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Society of Nuclear Medicine and Molecular Imaging Efforts Toward Standardization: From Procedure Standards to Appropriate Use Criteria

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The Society of Nuclear Medicine and Molecular Imaging (SNMMI) continues to develop clinical guidance documents to synthesize and disseminate clinical information for optimal patient care. Clinical guidelines help standardize delivery of care and improve quality. Chronology of SNMMI efforts in the development of nuclear medicine procedure standards (PS) and appropriate use criteria (AUC) is reviewed. Historically, the Society has focused its efforts on developing PS describing the accepted methodology for performing nuclear medicine procedures. However, legislative mandates and lack of existing evidence-based documents prompted SNMMI to take a lead in developing AUC for high-value nuclear medicine procedures. AUC presents common clinical scenarios where the use of nuclear medicine procedures is or is not appropriate. Methodology used by SNMMI for the development of PS and AUC is described. Following a multidisciplinary, transparent, and widely acceptable process can result in the development of widely acceptable clinical guidance documents that can standardize best practices, improve quality, and result in effective and efficient patient care. The Society has been developing and/or revising new PS and AUC documents for high-value nuclear medicine procedures. Updated real-time information on these clinical guidelines can be found at www.snmmi.org/ps and www.snmmi.org/auc.
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Introduction and Background

Clinical guidelines have been increasingly used over the past several decades to synthesize and disseminate clinical information describing best practices for patient care. Their primary objectives are to standardize the delivery of care, improve quality, efficiency, cost-effectiveness, and enhance appropriateness of practice. Consequently, clinical guidelines may also be used as quality measurement and quality improvement tools.

It has been postulated that the lack of standardization and the subsequent variety of approaches to treat a specific disease is partially to blame for wasteful spending of healthcare dollars.[1-3] This variation in practice may be caused, in part, by differences in availability of local resources, but it is also considered to be caused, in part, by failure of some healthcare providers to update their practices to reflect the current literature. One component of the rising cost of medical care could therefore be addressed by limiting the variations associated with medical practice, under the assumption that there are optimal cost-effective management pathways for most disease processes.

Recognizing the need for clinical guidelines, the leadership of the Society of Nuclear Medicine (SNM) and Molecular Imaging put together a guidelines committee in the early nineties to develop documents describing the best diagnostic approaches to disease processes that involved nuclear medicine procedures. The earliest efforts of the committee were aimed toward development of a clinical practice guideline describing the diagnosis of coronary artery disease, particularly

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relating to the role of nuclear medicine procedures (then known as the Society of Nuclear Medicine—SNM).

However, after initially pursuing the idea of writing clinical practice guidelines, the SNMMI Guidelines Committee recognized that the expertise of SNMMI members lies more with the performance and interpretation of nuclear imaging studies, and that the SNMMI membership would be better served by detailed practice guidelines, describing the optimal performance of nuclear imaging and therapy procedures.

The foundation of any guideline should be based on evidence in peer-reviewed literature; however, specialty societies, including SNMMI, have always recognized that there are large gaps in the literature supporting optimal diagnostic and management strategies for individual patients, particularly when considering specific presentations, comorbidities, age, and sex. If clinical practice guidelines are to be written without comprehensive supporting literature, other sources of clinical knowledge must be pursued. One solution has been to take advantage of expert knowledge through the use of the Delphi technique.

In brief, the Delphi method includes soliciting a panel of experts about their approach to a problem, such as the management of a patient with a specific disease presentation.[4] The answers are given independently, collated, and presented back to the members of the expert panel as an anonymous summary. The panel members are then encouraged to discuss the variation in answers and then restate their answers to the problem considering the collated information. Several rounds of anonymous resubmission and discussion of answers are performed until a consensus is reached.

