Components of a Curriculum for Molecular Imaging Scientists

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Molecular imaging is the visualization, characterization, and measurement of biologic processes at the molecular and cellular levels in humans and other living systems (*1*). It comprises an emerging set of technologies that builds on advances in imaging procedures (e.g., PET, SPECT, MRI, ultrasound, optical, and photoacoustic), improved understanding of biology, and the development of molecularly targeted agents. These continuously expanding sets of imaging methods are often used in combination, and advances in data acquisition and analyses facilitate a more complete understanding of biology. Molecular imaging aims to improve our understanding of mammalian biology and lead to advances in patient care by providing targeted therapies that will enable personalized medicine and the imaging tools to assess outcome. Implementation of these new technologies in clinical care has many educational, technical, and regulatory challenges that must be overcome before molecular imaging reaches its full potential. The impact of molecular imaging has been significant in several disciplines, because it represents a paradigm shift in how scientists and clinicians can observe biology in real time and in a relatively noninvasive manner to enable the power of repeated measures in living organisms.

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Training programs in molecular imaging have been recommended by the Bioengineering Consortium symposium of the National Institutes of Health (*2*) and the Whitaker Biomedical Engineering Education Summit (*3*); the consensus view is that these training programs must extend beyond current offerings in biomedical engineering (*4*). Recruitment and training of the best young scientists with broad academic interests and backgrounds are essential to drive the emerging paradigm of in vivo study. To provide guidance in education, the Society of Nuclear Medicine (SNM) created a task force whose goal was to define the field and establish a molecular imaging curriculum based on the core competencies and integrative nature of the field. This consensus report describes the process and recommended content for training molecular imaging scientists. As such, this publication can be used to assist academic institutions in the development of programs and curricula that prepare students for the dynamic changes in this emerging field.

GOAL, PROCESS, AND TARGET AUDIENCE

The overall goal of the task force was to establish a curriculum that provides an educational foundation for scientists in molecular imaging and impart a vision of future developments in this field. The design of this curriculum involved many stakeholders at various levels and from national organizations that are advancing the field of molecular imaging. This consensus report was reviewed and edited by the task force members and approved by the Board of Directors (BOD) of the Center for Molecular Imaging Innovation and Translation (CMIIT) and the BOD of the SNM. This document can also be regarded as an initial dialogue aimed at building bridges among the imaging societies for the purpose of pushing the limits of the field. As advances in the field are realized and links to other disciplines are created, it is expected that the curriculum and education guidelines will be revised accordingly. The long-term plans for the task force are to provide continued guidance on education standards and career development in molecular imaging and implement a process for improving the standardized curriculum. These efforts are aimed at recruiting scientists into the field; fostering innovation of novel, cost-effective molecular imaging probes, equipment, and methods; refining our understanding of mammalian biology; and, ultimately, improving patient care and quality of life.

The curriculum is targeted toward graduate or professional (MD, DO, PharmD, DVM, PhD) students who are considering careers as molecular imaging scientists. A

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prerequisite to the curriculum is an undergraduate degree in a relevant field (biology, chemistry, physics, engineering, or molecular biology) or a professional degree in the health sciences. The expectation is that this curriculum will provide a solid educational foundation in the principles and practice of molecular imaging such that individuals can build on their own prior education, training, and experiences to drive the field in new directions and advance their professional goals. A required core of entry-level knowledge and skills ensures that each student has a common base on which to build.

The core curriculum focuses on key areas of knowledge, referred to as domains, required for conducting research in molecular imaging and applying new imaging tools to preclinical and clinical studies. Within each domain, there are multiple levels of knowledge and expertise, expressed as competency levels (Table 1), that reflect the complexity of this interdisciplinary field and the demands on education. Competency at levels 1 and 2 is defined as the minimum requirements for all molecular imaging scientists, regardless of specialty and background. It is expected that molecular imaging scientists will demonstrate competencies beyond level 2 in more than one domain.

DOMAINS OF KNOWLEDGE FOR CURRICULUM

The education task force identified the following 8 domains of knowledge, which are critical components in a molecular imaging curriculum:

1. Mathematics and statistics
2. Imaging physics and instrumentation
3. Molecular probes and contrast agents
4. Cell and molecular biology
5. Biologic model systems
6. Pharmacology
7. Cross-cutting themes
8. Clinical imaging of disease

The domains are integrated through 4 developmental themes. The Basics includes the foundational sciences critical to molecular imaging. The Methodology uses the basic sciences to explore methods to highlight (contrast) potentially useful biologic analyses. The Utility looks at the usefulness of the methods. Translation moves the useful methods from benchtop through preclinical studies and to the bedside. Integrated throughout the curriculum are the cross-cutting themes of communication, leadership, and collaboration that will enable advances in this multidisciplinary field. Figure 1 highlights the vertical integration of these themes and further illustrates how all the domains come together in the cross-cutting themes to ultimately support innovative clinical imaging of disease.

