## Advancing Molecular Imaging from the Laboratory to Everyday Practice

n June 2006, SNM launched its Bench to Bedside Campaign to raise funds to support the translation of molecular imaging (MI) into clinical practice and to transform SNM into a broad-based MI society. The SNM Molecular Imaging Center of Excellence (MICoE) was charged with implementing the SNM strategic plan, establishing specific objectives, and providing key deliverables through the initiation of new programs. Since then, MICoE members have worked in concert with others throughout the society to accomplish many of these goals, some of which are described here.

The Communications Task Force, led by Albert Sinusas, MD, and the MICoE editorial board, formerly led by Martin Pomper, MD, PhD, and now Henry VanBrocklin, PhD, have created new venues for delivering MI information to both center members and SNM membership at-large. These groups oversaw the launch of the MICoE Web site and the quarterly newsletter, *MI Gateway*. New and timely content—such as monthly literature briefs, short articles and commentaries, an image library, and a new community bulletin board—is added regularly to the Web site. In this way, the center is striving to keep colleagues informed about and up-to-date on the latest MI innovations.

The Education Task Force, led by MICoE Vice President Carolyn Anderson, PhD, drafted a nuclear medicine residency curriculum that incorporates MI into the training program. Input was solicited from the Residency Review Committee and program directors to determine their needs for teaching new topic areas. An online resource compendium is now available and, once approved, this curriculum will be incorporated into residency programs nationwide. A curriculum for MI scientists is currently under development.

Outreach and advocacy efforts, which have resulted in significant achievements, were led by Robert Atcher, PhD, MBA; Val Cronin, CNMT; and David Mankoff, MD, PhD. In December 2007, Congress restored approximately \$17.5 million in funding for basic nuclear medicine support within the Department of Energy. We collaborated with other organizations, such as the American Society of Clinical Oncology and the American Society for Therapeutic Radiology and Oncology, on numerous educational sessions. We also hosted 2 joint patient advocacy briefings with the Academy of Molecular Imaging.

The MICoE recommended the creation and expansion of SNM's grants and awards program, through which \$300,000 in new MI grants and awards were presented in June, thanks to increased financial support of SNM's Education and

Research Foundation. New developments for next year include an MI young investigator award. These awards support and promote SNM's MI vision through the scientific efforts of the recipients.

The MICoE has sponsored successful workshops and retreats. The emerging technologies retreat in June 2007 and the second industry/expert Molecular Imaging Summit in February 2008 provided



Henry F. VanBrocklin,

strategic recommendations for engaging the pharmaceutical industry, fast-tracking technological developments (including regulatory issues), engaging referring physicians, and increasing clinical utilization of MI. A major outcome of these workshops was the recent formation of the SNM Molecular Imaging Clinical Trials Network (MICTN) and U.S. Food and Drug Administration approval of the SNM-sponsored Investigational New Drug application for <sup>18</sup>F-fluorothymidine clinical trials. This represents a new paradigm for advancing MI into everyday practice.

One of our more recent ventures is a partnership with the journal *Molecular Imaging*. For those unfamiliar with the journal, *Molecular Imaging* publishes research articles, brief articles, reviews, and articles reporting significant technological advances relevant to imaging at the whole organism or cellular levels. The journal serves both the scientific and clinical communities by disseminating novel results and concepts relevant to the biological study of normal and disease processes in both basic and translational studies ranging from mice to humans.

Under the guidance of Heinrich R. Schelbert, MD, PhD, *The Journal of Nuclear Medicine* has responded admirably over the years to MI strategic plan initiatives with increased publication of nuclear and nonnuclear MI articles and perspectives. Venues for publication of early preclinical MI research articles, however, are limited, so MICoE leadership initiated discussions with the publisher of *Molecular Imaging* regarding a sponsorship arrangement. Under the terms of this agreement, the SNM logo will appear on the journal cover, and MICoE and SNM will promote the journal and encourage member submissions. As an SNM member benefit, annual subscriptions will be available at the special rate of \$99.