Therefore, the SNMMI Practice Guidelines Committee began to develop documents describing acceptable parameters for the performance of nuclear imaging procedures. Each document was written by a panel of members of the SNMMI who generously volunteered their time and expertise. While there are isolated prior publications recommending specific imaging parameters, controlled trials comparing imaging methods are rare indeed, and trials showing the effect of nuclear imaging on patient outcomes are nonexistent for many nuclear imaging procedures. This lack of literature supporting specific imaging parameters means that the assembled expert panels all depended on the Delphi process described above.

The society reached out to other professional organizations with the hope that developing collaborative documents would serve the membership of more than just SNMMI. Organizations such as the American College of Radiology and the European Association of Nuclear Medicine (EANM) have therefore been involved in the development of these documents when appropriate and feasible.

In February 2014, it was determined by the SNMMI leadership that the terminology in healthcare in the United States had evolved and it became prudent to rename the "SNMMI practice guidelines" to "SNMMI procedure standards" to better reflect the terminology being used by external organizations. SNMMI Procedure Standards are currently being developed under the auspices of the SNMMI Procedure Standards Committee, overseen by the SNMMI Guidance Oversight Committee, and continue to remain an important resource for the practice of nuclear medicine in the United States as well as around the world.

Process for Developing Procedure Standards

The SNM Guideline for Guideline Development was the initial document produced by the Guidelines Committee, more recently rewritten in conjunction with the EANM to become the SNMMI and/or EANM Guideline for Guideline Development 6.0.[5] This document outlines the process by which SNMMI Procedure Standards (EANM procedure guidelines) are to be developed, including how the Chair of the Practice Standard Working Group selects working group members, how the literature search is accomplished, how the document is written and the recommended review cycle (Table 1). The Guideline for Guideline Development also provides a recommended outline for each document that includes topics to be covered such as goals, definitions, common clinical indications, qualifications of personnel, and others. This outline provides a foundation that can be consulted by all authors of the Practice Standards, as well as a reference for SNMMI staff to keep the document development process standardized and proceeding smoothly. The content and format of these documents have evolved over time to their present form but have always included recommendations for quality control (QC), imaging parameters, and reporting requirements specific to the procedure described. The Guideline on Guideline Development also underlines the importance of documenting conflict of interest (COI) at each step in the development of SNMMI clinical reference documents.

COI

To insure acceptance by the Centers for Medicare & Medicaid Services (CMS) and third-party payers, any SNMMI Procedure Standard or appropriate use criteria (AUC) must include readily available information about COI that may occur with any author. When a writing group for a document is assembled, members of the group are asked to sign an attestation outlining any COI they may have. The conflicts are reviewed by SNMMI staff. If a conflict is determined to be significant, the writing group member may be removed from the working group authoring the document. In some cases, an author with a significant conflict may possess important knowledge relevant to the document being written. In that case, the person with the conflict may be assigned a position as a nonvoting consultant to the working group. For the integrity of these documents, it is critical that information about significant COI be available to any organization considering adopting SNMMI documents as official policy.

Shortly after the Guideline on Guideline Development was written, the SNMMI Procedure Standard for General Imaging 6.0 was developed. This document provides information