Domain 1

Mathematics and statistics are fundamental to understanding the nature of exponential growth and decay, exploring relationships between outcome variables, assessing basic qualities of a given scientific dataset, and evaluating meaningful differences between mean outcome values or subject groups. Of additional importance is the consideration of sources of error and statistical limitations (i.e., sample size, multiple comparison correction, and counting statistics) that are valuable for the planning of experiments and exploring data relationships. The prominent role of imaging databases in nuclear medicine and radiology requires a basic understanding of picture archiving and communication systems and other data management tools, and this is included in domain 1. Expertise in this domain also relates to generation of pharmacokinetic data and their analysis, statistical data modeling to test study hypotheses, numeric

TABLE 1
Competency Levels

Level	Competency
Prerequisite	Minimal working knowledge or skill. Has minimum familiarity with basic sciences, including chemistry, biochemistry, physiology, human anatomy, physics, and molecular biology. May have some skills applicable to one or more domains.
Level 1, introductory	Some functional knowledge or skill but usually requires guidance or input from more experienced users. At this level, develops understanding and application of key concepts well enough to effectively communicate and interact with those more expert within specific domain.
Level 2, novice	Still developing but has sufficient knowledge or skill to function autonomously most of the time. Capable of using information, knowledge, and skills to develop independent research. Identifies when assistance is needed.
Level 3, expert	Uses knowledge or skill to increase understanding in area. Uses knowledge and skills to design and implement innovative research. Applies concepts to problem solving associated with primary research. Rarely needs assistance.
Level 4, master	Established or recognized expert whose input is sought by others within field. Established innovator.

Each competency listed is designed to be taught to or for a particular level of expertise, as defined in table. Competency levels are defined as standard of reference for development of students' expertise, as adapted from Bloom (*5*). It is estimated that core competency in specific domains for molecular imaging students should include competency levels 1 and 2. Areas of specialization should approach level 3. Level 4 is developed after completion of essential basic education and significant practice in field of expertise.

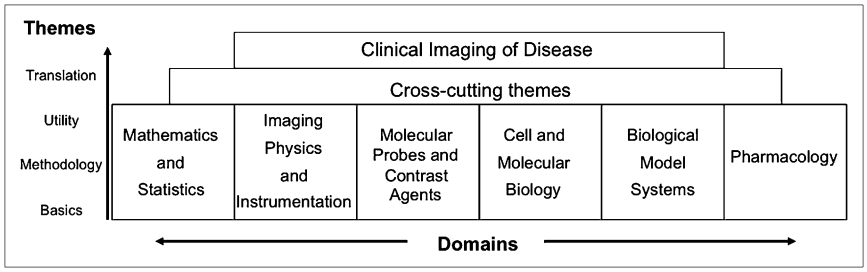

FIGURE 1. Summary of domains in relationship to overall themes.

methods relevant to image processing, multivariate approaches for voxel-level image analyses, and computer vision approaches for classification and diagnosis.

This domain includes bioinformatics approaches for analyzing multiparametric molecular analysis such as DNA microarrays, deep sequencing, and proteomics. Use of these data is related to selecting molecular targets and understanding their relevance to the biochemistry of tissues and resident cells. Moreover, such assays provide utility in validating results for studies using molecular probes. Molecular imaging can also be used to guide molecular analyses in animal models and humans, and knowledge of such "image-guided omics" approaches should be included in the curricula for imaging scientists.

Domain 2

Imaging physics and instrumentation comprise one of the fundamental technologies in molecular imaging. The concepts and basic principles of imaging hardware are essential to defining experimental parameters and designing molecular probes and as such are a key component of a molecular imaging curriculum. Within this domain are the skills to understand signal and image formation processes and the factors influencing image quality and quantitative capabilities of each modality. These skills include a fundamental knowledge of the different modalities used to generate images of molecular targets, including the capabilities, advantages, and limitations of each modality. An appreciation for the underlying physics of signal generation and propagation through tissue, signal detection, and image formation guides the design of molecular probes and then enables the development of multifunctional probes. The ability to extract quantitative functional, biochemical, and cellular information from an image differentiates molecular imaging from approaches that provide primarily qualitative anatomic information. Therefore, it is important to understand the physical factors that affect the precision of the data and the quality of the image and to integrate the quantitative and qualitative information obtained from different modalities. With the advent of hybrid imaging instruments for preclinical and clinical imaging, knowing the contribution of each component and understanding both the biology and how one aspect of the image improves the other are key. Knowledge of instrumentation physics is essential for understanding the basic image formation mechanisms of a modality and the factors that influence the quality of images produced.

