SNMMI Leadership Presentation

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SNMMI President
SNMNI Leadership

- Peter Herscovitch, MD, FACP, FRCPC, President
- Hossein Jadvar, MD, PhD, MPH, MBA, FACNM, President-Elect
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- Aaron T. Scott, CNMT, NMAA, FSNMNI-TS, President-Elect
Goal A: Advance the development and approval of nuclear medicine and molecular imaging technologies.

Goal B: Facilitate and support the availability and clinical utilization of nuclear medicine and molecular imaging technologies.

Goal C: Increase appropriate utilization of radionuclide therapy.

Goal D: Advance and promote quality, value and safety of molecular imaging and nuclear medicine.

Goal E: Support and enhance the professional workforce and environment.
Goal A

Advance the development and approval of nuclear medicine and molecular imaging technologies
Mission:
To create a more efficient and timely FDA approval process for new and non-proprietary radiopharmaceuticals

FDA Stakeholder Meeting, October 27, 2014
50 attendees from:
– SNMMI – FDA Task Force, leadership, staff
– Government – FDA, CMS, NRC, NCI, NIBIB
– Industry – CORAR, MITA, select companies
– Imaging Societies – ACR, ASNC, WMIS
FDA Stakeholder Meeting – Breakout Questions

- **Market/Commercialization Barriers**
  - CMS non-coverage for PET cardiology and brain agents
  - Phase III trials for FDA approval do not fulfill the requirements for CMS

- **Current FDA Approval Process**
  - Toxicology is a major barrier for academic researchers, for first-in-human studies
  - Need better FDA definition of efficacy, clinical benefit/utility

- **New Pathway**
  - A new streamlined approval pathway for non-pharmacologically active, low-mass radiotracers
  - Products can only be regulated as drugs or devices; no middle pathway for radiotracers

- **Outcome Measures for both FDA and CMS**
  - CMS wants improved health outcomes, a fundamental challenge to radiopharmaceutical developers
  - Joint FDA/CMS approval pathway

- SNMMI is writing a white paper detailing action items, recommendations and strategies.
Mission

Advance the use of molecular imaging radiopharmaceuticals in clinical trials through standardization of chemistry and imaging methods.

This includes using imaging agents during the course of drug development, and bringing new radiopharmaceuticals to regulatory approval.
Clinical Trials Network

Ensure standardized, quality PET imaging in clinical trials for drug development and of new radiotracers

- Scanner Validation Program – oncology chest phantom
  - Validated more than 240 scanners on 4 continents
- Assisted with 9 industry-sponsored trials
  - Using FDG, FLT and two proprietary agents
- Part of a team that received an NIH grant for harmonized PET reconstruction
  - to develop reconstruction methods on different scanners to produce comparable images across centers for clinical trials

Facilitate access to investigational PET radiotracers for multicenter clinical trials

- Obtained a centralized IND for $^{18}$F-FLT (cellular proliferation in tumors)
- Recipient of Movember grant for prostate cancer imaging
  - Managing international trials utilizing $^{18}$F-choline and $^{18}$F-FDHT
• The Gallium Users Group meets twice each year, and has monthly teleconferences
• A venue to discuss agents, generators, regulatory issues, and imaging
• Met with FDA officials to discuss the approval pathway for Ga-68 labeled drugs,
• $^{68}$Ga-labeled DOTA agents for imaging neuroendocrine tumors
  – Assisted several sites to obtain INDs via sharing of information
  – Received Orphan Drug Designation for $^{68}$Ga-DOTATOC from the FDA
  – Transferred designation to U of Iowa, which will file an NDA, and make it available to other centers
Goal B

Facilitate and support the availability and clinical utilization of nuclear medicine and molecular imaging technologies.
SNMMI members and patient advocates met with more than 70 Congressional offices this year to advocate for a domestic source of Mo-99 and to maintain current budget funding.

Submitted comments to the OECD on the Security of Supply of Medical Radioisotopes and presented to the high-level working group (HLG-MR) in Paris.

Participated in the White House working group on Mo-99 supply, which meets quarterly with OSTP, NNSA, FDA, CMS, NRC. Presented twice in 2014.
Ambulatory Payment Classification Remodeling Task Force

- Goal: Establish appropriate HOPPS reimbursement for indicated diagnostic nuclear medicine imaging services

- Task force is currently working other stakeholders
  - Working on a solution to the bad data used in Medicare outpatient reimbursement decisions
  - Met with CMS in the first quarter of 2015
  - New tiered, more refined system for radiopharmaceutical reimbursement proposed
Patient Advocacy Advisory Board
Eleven major patient advocacy organizations that advise us on patient-specific program development.