Table 1 Procedure Standard Development Process

Step	Comment
Select new Procedure Standard topic	Suggestions for topics originate with SNMMI membership, Procedure Standards Committee members, Guidance Oversight Committee, SNMMI administration
Discuss with EANM if this is to be a document that will officially be codeveloped with EANM	Depends on availability of EANM personnel, relevance of the topic to practice in Europe, and if a similar EANM document already exists.
Appoint Chair for the Working Group	Appointed by Procedure Standards Committee. If this is to be a document developed officially with EANM as coauthor, appoint an EANM Co-chair
Chair(s) of Working Group appoints Working Group members	Working Group is composed of SNMMI members. Working Group should include at least one technologist, one physicist, and one EANM member. If an official SNMMI/EANM document, more EANM members will be on the Working Group.
SNMMI staff obtains contact information, conflict of interest information, and sends the procedure standard development timeline and Guideline for Guideline development to all Working Group members.	SNMMI staff also manages any conference calls between the Working Group members and manages all drafts of the Procedure Standard. All edits to each draft are documented by SNMMI staff.
Chair of Working Group writes rough draft of the Procedure Standard	Following the recommended format documented in the SNMMI/EANM Guideline For Guideline Development.
SNMMI Staff obtains initial draft and disseminates it to Working Group members.	Working Group members individually edit the first draft and send their edits to SNMMI staff.
SNMMI staff collates all edits and sends them to the Working Group Chair.	
Working Group Chair either rejects or accepts individual edits.	For any edits that are rejected, the Chair must document a reason for the rejection.
All edits and comments on edits are returned to SNMMI staff who then reformat the document and return it to the Working Group members for review.	
Further rounds of Working Group edits and subsequent edit reviews by the Chair are continued until the Chair receives no further comments from the Working Group.	
The draft document is posted to the SNMMI website and SNMMI membership is allowed to comment. Feedback from Patient Advocacy groups, if applicable.	
Once all comments have been incorporated and the document receives final approval by the Working Group, it is presented to the SNMMI Procedure Standards Committee for final review of format, and dosimetry table review (if appropriate).	
The document is then presented to the SNMMI Board of Directors (and EANM equivalent) for approval.	If approved, document is published in either the Journal of Nuclear Medicine, the European Journal of Nuclear Medicine and Molecular Imaging, or the Journal of Nuclear Medicine Technology, then placed on the SNMMI website for member access.

about imaging logistics that are common to most nuclear medicine procedures, such as gamma camera QC, general recommendations for image processing and data storage, as well as general recommendations for reporting study results. The first version of this guideline was approved by the SNMMI* board in 1996 and the most recent version (6.0) was approved in 2010.

Most procedure standards are reviewed and revised approximately every 5 years, or earlier if needed, as determined by the Procedure Standards Committee. Six guidelines have been approved in 2018 (Table 2), and there are currently an additional 12 procedure standards under revision (Table 3). All SNMMI Procedure Standards can be accessed at www.snmmi.org/ps.

Collaboration for guideline development was initiated by SNMMI and EANM to avoid discordant recommendations from the two organizations, and to provide uniformity and clarity for nuclear medicine practitioners. In some cases, differing regional regulatory policy may prevent development of joint SNMMI and/or EANM documents, but the collaborative efforts have helped strengthen communication between the organizations. The two organizations remain committed to developing joint guidelines for nuclear medicine procedures, when feasible.

Table 2 SNMMI Procedure Standards Approved in 2018 (www.snmmi.org/ps)

Procedure Standards Title	Date Approved
A joint RANO/EANO/EANM Practice Guideline and/or SNMMI Procedure Standard for Imaging of Gliomas using PET with Radiolabeled Amino Acids and [18F] FDG: Version 1.0	September 23, 2018
The SNMMI and EANM Procedural Guidelines for Diuresis Renography in Infants and Children	June 22, 2018
Hepatobiliary Scintigraphy in Abdominal Pain FDG-PET/CT: EANM procedure guidelines for tumor imaging: version 2.0 with the exception that the SUV max is used in the United States as the quantitative measurement	June 22, 2018
The SNMMI and EANM Procedural Guidelines for Diuresis Renography in Infants and Children	June 21, 2108
SNMMI Procedure Standard and/or EANM Practice Guideline for Diuretic Renal Scintigraphy in Adults with Suspected Upper Urinary Tract Obstruction 1.0	January 27, 2018
Amyloid Imaging FDG-PET/CT(A) Imaging in Large Vessel Vasculitis and Polymyalgia Rheumatica: Joint Procedural Recommendation of the EANM, SNMMI, PET Interest Group, and endorsed by American Society of Nuclear Cardiology (ASNC)	January 27, 2018

Strengths and Weaknesses of Procedure Standards

Procedure standards are very practical and useful documents for nuclear medicine practitioners. These standards provide a structured and reasonable course of action based on current knowledge and expert consensus, and are meant to describe *acceptable* procedure parameters, not only cutting-edge technology. As mentioned above, personnel involved in developing these documents should include all relevant stakeholders including physicians, medical physicists, and technologists. When procedure standards are written as SNMMI and/or EANM collaborative documents, they are particularly helpful in further validating the value of the practice described in the document.