Domain 3

Molecular probes and contrast agents lie at the heart of molecular imaging in that they provide the specificity in the image data. Their effective development requires an understanding of the molecular targets and their cellular pathways. This aspect of molecular imaging interfaces with genomics and proteomics, and an understanding of multiplexed molecular assays is critical at the onset for selecting targets initially and then for validating the image data and refining approaches throughout imaging use. Advances in deep sequencing have enabled rapid generation of whole genome sequences, driving personalized medicine and guiding imaging probe development and selection. Once targets are selected, high throughput assays such as phage display technologies and screening of chemical libraries can be used for probe development and are an integral part of the molecular imaging interface with other disciplines.

Molecular imaging agents are defined as probes used to visualize, characterize, and measure biologic processes in living systems (*1*). Both endogenous molecules that comprise intrinsic molecular signatures and exogenous probes that are administered can be used for obtaining molecular signals in vivo (*1*). Knowledge of the basic physical properties of intrinsic molecules and different types of molecular probes and contrast agents is needed to design probes and optimize images obtained with those molecular markers. For example, understanding how the decay properties of radionuclides affect the resultant single-photon and PET images, knowing how relaxation properties of gadolinium-based MRI contrast agents affect MR images, and being familiar with the basis of microbubble contrast in ultrasonography are critical to understanding the images generated with these modalities.

Effective development of molecular probes requires an understanding of biologic barriers and molecular mechanisms for crossing these barriers such that the agent can interact with its molecular target. Much of this relates to pharmacology but also to molecular agents that facilitate crossing of biologic barriers such as the charged protein translocation domains for crossing cell membranes that include the tat peptide from HIV, antennapedia, and poly-arginine peptides.

A basic understanding of probe and contrast materials includes how radionuclides, paramagnetic metals, fluorophores, and such are incorporated into small-molecule compounds and how they are attached to biologic molecules such as peptides and antibodies. Similarly, the conjugation of peptides

and antibodies to nanoparticles or microbubbles for targeting is part of the chemistry included in this domain. This domain incorporates the fundamental characterization of the agent, ensuring the chemical identity of the material, validating bioactivity, and evaluating in vivo performance.

Also within this domain are the regulatory issues for clinical use of molecular agents including good manufacturing practices (GMP) in addition to the chemistry, manufacturing, and control (CMC) components. Knowledge of the general principles of molecular probe and contrast agent development will allow imaging professionals to better understand the physics, chemistry, and biology that are inherent in the development of any molecular probe or contrast agent.

Domain 4

Cell and molecular biology consist of all aspects of cellular biology and molecular sciences, including structure, function, signaling pathways and networks, cell death mechanisms (necrosis and apoptosis), and cellular uptake processes such as phagocytosis and pinocytosis. Cell biology reaches from cell–cell communication to interactions between DNA, RNA, and proteins and how these processes are regulated. The field of molecular biology—manipulation of nucleic acids in vitro and in cells and tissues—connects to imaging sciences through the use of reporter genes to provide molecular signatures for imaging. An understanding of the tools of molecular biology enables the adaptation of reporter genes to molecular imaging, and these can be exploited for cell tracking, assessing gene expression patterns, and revealing molecular processes. The use of reporter genes is largely limited to animal models; however, there are some clinical applications—for example, cell trafficking in cell therapies. As the field of regenerative medicine advances, there may also be applications in this emerging field. This thematic area also includes the study of methods that are capable of interrogating the entire complement of genes, proteins, and metabolites in a specific cell type or tissue. Such multiparametric, or "omics" analysis, can be applied to understanding disease, assessing therapeutic responses, validating imaging approaches, and evaluating new therapeutic strategies, including stem cell and gene therapy.

Domain 5

Biologic model systems are used with molecular imaging to understand mammalian biology and for the screening and evaluation of new probes and development and validation of molecular targets. In these studies, cells and tissues in culture are used to develop and test molecular targets and probes that are then translated to animal models. Animal models of human biology and disease are used to evaluate the targeting of imaging probes and to determine the suitability of probes to detect disease, monitor progression, and evaluate therapeutic responses. Advances in molecular biology have driven an explosion of sophisticated models in which human genes can be used to direct disease states. Genetic manipulation of murine genomes enables the site-specific introduction of genes, referred to as knocked in, or selective deletion, knocked out. Understanding the tools that enable these genetic manipulations is essential for effectively developing and testing disease models. It is these advances that are making animal models more predictive of the human response and are refining the development of new drugs. Imaging accelerates these studies and, as such, is a critical part of the drug development pathway.

