## Health Care Reform, Cost Effectiveness Research, and Guidelines

mong the goals of the health care reform law enacted in 2010 are to provide access to medical care to more individuals and to control costs. Because the costs associated with advanced imaging procedures have grown faster than health care costs as a whole, imaging costs will undoubtedly be a focus. Decisions about utilization and reimbursement of imaging procedures will rely increasingly on evidence-based practice guidelines and appropriate use criteria.

SNM is dedicated to ensuring that patients continue to have access to critical medical diagnostic tests and high-quality care. Molecular imaging is not only an essential component for the diagnosis and treatment of diseases, it can also contribute to more efficient and cost-effective health care by ensuring use of the most appropriate therapies and sparing patients from unnecessary treatment, especially expensive invasive procedures.

In June, SNM's board of directors approved a new 3-y strategic plan to guide the society in achieving its mission: to improve human health by advancing molecular imaging and therapy. Keeping health care reform in mind, the board of directors has identified the development of comparative effectiveness research (CER) and practice guidelines as a major goal in the strategic plan.

CER and well-designed clinical trials showing improved patient outcomes are necessary for a sound scientific foundation and clinical acceptance of hybrid imaging procedures such as PET/CT and SPECT/CT, especially with new tracers. In the summer of 2010, SNM hosted a workshop with stakeholders to review available methodologies and identify priorities in the fields of oncology, cardiology, and neurology. Experts in CER have developed a strategy to facilitate high-quality CER and address evidence gaps. By launching educational efforts and leveraging diverse networks of partners, SNM will establish itself as a leader in this area.

Warren Janowitz, MD, chair of the SNM Commission on Health Care Policy and Practice, wrote:

Our major deficiency, along with other imaging-based specialties, is the general lack of outcomes data for most of our procedures. This is not something that can be easily resolved. There is no consensus about what outcomes data mean for imaging or diagnostic testing—is it increased survival for cancer patients undergoing PET or improved treatment planning and avoidance of unnecessary surgical procedures? How are appropriate use criteria to be written without data? While primary care specialties can show that specific drug therapies improve patient outcomes, this is much more difficult to do with a procedure that provides information that must be acted upon by the patient's treating physician to produce results.

Apart from the difficulties involved with the development of outcomes data, there is the problem of appropriate use criteria (AUC)

development. It is becoming obvious that the clinicians who order molecular imaging procedures must be prime movers in the development of AUC. While it is all well and good for SNM or the American College of Radiology (ACR) to say that PET/CT should be performed in all lung cancer patients, unless the pulmonologists, surgeons, and oncologists agree, our AUC will be seen as selfserving and will not be accepted. Obviously, guidelines developed jointly with clinical specialties will carry much more weight with third-party payers and organizations such as radiology benefit managers. SNM is not in the position to develop AUC on its own.



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Therefore, SNM is collaborating with other medical organizations, such as ACR and the American College of Cardiology, to define and update AUC for imaging. SNM also monitors the National Comprehensive Cancer Network practice guidelines regarding the use of molecular imaging and hybrid procedures and gives input as appropriate.

The SNM procedure guidelines have been renamed "SNM Practice Guidelines," because the content has been updated and is similar to the ACR Practice Guidelines. All SNM guidelines are being revised and updated to include: (1) recommendations about the best state-of-theart protocols and technology; (2) radiopharmaceutical dose reduction, where applicable, and more extensive radiation exposure information to address concerns; (3) qualifications of personnel to address concerns about quality performance, interpretation, and radiation exposure; and (4) common clinical indications with more extensive references to support evidence and reference to AUC. For practice guidelines involving radiopharmaceuticals, SNM is collaborating with other organizations whenever possible (for example, the ACR, the American Society of Nuclear Cardiology [ASNC], and the American Thyroid Association).

Public concern about radiation exposure is rising. Reduction of radiation exposure is a high priority for SNM. The Pediatric Council of SNM is actively participating in the Image Gently initiative to reduce radiation exposure in children. In addition, SNM and the Society for Pediatric Radiology's board of directors recently approved new "North American Guidelines for Radiopharmaceutical Doses for Children" that standardize doses (based on body weight) for 11 nuclear medicine procedures commonly performed in children. Also, in an effort to reduce radiation exposure for myocardial perfusion imaging, SNM has