Despite the extensive effort, SNMMI and EANM have put forth in the development of procedure standards (EANM Procedure Guidelines), there remains room for improvement. One weakness of the SNMMI Procedure Standards is that they are not always developed based on a systematic review of the published literature, a standard practice that forms the literature-supported basis of most clinical practice guidelines. The push for evidence-based practice expects clinical decision making to be based on evidence published in the peer-reviewed literature. Patients should receive care that is based on the best available evidence and that care should not vary from clinician to clinician or from place to place.[6] However, a systematic review and grading of the available literature performed by an organization independent of SNMMI and EANM can be very expensive. In our experience, depending upon the topic, the cost of the literature review alone may exceed $100,000.00 for a single clinical practice guideline.

As mentioned above, however, a systematic review of the literature rarely, if ever, provides information complete enough to write detailed recommendations for any nuclear medicine procedure. With rapidly evolving technology, such as that which encompasses the practice of nuclear medicine, complete evidence-providing outcomes data for all patient populations will never exist. Rapidly evolving technologies more often benefit from expert panels and the Delphi process described above. Experts often have an in-depth knowledge of relevant literature and are particularly suited to extrapolation of technology proven in one clinical scenario to a clinical scenario where literature support is less detailed.

Table 3 SNMMI Procedure Standards Currently Under Development or Revision (www.snmmi.org/ps)

SNMMI/EANM Procedure Standard and/or Guideline for Scintigraphy of Differentiated Thyroid Cancer (New)
EANM/SNMMI Procedure Guideline and/or Standard for Radionuclide Imaging of Pheochromocytoma and Paraganglioma (New)
18F-Fluciclovine: Joint EANM and SNMMI Procedure Guideline for Prostate Cancer Imaging (New)
EANM/SNMMI Procedure Guideline and/or Standard for Dopaminergic Imaging in Parkinsonian Syndromes (New)
EANM/SNMMI Practice Guideline for FDG-PET/CT External Beam Radiotherapy Treatment Planning in Uterine Cervical Cancer (New)
EANM/SNMMI Procedure Guideline/Standard on FDG-PET/CT in Radiotherapy Treatment Planning in Lung Cancer (New)
SNMMI Procedure Standard for Gated Equilibrium Radionuclide Ventriculography, V 3.0
EANM SNMMI Procedure Guideline and/or Standard for Radioactive Iodine Uptake (RAIU) and Scintigraphy, V 3.0
SNMMI Procedure Standard for Tc-99m HMPAO-Labeled Leucocyte Scintigraphy for Suspected Infection and/or Inflammation
SNMMI Procedure Standard for In-111 Leucocyte Scintigraphy for Suspected Infection and/or Inflammation
SNMMI Procedure Standard for Therapy of Thyroid Cancer with Iodine-131
SNMMI Procedure Standard for Palliative Treatment of Painful Bone Metastases

Another consideration for the SNMMI Procedure Standards is the lack of true multidisciplinary membership on the expert panels developing these guidelines. All subject matter experts developing these procedure standards are nuclear medicine professionals. According to the Institutes of Medicine recommendations,[7] engaging with and involving all pertinent stakeholders from the beginning of the clinical guideline development process helps in creating a well-balanced guideline and helps in the rapid dissemination and acceptance of those recommendations. However, the SNMMI Procedure Standards are written to describe the acceptable performance of nuclear medicine procedures, primarily imaging procedures. It may be argued that technical details such as energy windowing, collimator choice, and radiopharmaceutical QC are not of interest to internists, oncologists, other referring physicians, and patients.