Programs:

• Patient Portal: Patient-focused website to explain molecular imaging and therapies for each disease
• Patient Advocate Hill Day, Oct 2014: 23 congressional offices
• Fact Sheets: Modality and disease specific brochures in print and online
• Interactive Webinars: Allow patients to learn more and ask questions
• Patient Education Day: Patient-focused track at our Annual Meeting; overview of nuclear medicine and breakout sessions (120 attendees)
Creating Partnerships with Referring Physicians

- Referring physician initiatives
  - Guidelines and bibliographies organized by topic on new interactive website
  - Joint sessions with referring physician societies
    - APA - session on Amyloid PET Imaging
    - NANETS Symposium: Improvements in NET Imaging
  - Road shows to reach local physicians unable to attend national meetings
  - Free disease-specific webinars for CME
  - Choosing Wisely Program
Issues with Perception of NM

Concern for radiation exposure

- Working closely with NRC on rewrite of Part 20 and Part 35 – comments were submitted on November 2014
- SNMMI maintains a website on dose optimization: www.snmmi.org/dose
- Two dose tools: Nuclear medicine radiation dose tool, Pediatric injected activity tool
- SNMMI participates in and promotes:

[Image of IMAGE WISELY™]

Radiation Safety in Adult Medical Imaging

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Industry Forum (SNMMI, MITA, CORAR)

• Collaboration with industry groups to determine how we can work together, in response to the challenges facing nuclear medicine.
• Three areas were identified, working groups formed

1. Government reimbursement reform
   Charge compression and inappropriate CMS packaging under the hospital outpatient prospective patient system (HOPPS)

2. Evidence development
   Help identify areas for AUCs; continuing to meet with CMS to discuss concerns on deficiencies in AUC process

3. Education and outreach
   Increase the knowledge of referring physicians of the appropriate use and benefits of NM
Goal C

Facilitate and support the availability and clinical utilization of radionuclide therapy
Increase Appropriate Utilization of Radionuclide Therapy

• Advocate for the regulatory approval and reimbursement of emerging agents.

• Advance the use of approved agents.
  – Radium-223 Cl₂ and radioimmunotherapy
  – NCI/SNMMI workshops on Targeted Radionuclide Therapy (March 2013, October 2014)
  – Online education modules
  – Patient brochures on available therapies
  – Webinar series for referring physicians (Part 1, offers free CME) and patients (Part 2)
  – Formation of a Radionuclide Therapy Center of Excellence
Goal D

Advance and promote quality, value and safety of molecular imaging and nuclear medicine
Evidence and Quality Department

- New Department of Evidence and Quality created in 2014; physician director hired

- Focus and goals
  - Develop evidence-based clinical guidance documents: clinical practice guidelines and AUC
  - Collaborate and partner with other organizations to develop joint guidelines
  - Pilot clinical data registry on variability of administered dose in nuclear medicine
  - Develop new quality measures for reporting in nuclear medicine
  - Compile cost-effectiveness data and generate evidence
  - Education and training
As part of the Medicare Sustainable Growth Rate (SGR) system, Congress passed the “Protecting Access to Medicare Act of 2014.”

Tied advanced diagnostics imaging services / physician reimbursement to appropriate use criteria (AUC).

Advanced Diagnostic Imaging Services (ADIS) are defined as diagnostic MRI, CT, nuclear medicine (including PET), and other diagnostic imaging services specified by the Secretary.
Directs the Secretary of HHS to launch (by 2017) a program that encourages the use of AUC for ADIS

Ordering professionals will have to consult AUCs via a clinical decision support tool prior to ordering ADIS, for help in determining whether an exam is clinically appropriate for a patient’s condition

By November 15, 2015, in consultation with stakeholders, the Secretary will choose which AUCs will be included in the program
AUC Topic Prioritization

• Based on CMS data on high volume Nuclear Medicine procedures and lack of existing evidence-based AUCs, our Guidance Oversight Committee recommended the following topics for AUC development

• Approved by our BOD

Bone scintigraphy in malignant disease
Ventilation/Perfusion Imaging in pulmonary embolism
Hepatobiliary scintigraphy in abdominal pain
FDG-PET for re-staging malignant disease
Objective:
Identify patients who will most appropriately benefit from a procedure, thus resulting in a more effective and equitable allocation of healthcare resources.

