New SNMMI Fellows Honored

At its 2018 Annual Meeting in Philadelphia, PA, SNMMI recognized 14 new SNMMI Fellows during a special plenary session on June 26. The SNMMI Fellowship was established in 2016 to recognize distinguished service to the society as well as exceptional achievement in the field of nuclear medicine and molecular imaging. It is one of the most prestigious formal recognitions available to long-time SNMMI members.

All past SNMMI presidents were granted fellowship at the 2016 Annual Meeting. This year SNMMI's 2017–2018 president, Bennett S. Greenspan, MD, Medical College of Georgia, Augusta University, was inducted. Other new fellows include Salvador Borges-Neto, MD, Duke University Medical Center (Durham, NC); A. Bertrand Brill, MD, PhD, Vanderbilt University School of Medicine (Nashville, TN); William C. Eckelman, PhD (Bethesda, MD); Georges El Fakhri, PhD, Massachusetts General Hospital/Harvard Medical School (Boston, MA); Leonie L. Gordon, MD, Medical University of South Carolina (Charleston); Ora Israel, MD, Rambam Health Care Campus (Haifa, Israel); Jeffrey Norenberg, PharmD, PhD, University of New Mexico Health Sciences Center (Albuquerque, NM); Barry A. Siegel, MD, Mallinckrodt Institute of Radiology, Washington University at St. Louis (MO); Rathan Subramaniam, MD, PhD, MPH, University of Texas Southwestern Medical Center (Dallas, TX); Julie Sutcliffe, PhD, University of California, Davis; S. Ted Treves, MD, Boston Children's Hospital (MA); Henry VanBrocklin, PhD, University of California, San Francisco; and Harvey Ziessman, MD, Johns Hopkins Medicine (Baltimore, MD).

Selection of SNMMI fellows is based on documented excellence in volunteer service to the society and at least 1 of 3 additional areas: excellence in scientific discovery and innovation, educational efforts in nuclear medicine and molecular imaging, or clinical practice of nuclear medicine and molecular imaging. SNMMI fellows may use the honorific FSNMMI designation in their titles.

Satoshi Minoshima, MD, PhD, SNMMI president, inducted 14 new fellows at the 2018 Annual Meeting. Not pictured: Salvador Borges-Neto, MD.

NEWSBRIEFS

PET/CT in LVV and PMR: Joint Recommendations

In April, members of the Cardiovascular and Inflammation & Infection Committees of the European Association of Nuclear Medicine, the Cardiovascular Council of the SNMMI, and the PET Interest Group released a joint procedural recommendation on ^{18}F-FDG PET/CT angiographic imaging in large-vessel vasculitis (LVV) and polymyalgia rheumatica (PMR). The recommendations were endorsed by the American Society of Nuclear Cardiology. The recommendations, based on a best-available-evidence survey of the literature and resulting expert consensus, cover patient preparation, ^{18}F-FDG PET/CT angiography acquisition and interpretation, and imaging follow-up in patients with suspected or diagnosed LVV and/or PMR. The task group pointed to the need for an internationally accepted standard for ^{18}F-FDG PET/CT imaging and reporting in LVV and PMR. The group concluded that:

- ^{18}F-FDG PET/CT angiography has an important role in the diagnosis of extracranial vascular involvement in patients with LVV/PMR; however, additional randomized studies are needed.
- Improvements in ^{18}F-FDG PET/CT angiography procedures will help to optimize the diagnostic and monitoring value of this technique in LVV/PMR.
- Although visual qualitative methods are most often used, semiquantitative methods, such as the vascular/blood ratio and vascular/liver ratio using SUVs, are increasingly being applied.

- The addition of CT angiography to ^{18}F-FDG PET provides high-resolution imaging of vascular morphology that can potentially improve diagnostic accuracy, but, more important, provides information on the presence of possible complications, such as stenosis, organ ischemia, aneurysm formation, and dissection.
- Further prospective studies involving large cohorts of giant cell arteritis/PMR patients are needed to investigate and validate the role of semiquantitative methods for assessment of LVV.
- Several other open issues must be studied for optimal performance of ^{18}F-FDG PET/CT angiography in diagnosis, treatment monitoring, and future theranostics in LVV/PMR, further improving the levels of evidence and grades of recommendations.

The recommendations were published in the July issue of the *European Journal of Nuclear Medicine and Molecular Imaging* (2018;45:1250–1269) and are available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5954002/.