The performance of nuclear medicine procedures involves direct contact with patients, and therefore it may be more relevant to obtain patient feedback on aspects of procedures such as positioning, imaging bed comfort, and scan duration. Because patients would not be expected to have input on technical aspects of the procedures, they would probably be more valuable as consultants through patient advocacy groups than as panel members involved from the beginning of the writing process. SNMMI has therefore developed an outreach program which is beginning to solicit input from patient advocacy groups. When any new procedure standard is developed or an existing one revised, one of the steps during that process is to solicit comments and feedback from SNMMI members as well as public. At that time, it is also shared with any relevant patient advocacy group to get their input (Table 1).

From Procedure Standards to AUC

In early 2015, the society revisited the decision of developing only procedure standards and started developing AUC for high-value nuclear medicine procedures. This initiative was primarily undertaken to assist referring physicians and ordering professionals fulfill the requirements of the 2014 Protecting Access to Medicare Act (PAMA).[8] Section 218(b) of PAMA established a new program under the statute for fee-for-service Medicare to promote the use of AUC for advanced diagnostic imaging services, including CT, MRI as well as all nuclear medicine procedures, including PET. PAMA requires referring physicians to consult AUC developed by a CMS-approved provider-led entity or "PLE" (usually a specialty society, such as SNMMI) to ensure cost-effective and appropriate utilization of advanced diagnostic imaging services. Lack of existing evidence-based AUC for high-value nuclear medicine procedures made a very compelling case for the society to take a lead in this regard.

Under this program, AUC may be developed only by organizations that are deemed as "qualified provider-led entities (Q-PLE)" by the CMS. After going through a rigorous and extensive application that required SNMMI to document their guideline development process, including conflicts of interest adjudication and composition of expert panels, the society was approved as a qualified PLE in June 2016. It was one of only three medical specialty societies granted that designation; the other two were American College of Cardiology and the American College of Radiology.

While AUC have some similarities to clinical practice guidelines in that they advise clinicians about the management of patients presenting with specific signs and symptoms, the AUC differ from the earliest efforts made by SNMMI toward the writing of practice guidelines in that rather than making general recommendations about the management of patients presenting with specific signs and symptoms, AUC make recommendations about the appropriate and inappropriate use of relevant nuclear medicine procedures in those patients.

SNMMI modeled its AUC development process after the RAND and/or University of California at Los Angeles Appropriateness Method[9] and includes a systematic review of evidence followed by development of AUC for various common clinical scenarios using a modified Delphi approach (Table 4). This process is also consistent with the Institute of Medicine's standards for developing trustworthy clinical guidance documents.[7] The process includes identification of relevant clinical scenarios, and a systematic literature search and ranking of the quality of available evidence showing the utility of nuclear medicine procedures in those clinical scenarios. The available literature and expert opinion are separately considered and then combined for individual and subsequently for group ratings of the appropriateness of a specific procedure using a formal consensus process. The resulting AUC document is then based on the group ratings and discussions.

To conduct independent and objective systematic reviews of the literature, SNMMI has contracted with the Oregon Health and Science University's evidence-based practice center. The primary purpose of these systematic reviews is to assess the literature for evidence describing the diagnostic accuracy and comparative effectiveness of selected nuclear medicine procedures in clinical decision making and patient outcomes.[10] The strength of each publication collected and reviewed is graded as high, moderate, low, or very low based on quality of evidence, consistency, directness, precision, and reporting bias. These publications then form the foundation for the expert panel to score the use of a specific nuclear medicine procedure in the different clinical scenarios as usually appropriate, maybe appropriate, or rarely appropriate.