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## **CMS** and **PET** for Solid Tumors

n October 17 SNM, the American College of Radiology (ACR), the Academy of Molecular Imaging, the American Society for Therapeutic Radiology and Oncology, and the National Oncologic PET Registry (NOPR) submitted comments to the Centers for Medicare & Medicaid Services (CMS) regarding national coverage analyses for <sup>18</sup>F-FDG PET for Solid Tumors (CAG 00181R). The letter was written in response to CMS's request for additional comments regarding whether its current framework of cancer-bycancer coverage for oncologic <sup>18</sup>F-FDG PET imaging could be replaced by an omnibus framework.

In the letter, the societies strongly supported efforts by CMS to update and modernize the current PET national coverage determination (NCD) to allow for expanded coverage of PET for cancer diagnosis, staging, and restaging. In addition, the group shared its belief that it is both clinically appropriate and practical for CMS to adopt a comprehensive cancer coverage framework for PET. The group believes that this new approach offers 4 advantages by: (1) incorporating current noncoverage decisions; (2) providing clinically appropriate coverage for additional less common cancers; (3) simplifying the language of the existing NCD; and (4) providing CMS with the opportunity to introduce additional safeguards and features that ensure clinical appropriateness of utilization.

One of the key elements of the letter was the attention to safeguards that were included in the draft comprehensive coverage policy model to ease CMS concerns about overutilization of PET. The letter laid out a plan to require a clear record of the clinical decision in question, provide additional guidance on appropriate usage, and create accreditation or experience requirements.

In addition, this correspondence allowed SNM and others to showcase the multiple PET educational efforts that have occurred for years. SNM chose to highlight the PET

Utilization Task Force's recent recommendations for <sup>18</sup>F-FDG PET and PET/CT practice guidelines in oncology and the dedicated PET coding and reimbursement coverage in its annual Reimbursement Roadshows. The ACR emphasized its work in publishing practice guidelines regarding <sup>18</sup>F-FDG PET for the performance of PET/CT in oncology,



**Hugh Cannon** 

as well as appropriateness criteria guidelines on <sup>18</sup>F-FDG PET and PET/CT.

This recent reconsideration by CMS began when NOPR published its findings in March 2008, showing that PET use in 36% of cases submitted to NOPR had resulted in major changes in management. NOPR also reported that PET scans included in the study changed clinical management decisions as frequently for less common cancers as for more common and longer studied cancers.

The NOPR was launched in May 2006, in response to CMS's novel "coverage with evidence" policy, to collect data through a clinical registry to inform the <sup>18</sup>F-FDG PET coverage determination decisions for cancer indications currently not covered. The registry is designed to collect questionnaire data from referring physicians on intended patient management before and after <sup>18</sup>F-FDG PET imaging.

CMS is expected to publish its proposed rule for the NCD on <sup>18</sup>F-FDG PET for solid tumors in January 2009. After publication, the public will have the opportunity to comment on the decision.

Hugh Cannon SNM Director, Health Policy and Regulatory Affairs

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The SNM/MICoE sponsorship of the journal begins with the first issue of volume 8 (2009). I am honored to serve as guest editor for this issue and look forward to working with Dr. Pomper, *Molecular Imaging* editor-in-chief, on this enterprise. I ask all SNM members to consider submitting original research and review articles related to early preclinical molecular imaging for future issues.

Space does not permit enumeration of all the undertakings and programs that have been established over the last several years nor individual acknowledgment of the dedicated volunteers who have contributed time and effort on behalf of MICoE and SNM. I gratefully acknowledge SNM staff, especially MICoE Director Marybeth Howlett; without her support, many of these accomplishments would never have happened.

Together, we are developing a path to bring MI technologies out of the laboratory and into clinical practice.

Henry F. VanBrocklin, PhD President, Molecular Imaging Center of Excellence