European Journal of Nuclear Medicine and Molecular Imaging

^{18}F-NaF PET Reconsideration Denied

On May 9, after a concerted effort from a broad range of professional societies, specialty experts, and patient groups to secure Centers for Medicare & Medicaid Services (CMS) coverage for ^{18}F-sodium fluoride (^{18}F-NaF) PET imaging in patients with bone metastases, CMS declined coverage. "We are disappointed that CMS did not open a reconsideration and allow public comment on the published evidence to support coverage for NaF PET. Many cancer patients would be helped by CMS reconsidering coverage for these exams," said National Oncologic PET Registry (NOPR) cochair Barry Siegel, MD.

In its decision, CMS maintained that evidence submitted by NOPR on the benefits of ^{18}F-NaF PET for patient management and curative or palliative care was not adequate to warrant reconsidering the current national coverage determination (NCD). SNMMI and 2 other organizations had called on CMS to reassess the determination and expressed disappointment and frustration with the most recent denial. The World Molecular Imaging Society (WMIS), the American College of Radiology (ACR), SNMMI, and members of the NOPR Working Group urged CMS on June 7 to open a reconsideration of the NCD for ^{18}F-NaF PET.

The CMS reimbursement policy for ^{18}F-NaF PET became more restrictive on December 14, 2017, when the in-place NCD and Medicare coverage for ^{18}F-NaF PET (under coverage with evidence development) expired and the NOPR stopped allowing new case registrations. In issuing its decision to allow the NCD to expire 24 mo after a 2015 CMS Decision Memorandum announcing the intended expiration, CMS had left room for reconsideration with the anticipated publication of additional peer-reviewed data. Among the published studies cited by advocates of reconsideration were studies published in *The Journal of Nuclear Medicine* in November and December 2017, validating ^{18}F-NaF PET as reasonable and necessary for Medicare beneficiaries. In the first study, NOPR members analyzed concordance between intended patient management as reported on post–^{18}F-NaF PET treatment plans provided to the NOPR and actual patient management based on Medicare claims data. The study showed substantial concordance between intended and claims-inferred post–^{18}F-NaF treatment plans—concordance levels similar to those that CMS found adequate to support coverage for ^{18}F-FDG PET. In the second study, NOPR data showed high correlations between ^{18}F-NaF PET results, hospice admissions, and survival, with the effect increasing further along in disease progression.

"The NOPR data clearly show that use of NaF PET led to more appropriate care for many cancer patients. We urge CMS to reconsider coverage for these potentially lifesaving and life-improving exams," said NOPR principal investigator Bruce Hillner, MD, on June 7.

With the closure of the NOPR to patient accrual in December 2017 and the May denial of reconsideration of coverage, ^{18}F-NaF PET in patients with bone metastases is no longer covered for Medicare beneficiaries. "Many seniors may ultimately receive care that is not as effective or helpful as it could be if CMS does not reconsider Medicare coverage for NaF PET. This is a step backwards in care for these patients. We urge CMS to reconsider coverage so that these seniors can have access to care that can better help them," said NOPR cochair Anthony Shields, MD.

WMIS, ACR, and SNMMI stated jointly that they will continue to work with CMS to support Medicare coverage and beneficiary access to ^{18}F-NaF PET.

SNMMI

^{177}Lu-DOTATATE Therapy and Amino Acids: Comments to FDA

SNMMI, the Mayo Clinic (Rochester, MN), Washington University School of Medicine in St. Louis, and Memorial Sloan Kettering Cancer Center (New York, NY) on May 25 jointly filed comments with the U.S. Food and Drug Administration (FDA) with recommendations intended to make it easier for patients with somatostatin receptor–positive gastroenteropancreatic neuroendocrine tumors (GEP NETs) to tolerate and benefit from ^{177}Lu-DOTATATE therapy. The FDA approved ^{177}Lu-DOTATATE therapy on January 26 for treatment of somatostatin receptor–positive GEP NETs, including foregut, midgut, and hindgut NETs in adults. This promising therapy was added to the National Comprehensive Cancer Network guidelines in May as an appropriate anticancer therapy for patients with progressive NETs. ^{177}Lu-DOTATATE therapy, however, can cause renal damage. Intravenous administration of an amino acid solution of arginine and lysine is effective

in reducing this injury and is specified in the therapy package insert and in general recommendations. These proteins are unfortunately not commercially available on their own; they are offered only in combination with other proteins and substances that can and have caused patients significant discomfort, including gastrointestinal distress. Alternative formulations of amino acid solutions can be compounded that do not cause these severe reactions. In the recommendation letter, the groups recommended that FDA support actions that could result in making these alternative amino acid solutions more broadly available for clinical use in the United States. The groups recommended specifically that FDA consider placing arginine and lysine on the 503B bulks list so that outsourcing facilities can begin using these 2 acids in compounding the amino acid solution for ^{177}Lu-DOTATATE treatment. Alternatively, the group suggested that FDA consider moving arginine and lysine to the 503B Category 1 list, Substances Nominated for the Bulks List Currently Under Evaluation.