AUC development by the SNMMI has been a true multidisciplinary effort with official representation from 19 different specialty societies (Table 5). Overall, subject matter experts representing over 30 specialties were involved in the development of SNMMI sponsored AUC. The multidisciplinary nature of this effort also helps in the acceptance, and in some cases endorsement, of these guidelines by other specialty societies. For instance, the American College of Emergency Physicians endorsed the SNMMI AUC for Ventilation-Perfusion Imaging in Pulmonary Embolism,[11] after having participated in the development of this AUC. The SNMMI Guidance Oversight Committee has set a goal of developing

Table 4 AUC Development Process

Select new AUC topic	Suggestions for topics originate with Guidance Oversight Committee, SNMMI membership, and SNMMI administration.
Appoint Chair for the AUC Expert Panel	Appointed by the chair of the Guidance Oversight Committee, in consultation with the rest of the committee.
Form Multidisciplinary Expert Panel	All relevant stakeholder specialties are invited to participate in the development of well-rounded AUC document. Patient advocacy groups are also invited, if applicable.
Adjudicate conflicts of interests	Expert panel members fill out standard SNMMI COI form in accordance with CMS Q-PLE requirements. SNMMI staff adjudicates any potential COI and provides feedback to the chair.
Identify most common clinical indications	Expert panel identifies most common clinical indications for that procedure, both appropriate as well as rarely appropriate.
Set parameters for systematic review	Expert panel sets up the inclusion-exclusion criteria for the systematic review of evidence using PICOTS criteria, formulating key clinical questions to drive the review.
Systematic review and grading of evidence	Evidence-based Practice Center at Oregon Health and Science University conducts systematic review of literature based on the criteria provided by the expert panel. Oregon Health & Science University (OHSU) also grades the evidence and creates evidence tables.
Rate and/or score strength of indications	Expert panel scores the appropriateness of clinical indications using RAND and/or University of California, Los Angeles (UCLA) criteria. After at least two rounds, the scores are finalized using evidence and expert opinions, where applicable.
Write the AUC document	Under the supervision of the chair, the expert panel writes the AUC document.
Peer review of the AUC draft and/or public comments	Expert panel members identify relevant subject matter experts from different specialties to conduct the peer review of the AUC draft. The AUC draft is shared with relevant patient advocacy groups for feedback and posted on SNMMI website for public comments.
AUC draft copy edited and finalized	After incorporating feedback from peer review as well as public comments, the AUC document is sent for copy-editing.
Approval by the SNMMI Board	Once finalized, the AUC document is sent for SNMMI Board of Directors approval. It is then posted on SNMMI website.
Endorsement from other specialties	Final AUC document is shared with relevant specialties for potential endorsement.

4-5 AUC each year for the next several years. Updated real-time information regarding the AUCs already developed and the list of those under development can be accessed at www.snmmi.org/auc (Table 6).

The PAMA legislation requiring the development of AUC also stipulated the mechanism of their delivery through a "qualified clinical decision support mechanism" (Q-CDSM) prior to ordering any advanced imaging. Therefore, successful

Table 5 Specialty Societies and/or Organizations Officially Represented on SNMMI AUC Workgroups

Alzheimer's Association
European Association of Nuclear Medicine
American Society of Clinical Oncology
American College of Emergency Physicians
American College of Radiology
American Society of Hematology
Society of Thoracic Surgeons
American Gastroenterological Association
American College of Nuclear Medicine
North American Neuroendocrine Tumor Society
Endocrine Society
American College of Physicians
American Board of Nuclear Medicine
American College of Cardiology
American Academy of Family Physicians
American Thyroid Association
American Head and Neck Society
American Association of Clinical Endocrinology
North American Neuroendocrine Tumor Society

Table 6 Status of SNMMI appropriate use criteria (www.snmmi.org/AUC)

Title	Date Approved
Somatostatin Receptor PET Imaging in Neuroendocrine Tumors	September 9, 2017
FDG-PET/CT Restaging and Response Assessment of Malignant Diseases	June 9, 2017
Hepatobiliary Scintigraphy in Abdominal Pain	June 5, 2017
Ventilation Perfusion (V/Q) Imaging in Pulmonary Embolism	January 20, 2017
Bone Scintigraphy in Prostate and Breast Cancer	January 20, 2017
Amyloid Imaging	January 28, 2013
PET Myocardial Perfusion Imaging	Under development
Nuclear Medicine in the Evaluation and Treatment of Differentiated Thyroid Cancer	Under development
Prostate Cancer Imaging	Under development
Gastrointestinal transit	Under development
Infection Imaging	Under development

implementation and complete adoption of this program relies on integration of AUC developed by PLEs into these Q-CDSMs. The Society has partnered with leading CDSM providers to facilitate the adoption and utilization of SNMMI AUC.