Imaging tools that reveal changes in physiology and anatomy are also essential in model development, in that they can provide an understanding of similarities and differences between animal models and humans relative to the altered genetics and novel therapeutics. Therefore, to effectively study animal models of human disease a balanced curriculum should contain knowledge of the key biologic systems (e.g., respiratory, circulatory, nervous, digestive, endocrine, and skeletal). This knowledge also improves compliance with regulatory requirements (Institutional Animal Care and Use Committee, biosafety, chemical safety, and radiation safety) and as such is included in this domain.

Domain 6

Pharmacology studies the interactions of chemical and physical compounds with the cells and tissues of living organisms and is an essential part of developing new imaging agents and understanding therapeutic response. Molecular imaging takes advantage of these advances in drug development, and imaging agents are often based on the same chemical interactions targeted in pharmaceutical development.

Radiopharmaceuticals are a special case because of their use as imaging agents at extremely low, subtherapeutic, concentrations. Chemical properties and preparation of a molecular probe can affect the interaction of the probe with living systems and biochemical function—from the molecular level to organ systems. More specifically, the properties of the probe affect pharmacokinetics (effect of the body on the compound, for example, half-life and volume of distribution), pharmacodynamics (effect of the compound on the molecular target, for example, desired or toxic), and therapeutic efficacy. An imaging scientist must understand how to test molecular imaging agents, first in vitro (in the laboratory) for biochemical activity and then in vivo (on animals, human volunteers, and patients) for safety; effectiveness; side effects; interactions with other compounds; and determination of the best dose, timing, and route of administration (e.g., oral, intravenous, and subcutaneous). Knowledge of basic pharmacology is applicable in understanding normal biologic processes and changes in function that underlie disease states. How molecular probes will be metabolized in normal and diseased states is inherent to the development and evaluation of new probes.

Domain 7

The cross-cutting themes refer to knowledge, skills, and abilities that will enhance success by enabling the investigator to reach across traditional academic and thematic boundaries. These include effective communication, leadership, and collaboration as part of a team. Research ethics

and regulatory compliance are within this domain, and training in this area is essential for effectively developing, testing, and translating new imaging approaches. Although no specified competency levels are defined here, the professional success of the scientist will be enhanced by recognition of the importance of these skills. Short courses in these areas are available at many academic centers, national meetings, and government agencies, and these can be integrated into training programs.

Domain 8

Clinical imaging of disease is a key application of molecular imaging agents and techniques. The appreciation of state-of-the-art medical imaging systems used in clinical practice will facilitate improvements in patient outcomes, the ultimate goal of molecular imaging. The molecular imaging scientist must become familiar with aspects of human anatomy, physiology, and pathophysiology to design and implement translational imaging approaches. An understanding of the various imaging options available for answering key biologic questions of interest in preclinical models at the cellular and molecular–genetic levels, and their translation to applicable clinical imaging tools, is the crux of molecular imaging. This translation includes knowledge of targeted molecular probes used for metabolic imaging or receptor-based imaging in addition to the use of standard, clinically approved imaging agents (e.g., nontargeted PET tracers, freely diffusible MRI or CT contrast agents), and methods to quantify tissue metabolic or physiologic imaging parameters. Extraction of quantitative functional and biochemical information from the image differentiates molecular and physiologic imaging techniques from those that provide primarily anatomic (structural) information, and familiarity with image quantification and postprocessing software tools is critical. For the effective application of these techniques, the relationships between anatomy and physiology must be considered in the context of probe or contrast agent pharmacokinetics and pharmacodynamics in disease states. Finally, clinical trials are necessary to establish the safety and efficacy of molecular imaging agents, requiring Investigational New Drug (IND) applications to the Food and Drug Administration; therefore, extensive knowledge is required on clinical trial design and all applicable regulatory requirements (institutional review board, CMC, GMP, and such).

In summary, this domain builds on, and integrates features of, the other domains to provide a mechanism for exploring biologic or clinical questions of interest through the application of suitable molecular imaging probes and methods. The goal is to identify promising disease-specific diagnostic imaging agents or therapeutics and enhance our understanding of human pathophysiology in oncologic, cardiovascular, and neuropsychiatric disorders. The imaging scientist will understand the role of targeted molecular imaging for the evaluation of critical pathophysiologic processes of the specific organ system or area of interest.

COMPETENCY

Table 2 provides examples of competencies at levels 1 and 2 for each of the 7 applicable domains. Additional details are provided on the SNM Web site www.snm.org/scientists_curriculum. There is some overlap expected between the domains, and this is considered to be appropriate.