SNMMI

NRC Issues Annual Abnormal Occurrences Report

The Nuclear Regulatory Commission (NRC) each year compiles a *Report to Congress on Abnormal Occurrences*. The report for fiscal year 2017 was released in June. Abnormal occurrences are defined as unscheduled incidents or events that the NRC determines to be significant from the standpoint of public health or safety. The report described 5 events involving NRC licensees. All were medical events as defined in Title 10 of the Code of Federal Regulations (10 CFR) Part 35, "Medical Use of Byproduct Material." No events were reported from nuclear power facilities. In addition, the report described 6 other medical events, as defined in 10 CFR Part 35, that occurred in Agreement States and were identified as abnormal occurrences. Of the 11 events described, 7 involved ^{90}Y microsphere brachytherapy, 1 involved prostate brachytherapy, 1 ^{131}I-associated imaging, and 1 ^{103}Pd brachytherapy. All were attributed to human error, including incorrect dose calculations and administration, seed misplacement, preparation errors, and movement between imaging and placement. A 12th event was also included in the report and involved individual laboratory exposure at the National Institute of Standards and Technology (Gaithersburg, MD) after breakage of an ampoule containing ^{241}Am. The complete report, with details of each incident and follow-up on events from past years, is available at https://www.nrc.gov/docs/ML1815/ML18157A051.pdf.

U.S. Nuclear Regulatory Commission

Trans-NIH Pediatric Research Consortium Launched

On June 13, the National Institutes of Health (NIH) announced the formation of the Trans-NIH Pediatric Research Consortium, intended to coordinate pediatric research programs across the NIH institutes and centers. Almost all of the 27 NIH institutes and centers fund some aspects of child health research. In fiscal year 2017, this support totaled more than $4 billion. NIH reported that the new consortium aims to harmonize these activities, explore gaps and opportunities in the overall pediatric research portfolio, and set future priorities. "NIH-funded research has resulted in tremendous advances against diseases and conditions that affect child health and wellbeing, including asthma, cancer, autism, obesity, and intellectual and developmental disabilities," said Diana W. Bianchi, MD, director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the lead NIH institute for the consortium. "This consortium aims to capitalize on this momentum by enhancing crosstalk between scientific disciplines to address the wide range of health conditions experienced by children in this country and around the world." The new consortium will be led by the NICHD director. In addition to project-based interactions, the full consortium will meet several times each year to discuss scientific opportunities and potential new areas of collaboration, including efforts to enhance training for the next generation of pediatricians.

National Institutes of Health

NIH Releases Strategic Plan for Data Science

The National Institutes of Health (NIH) on June 4 released the first *Strategic Plan for Data Science*, providing a roadmap for modernizing the "NIH-funded biomedical data science ecosystem." Over the course of the next year, NIH will begin implementing the strategy, with some elements of the plan already underway. NIH will also seek community input during the implementation phase.

Storing, managing, standardizing, and publishing the large amounts of data produced by biomedical research is identified as a critical mission for NIH, and accessible, well-organized, secure, and efficiently operated data resources are critical to modern scientific inquiry. In a brief press release, NIH noted that "by maximizing the value of data generated through NIH-funded efforts, the pace of biomedical discoveries and medical breakthroughs for better health outcomes can be substantially accelerated." NIH will work to address:

- Findability, interconnectivity, and interoperability of NIH-funded biomedical data sets and resources;
- Integration of existing data management tools and development of new ones;
- "Universalizing" innovative algorithms and tools created by academic scientists into enterprise-ready resources that meet industry standards of ease of use and efficiency of operation; and
- Measures to deal with the growing costs of data management.

To advance NIH data science across the extramural and intramural research communities, the agency will hire a Chief Data Strategist. This management function will guide the development and implementation of NIH's data science activities and provide leadership within the broader biomedical research data ecosystem.

National Institutes of Health