- Must be created or endorsed by national medical specialty societies or other provider-led entities
- Must have stakeholder consensus
- Be scientifically valid & evidence-based
- Be based on publicly available studies: published, reviewable by stakeholders
SNMMI and the Alzheimer’s Association developed AUC to aid in the diagnosis of people with suspected Alzheimer’s disease


CMS NCD on amyloid brain imaging – Sept 2013 - allows one PET amyloid scan per patient through CED

CED study for PET amyloid imaging (AA, WMIC, ACRIN, SNMMI)

- Amyloid Imaging Coverage with Evidence Development workgroup submitted a protocol to CMS for PET amyloid imaging in patients satisfying the AUC

- “Imaging Dementia - Evidence for Amyloid Scanning (IDEAS) Study; approved by CMS on March 31st
IDEAS – Study Aims

• Open-label, longitudinal cohort study to assess the impact of amyloid PET on patient outcomes in patients meeting AUC

• Aim 1: Test whether amyloid PET imaging will lead to a change between intended and actual patient management within ~90 days

• Aim 2: To assess the impact of amyloid PET on hospital admissions and emergency room visits in patients enrolled in the study cohort compared to matched patients

• A total of 18,488 Medicare beneficiaries meeting AUC will be enrolled over 24 months at sites throughout the U.S.
Goal E
Support and enhance the professional workforce and environment
• Provide education to promote best practices, review current research, and understand emerging technologies and their applications:
  – CE courses and scientific presentations at SNMMI meetings
  – Enduring CE courses delivered online through the new SNMMI Learning Center
  – Live webinars on a variety of topics throughout the year
  – Journal of Nuclear Medicine CE articles
  – MOC activities for physicians to support both Self-Study (Part II) and Practice Improvement (Part IV) requirements delivered in live and enduring formats
PET/MR Credentialing Task Force

• ACR/ SNMNI joint effort

• Co-chaired by Rathan Subramaniam, MD, PhD (ACR) and Hossein Jadvar, MD, PhD (SNMNI)

• Developed a joint credentialing and privileges statement for PET/MR for brain imaging

• Approved by both boards

• Other applications in the future
SNMMI hosted the 1st Future Leaders Academy prior to 2014 Mid-Winter Meeting (11 young professionals)
  - Included facilitated discussion on communication, conflict resolution, ethics and professionalism
  - Attendees assigned mentors (current leaders in the field)
  - Attendees were assigned to SNMMI committees to ensure continued leadership development.

2nd Future Leaders Academy:
  - 2015 Mid-Winter Meeting (San Antonio, TX)
Thank you!
Questions?
Nuclear Medicine Global Initiative

- Organizations involved:
  - Nuclear medicine societies – China, Japan, Korea, India, Australia/New Zealand, Canada, South Africa
  - Multinational organizations – EANM, IAEA, WFNMB, ALASBINM, AOFNMB


- 2nd Project – *Availability of Radiopharmaceuticals* – aims to establish the availability, use, access issues and impediments to the use of diagnostic and therapeutic radiopharmaceuticals globally.
• Campaign to help physicians and patients engage in conversations about the overuse of tests

• Participating societies create a list of “Five Things Physicians and Patients Should Question.”
  – 35 societies to date; 130 recommendations

• Supported by Consumer Reports, AARP and Wikipedia

• SNMMI’s participation allows us to educate referring physicians and patients
SNMMI’s List of “Five Things”

*Developed with input from leadership, councils and members
Published February 2013 on www.choosingwisely.org*

1. Don’t use PET/CT for cancer screening in healthy individuals.

2. Don't perform routine annual stress testing after coronary artery revascularization.

3. Don’t use nuclear medicine thyroid scans to evaluate thyroid nodules in patients with normal thyroid gland function.

4. Avoid using a CT angiogram to diagnose pulmonary embolism in young women with a normal chest radiograph; consider a radionuclide lung study (“V/Q study”) instead.

5. Don't use PET imaging in the evaluation of patients with dementia unless the patient has been assessed by a specialist in this field.