CONCLUSION

The identification of domains and competencies (levels 1 and 2) is necessary to establish basic educational criteria and training requirements; herein, we develop this identification for molecular imaging scientists. It is anticipated that molecular imaging scientists will specialize in more than one domain and achieve competency beyond level 2 within those domains. More detailed curricula must be developed and expanded for each of the domains, including identification of competencies at levels 3 and 4, as detailed on the SNM Web site. Although detailed identification of competencies at levels 3 and 4 is beyond the scope of the current report, students must acquire the appropriate depth of knowledge and competencies associated with such a subject-matter expert. This may be done more easily for some domains. For example, one can envision a chemistry program having a track for probe development. Similarly, a biomedical engineering program could have tracks on instrumentation development. Graduate programs in areas such as biochemistry or molecular biology might include courses in high throughput screens for target identification, protein modification for probe development, or related areas. These tracks could be supplemented with courses or rotations in other departments. Interdisciplinary programs represent another solution, for which several schools and departments contribute expertise and experiences to enable the students to achieve the needed competencies in the domains.

Translation of molecular imaging approaches to the clinical realm is the focus of domain 8. Although other domains may have existing infrastructure supported by academic departments, this culminant domain differs in that regard. Universities do not typically have a Department of Translational Medicine, although many institutions now have funding from the National Institutes of Health for Clinical and Translational Science Awards that provide training in translation of technologies into human studies and the design of clinical trials. Scientists are needed with a unique set of skills that are typically acquired by experience over many years, and molecular imaging is just one of many areas for clinical translation. There is extreme competition for these individuals. This is yet another reason to give priority to expanding the curriculum for this domain, because it will aid with recruitment and help focus resources. Skills necessary for the practice of translational medicine and clinical trials are different from those used in clinical practice. The SNM Clinical Trials Network has focused efforts on training imaging site personnel in how clinical trials are conducted; improving standardization

TABLE 2
Competency Levels 1 and 2: Examples for Domains

	Domain						
Competency level	Mathematics and statistics	Imaging physics and instrumentation	Molecular probes and contrast agents	Cell and molecular biology	Biologic model systems	Pharmacology	Clinical imaging of disease
1	Exponential functions	Production of radionuclides	Probe design	Cell processes or structure	Cell culture	Target selection	Modality selection
	Sensitivity and specificity	Interaction of radiation with matter	Coordination chemistry	Metabolic pathways	Animal models, anatomy, physiology	Pharmacokinetics	Probe selection
	Basic descriptive statistics	Detectors	Conjugation chemistry	Molecular biology	Anesthesia, biologic systems	Pharmacodynamics	Imaging methods
	Probability distribution	Formation of images	Quality control	Gene transfer vectors	Imaging and biodistribution	Sampling and analyses	Biomarker metrics
	Nuclear statistics	Imaging modalities	Probe evaluation	Gene therapy	Ethics and compliance	Toxicology	Regulatory
2	Differential equations	x-ray production	Automated synthesis	Gene mapping	Stem cell and trafficking	Pharmacologic classification	Response metrics
	Curve fitting	γ-camera performance	MRI and optical probes	Gene profiling	3-dimensional organ cultures	Receptor interactions	Targeted imaging
	Hypothesis testing	PET performance	Combinatorial chemistry	Protein profiling	Pathophysiology models	Use of radiotracers	Anatomy and physiology
	Power, sample size	Tomographic reconstruction	Synthetic chemistry	Genomics	Animal monitoring	Analyses methods	Informatics
	Survival curves	Image processing	GMP issues; CMC component	Epigenetics	Specialized surgery	IND preparation	Compliance for IND

of imaging acquisition, reconstruction, and interpretation; qualifying clinical imaging sites; and facilitating the use of molecular imaging approaches as outcome measures in therapeutic clinical trials. Other stakeholders share this interest: The Radiological Society of America (RSNA) sponsors an annual Clinical Trials Workshop to familiarize imaging researchers with the process of developing and executing protocols for imaging clinical trials, and the American College of Radiology Imaging Network (ACRIN) has been instrumental in facilitating multicenter imaging clinical trials for the past decade. Continued commitment and support for the necessary quantitative approaches required of this domain are exemplified by the recently announced Center of Quantitative Imaging Excellence (CQIE) project from the National Cancer Institute (NCI) awarded to ACRIN for the specific purpose of qualifying interested NCI-designated cancer centers in the performance of advanced quantitative imaging. Importantly, the cooperation of all stakeholders is desired.

DISCLOSURE STATEMENT

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