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PET assessment of metabolism with <sup>18</sup>F-FDG, tumor proliferation with <sup>18</sup>Ffluorothymidine (18F-FLT), and hypoxia with <sup>18</sup>F-fluoromisonidazole (<sup>18</sup>F-FMISO) before and during radiotherapy in patients with non-small cell lung cancer (NSCLC). The study included 5 patients (4 men, 1 woman) with histologic proof of NSCLC who were candidates for curative-intent radiation therapy. Each patient underwent 3 PET/CT scans (1 with each of the tracers) before and during (at 46 Gy) treatment, with minimal intervals of 48 h between each different tracer scan (for a total of 6 scans for each patient). The 3 image sets at each time point were coregistered. Initial <sup>18</sup>F-FDG PET/CT images identified 4 tumors and 12 nodes. Maximum standardized uptake values (SUV<sub>max</sub>) were significantly decreased between baseline and treatment scanning times in both tumors and nodes. 18F-FMISO SUV<sub>max</sub> assessments were significantly higher in tumors than in nodes and did not change from baseline to therapy imaging. <sup>18</sup>F-FDG uptake was significantly and separately correlated with <sup>18</sup>F-FLT and <sup>18</sup>F-FMISO uptakes at both timepoints. The authors concluded that these studies indicate that 3 different PET acquisitions can be performed quasisimultaneously (within a 4-7-d span) before and during radiotherapy in patients with NSCLC and that "a fast decrease in the proliferation of both tumors and nodes exists during radiotherapy with differences in metabolism (borderline significant decrease) and hypoxia (stable)."

Radiotherapy and Oncology

## New Rat Model of Bone Cancer Pain

In an article e-published on October 29 in the online journal PLoS One, Doré-Savard et al. from the Université de Sherbrooke (Quebec, Canada) reported on behavioral, medical imaging, and histopathologic features of a new rat model of bone cancer pain. The authors monitored pain onset and tumor growth for 21 d in their model of rat femoral mammary carcinoma MRMT-1 cell implantation. They monitored the gradual development of mechanical allodynia and hyperalgesia, as well as behavioral signs of ambulatory pain, which were first observed at d 14 after implantation. Osteopenia with disorganization of the trabecular architecture was also first observed on this date. MR imaging visualized bone metastases as early as d 8, well before pain observation. <sup>18</sup>F-sodium fluoride PET was coregistered with MR to show intraosseous activity. Pain and bone destruction were chronicled along with histochemical and other changes. The authors concluded that "our animal model demonstrates the importance of simultaneously recording pain and tumor progression and will allow us to better characterize therapeutic strategies in the future."

PLoS One

## REVIEWS -

Review articles provide an important way to stay up to date on the latest topics and approaches by providing valuable summaries of pertinent literature. The Newsline editor recommends several reviews accessioned into the PubMed database in late October and November. Two reviews of note were e-published on October 29 ahead of print in Current Drug Discovery Technologies. Lin and Iagaru from Stanford University Medical Center (CA) described "Current concepts and future directions in radioimmunotherapy," and Cornelissen and Vallis presented "Targeting the nucleus: an overview of Augerelectron radionuclide therapy." In an article in the November 15 issue of Molecules (2010;15:8260-8278), Hicks, from the University of Toronto (Canada), and colleagues reviewed "Radiolabeled small molecule protein kinase inhibitors for imaging with PET or SPECT." Winter and colleagues from Cincinnati Children's Hospital (OH) in the November 3 issue of the Journal of Cardiovascular Magnetic Resonance (2010;12:62) provided an overview of "Quantitative cardiovascular magnetic resonance for molecular imaging." In an article e-published on November 10 ahead of print in Trends in Molecular Medicine, Cho et al. from Washington University (St. Louis, MO) described "Inorganic nanoparticlebased contrast agents for molecular imaging." Rathore and Kadin from Roger Williams Medical Center (Providence, RI) provided perspective on "Hodgkin's lymphoma therapy: past, present, and future" in the December issue of Expert Opinion on Pharmacotherapy (2010;11:2891-2906).

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appointed a task force of Cardiovascular Council members and ASNC members to generate evidence that image quality using half-dose radiopharmaceuticals with commercially available new hardware and software developments is equivalent to image quality with doses and protocols currently recommended in guidelines.

Creating new ties with other clinical specialty organizations involved with the development of AUC and practice guidelines is critical. Robert Henkin, MD, member of the SNM

Committee on Collaborative Guidelines and SNM representative to the Council of Medical Specialty Societies (and to the Physician Consortium for Performance Improvement), wrote: "Over the long haul, our first goal must be to put into place an evidence-based system for SNM guidelines to support the development of quality measures. Failure to make this key commitment will undermine all other efforts we might undertake."

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