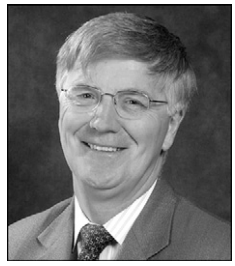
How Do We Introduce the Next Generation of Radiotracers into Clinical Practice?

SNM will take an active role in moving emerging molecular imaging probes from bench to bedside, providing our members with a new generation of imaging investigations with which to help our patients and clinical colleagues. We also recognize the importance of providing a pathway for increasing utilization of currently accepted molecular imaging probes (such as ^{18}F-FDG). Members of our Molecular Imaging Center of Excellence's Leading Technologies/Assessment Task Force met this summer—along with government, academic, and industry experts—to develop a strategic plan that will ensure this vision can be rapidly translated into clinical reality.

With this visionary and groundbreaking action plan, we will drive a new set of processes for molecular imaging agent approval. Initially these processes will be focused in 3 areas where the validations of molecular imaging probes as imaging biomarkers will have the greatest short-term clinical impact: imaging hypoxia, cell proliferation, and amyloid deposits in patients with Alzheimer's disease. As president and task force chair, I believe that these 3 areas will serve as models for addressing issues related to Food and Drug Administration (FDA) policy for radiopharmaceuticals, expand clinical utilization and improve opportunities for appropriate reimbursement, enhance standardization of procedures and protocols, and improve opportunities for commercialization of intellectual property. The complete findings and recommendations of the task force will be published in a future issue of *The Journal of Nuclear Medicine*.

The development of validated imaging biomarkers will become the most important challenge for our community over the coming 5 years. Nuclear medicine imaging has always contributed functional assessment to the anatomical definition of the presence or absence of disease. The new tools made available through PET and molecular imaging offer our community the opportunity of enhancing patient management through predictive assays of treatment response, techniques for monitoring treatment response, genomic and metabolomic assays, and—by treatment—stratification. These imaging methodologies in patient care, clinical trials, drug development, and translational research have the potential to contribute to the personalized medicine revolution.



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Although several sophisticated molecular imaging technologies are currently available for clinical trials at academic institutions, the number of imaging agents receiving FDA approval is on the decline, and there have been few initiatives to enhance the regulatory process for new imaging biomarkers. Moreover, few imaging studies are appropriately designed to support funding approvals or the expansion of approved indications for FDG.

To successfully bring molecular imaging technologies to the bedside, several important factors need to be addressed. Quantitative and qualitative change in imaging biomarkers must correlate with a specific clinical outcome. Imaging biomarkers must be incorporated in the earliest stages of clinical trial design. Imaging methodologies and biomarkers must be discussed with regulators early in the development process and appropriately validated for regulatory approval. Collaborative efforts and data sharing among industry, academic institutions, professional societies, and government bodies are essential to make new radiotracers available for routine clinical use. Task force members have determined several specific goals to facilitate the expansion of available PET tracers:

- *The clinical effectiveness of molecular imaging must be demonstrated to expand indications and enhance availability for patient care.*
- *FDA approval should be based on the identification of pathophysiology rather than the diagnosis of a specific disease condition.*
- *Collaboration is necessary to ensure appropriate reimbursement for the use of molecular imaging agents.*
- *Standardization of qualitative and quantitative imaging data is crucial to take advantage of the unique capabilities of PET imaging tracers.*

SNM is uniquely positioned to ensure that these opportunities are not lost to the nuclear medicine community. Over the past 2–3 years we have put in place the expertise

(Continued on page 30N)

rule affects physicians and office payment for services paid under the resource-based relative value scale (RBRVS). The rule includes the following policies, which will affect nuclear medicine if adopted:

Without an act of Congress, CMS will implement a 9.9% reduction in payment rates for physician-related services. The conversion factor (CF) for 2008 will be set at $34.1457, 9.9% below the 2007 CF that was frozen at $37.8975.

Due to the acceptance of recommendations by the American Medical Association RBRVS Update Committee, CMS proposes to implement a budget neutrality adjustor (0.8816), which is applied only to the work relative value units (RVUs) for all CPT codes. This means that CMS has implemented a −11.8% adjustment to all CPT code work RVUs in the formula to make the overall payments in this system budget neutral.

The proposed rule continues phasing in a new methodology for determining practice expenses (PE) RVUs. For 2008, CMS will apply 50% of the new methodology; in 2009, 75%; with full implementation in 2010. SNM's recommendations for changes to many PE items for nuclear medicine procedure codes were accepted by CMS. Refinement is important with this new bottom-up calculation. The impact to nuclear medicine procedures results in a mix of more increases than decreases with these methodology changes. In general, for procedures with high equipment costs, the rates will increase over time, whereas those procedures with lower equipment expenses will see reductions.

Two other important notes regarding the PE methodology calculations are: (1) CMS has not changed the equipment usage percentage assumption of 50%; and (2) CMS proposes NOT to change the equipment interest rate assumption, maintaining it at 11%.

There are NO proposed changes for the radiopharmaceutical payment methodology in the physician office or independent diagnostic testing facility (ITDF) setting for 2008.

Consistent with requirements of the Deficit Reduction Act, this proposed rule caps payment rates for imaging services under the MPFS at the amount paid for the same services when performed in hospital outpatient departments. When the proposed 2008 HOPPS rates are posted, the SNM MPFS materials will be updated.

The proposed 2008 MPFS rule also continues a policy of reducing the payment for before technical component of multiple imaging procedures on contiguous body parts by 25%. CMS will apply the multiple imaging reductions first, followed by the HOPPS imaging cap, if applicable.

CMS is modifying a number of the physician self-referral provisions to close loopholes that have made the Medicare program vulnerable to abuse and is modifying the enrollment standards for IDTFs. Last year CMS finalized IDTF rules that were then rescinded.

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(Continued from page 28N)

and infrastructure to facilitate these developments and innovations. Through our molecular imaging campaign, we will be able to facilitate these initiatives.

I thank the many individuals who participated in our Leading Technologies/Assessment Task Force meeting: Sue Abreu, MD; Eric Agdeppa, PhD; Robert W. Atcher, PhD; Laurence Clarke, PhD; Peter S. Conti, MD, PhD; Barbara Y. Croft, PhD; Chaitanya Divgi, MD; Janet Eary, MD; Richard A. Frank, MD, PhD; Kim Gallagher, PhD; Peter Herscovitch, MD; Ed Jackson; Joel S. Karp, PhD; Paul E. Kinahan, PhD; Maxim Y. Kisilev, PhD; Peter Martin, PhD; Adrian D. Nunn, PhD; Ron Nutt, PhD; Martin G. Pomper, MD, PhD; Debasish Roychowdhury, MD; Harendra D. Rupani, MD; Paul Shreve, MD; Albert J. Sinusas, MD; Mark Soffing, MBA, RPh, BCNP; Thomas T. Tulip, PhD; Henry F. Van Brocklin, PhD; and George Zubal, PhD.

The results of this meeting show that SNM has the knowledge and the plan to advance our mission (to improve health care by advancing molecular imaging and therapy) and our vision (to become the leader in advancing and unifying nuclear medicine, molecular imaging, and therapy).

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