and theranostics. Through committees and task forces, its therapy center of excellence is dedicated to all aspects of the development and use of radiopharmaceutical therapy as an alternative to other treatments. A resourceful trove and prime collection of educational and clinical information, the therapy.snmni.org web portal of the SNMMI now has therapy guidelines available for nuclear medicine professionals and patients. In addition, the SNMMI has benchmarked criteria for designating radiopharmaceutical therapy centers of excellence where patients and trainees can obtain state-of-the-art radiopharmaceutical treatment and education.

UNIVERSAL FRAMEWORK FOR POSTGRADUATE EDUCATION AND TRAINING OF NUCLEAR MEDICINE PHYSICIANS FOR PROFICIENCY IN NUCLEAR THERANOSTICS

Across the globe, physicians involved in the administration of radionuclide therapies include, for the most part, nuclear medicine, internal medicine, and radiologist and radiation oncology specialists.

Given the diversity in the backgrounds of providers and to ensure appropriate and safe use of nuclear theranostics, a curriculum template with minimum requirements is desirable to provide proper education, training, and expertise for the use of theranostic radiopharmaceuticals.

This paper offers generic guidelines for training and practice based on international recommendations, expert consensus, and relevant medical publications when available in relation to the practice of theranostics and molecular targeted radionuclide therapies.

Besides experts in the radiopharmaceutical and equipment manufacturer industry, also critical to the practice of nuclear medicine are radiochemists, radiopharmacists, nuclear physicists, technologists, nurses, nurse practitioners, allied health professionals, support staff, and physicians. Elaborating a generic educational and training framework addressing the needs of all these professions would be quite challenging and definitely outside the scope of this paper. We therefore focus on the training of nuclear medicine physicians, particularly those who treat adults. Pediatric radiopharmaceutical therapies require further specialized education and training and will be addressed in a separate publication.

Educational and training requisites for physicians using theranostic radiopharmaceuticals should include basic and specific aspects.

Basic entry requirements and pathways include a formal medical degree with appropriate certification by the accrediting body; 1 y of clinical experience that can be completed in a clinical medicine specialty, preferably in a field relevant to theranostics (e.g.,
sports medicine, ophthalmology, and dermatology would not be satisfactory; and a board certification in nuclear medicine as a specialty or subspecialty of, for example, internal medicine, radiology, and radiation oncology after a minimum of 3 y of a residency or fellowship in nuclear medicine.

The additional minimum curriculum requisites or the education, training, experience, and expertise for theranostic proficiency and accreditation should entail an additional residency or fellowship year in an accredited nuclear medicine or nuclear radiology center or program.

The accredited program should operate in a multidisciplinary setting, ideally a hospital or medical center with a comprehensive oncology practice. The program should have proper and adequate infrastructure, personnel, and equipment to practice standard-of-care and preferably state-of-the-art diagnostic and therapeutic nuclear medicine procedures, including a systemic dosimetry program.

Theranostic radiopharmaceutical physicians are expected to have sufficient knowledge and understanding of basic aspects of the practice of nuclear medicine such as mathematics and statistics applied to diagnostic and therapeutic nuclear medicine; natural, medical, and professional radiation exposure and radiation biology; radiopharmacy and radiochemistry; all equipment and instrumentation used in nuclear medicine; principles of radionuclide therapy; principles of quality management systems; and quality control and regulatory issues.

Theranostic nuclear medicine physicians should also have, as part of their education and training, a detailed understanding of the physiology and anatomy of the specific organ or region being studied or targeted; an in-depth knowledge of the anatomy, pathophysiology, anatomic pathology, and histopathology and of the genomics, proteomics, and other omics of the disease being assessed, treated, and followed; a clear understanding of the current diagnostic and therapeutic algorithms used by the oncology providers to diagnose, stage, treat, and follow up their patients; an in-depth knowledge of the chemical, biochemical, pharmacokinetics, and biodistribution of the diagnostic and therapeutic theranostics and their associated radionuclides; an in-depth understanding of the appropriateness, administration, and side effects of the theranostics used in their practice; a minimum number of diagnostic and therapeutic theranostic procedures defined by their national accreditation and regulatory bodies based on guidelines recommended by experienced theranostic specialist physicians via their national and international associations; a clear understanding of local, regional, and national legal and regulatory requirements; quality management applied to nuclear medicine; departmental, interdepartmental, medical center, and hospital operations and policies; and sufficient knowledge of the cost, reimbursement, and financial aspects of the diagnostic and therapeutic theranostic radiopharmaceuticals.

Complementary additional and important, if not critical, aspects for theranostic physicians that should be acquired through their education and training include mandatory participation in multidisciplinary tumor boards and meetings relevant to their local theranostic practice; continuing scientific and medical education related to the field of theranostics; attendance at and active participation in medical and scientific meetings that are directly or indirectly related to theranostics; and participation in patient support and advocacy groups.

### FRAMEWORK FOR EDUCATION AND TRAINING OF CURRENT NUCLEAR MEDICINE PHYSICIANS FOR PROFICIENCY IN NUCLEAR THERANOSTICS

In most parts of the world, physicians who are board-certified in nuclear medicine should have received education and training in thyroid disease therapy with radioiodine. Education, training, and clinical experience and expertise with most recently available theranostic radiopharmaceuticals is variable across the globe and is directly and indirectly related to availability, access, and regulatory approval. For those board-certified practicing nuclear medicine physicians who want to be actively involved in theranostic radiopharmaceuticals and treat patients but might not have had an adequate educational or training opportunity during their residency or fellowship, there is now ample information, educational material, and opportunity available through nuclear medicine societies and association web portals and specialized theranostic radiopharmaceutical centers to obtain proper education and possibly training experience in theranostic radiopharmaceuticals.

Like the other fields in medicine, the science and practice of theranostic radiopharmaceuticals are rapidly evolving. Continuing medical education will be critical to maintain sufficient up-to-date knowledge and expertise to perform diagnostic and therapeutic nuclear medicine procedures.

### CONCLUSION

Today’s medical use of unsealed radioactive compounds is driven by an unprecedented level of diagnostic and therapeutic molecular targeting opportunities that the human genome project and the omics of diseases, particularly in oncology, have unraveled and continue to discover. As an intimate part of the patient management team, nuclear medicine physicians across the globe are now challenged by the need to understand and eventually master a vast amount of specialized and sophisticated knowledge on various type of cancers and their cognate diagnostic and therapeutic radiopharmaceutical probes that have been or are actively being developed. Becoming proficient in this new field requires significant dedication to education and training as well as an additional level of experience and expertise.

This review has outlined the world’s currently available offerings in education and accreditation for theranostics. It also frames the educational and proficiency challenges that countries across the globe face in developing educational and training curricula, and it offers generic guidelines toward providing physicians with sufficient knowledge and experience to confidently and safely perform nuclear theranostic procedures.

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