Final implementation of the AUC program has been delayed until January 2020, in part, so that CMS can issue more substantive guidance for the priority clinical areas and exceptions for ordering professionals for whom consultation with AUC would pose significant hardship. Delaying implementation also provides more preparation time for the referring physicians and healthcare institutions to comply with the legislative requirements.

Vision for Standardization Going Forward

As important as AUC are for clinical decision making, they are not a substitute for clinical practice guidelines, or in the Society's case, procedure standards. For example, the AUC provide guidance on the appropriateness of a specific nuclear medicine procedure for a specific clinical indication. Simply putting, it provides guidance about "when" a procedure is appropriate and not necessarily "how" the procedure is performed, whereas a procedure standard attempts to answer the "how" part of the practice of nuclear medicine. In a way, these documents are complementary in providing clinical guidance to referring physicians and nuclear medicine practitioners.

Questions remain

Recommendations in the PAMA legislation provide an outline for the future ordering and reimbursement of advanced imaging studies; however, there are several details that have yet to be addressed.

- How will AUC be presented in the clinical decision support (CDS) software?

Several PLEs are writing AUC to help referring physicians order advanced imaging studies. How will the recommendations of each of these documents be presented to the referring physician? Will all the recommendations be presented, ranked, "appropriate" to "rarely appropriate?" Or will only studies deemed "appropriate" be presented? How much additional burden will access to CDS software be for the already busy referring physician and reimbursement office?

- How will conflicting recommendations be presented?

As discussed earlier, detailed literature support for specific clinical indications is rarely available, therefore, most recommendations will, by necessity, be based on expert opinion. It is possible, or even likely, that AUC from different specialty societies will contain conflicting recommendations. At present, it seems that any advanced imaging study deemed "appropriate" for a particular clinical indication by any PLE will mean the "appropriate" ranking will supersede any recommendations of "rarely appropriate." It is hoped that as these conflicts appear, the various PLEs will be able to convene to discuss the conflicts and come to a resolution.

- How will referrers in small practices access CDS tools to review AUC?

One goal of PAMA legislation is to lower the costs of healthcare, yet the processes of AUC development and CDS incorporation into clinical practice described above are very expensive. Adoption of CDS support software will add a cost to the practice of medicine that may be prohibitive for smaller practices. While PAMA legislation recommends that a free CDS software tool be made available, the utility and ease-of-use of some currently available free software packages suggests the free tool may not be worth the effort needed to use it. More advanced software packages will be costly but may offer integration with the online medical record of the healthcare organization, with the hopes of making ordering and reimbursement of advanced imaging studies easier than the current prior-approval process. However, small practices that do not have access to the most advanced CDS tools may see an increase in administrative costs, increase in penalties

for not consulting AUC, and subsequent decreased availability of advanced imaging studies for their patients.

- Will the mandate for CDS and/or AUC consultation prior to ordering of advanced imaging studies save healthcare dollars and improve patient care?

Early analysis of CDS software unrelated to the ordering of advanced imaging studies is not unanimously in favor of CDS systems.[12-15] The costs of such a complex technology are difficult to determine, but articles evaluating CDS do not always include the cost of developing the AUC by the specialty society in the first place. While this new technology offers some promise for standardization and decrease in costly overutilization of advanced imaging technology, it is far from clear the benefits of the PAMA recommendations for the use of AUC for advanced imaging studies will outweigh the costs.

The Society nonetheless recognizes the importance of the PAMA legislation regarding the practice of nuclear medicine and therefore SNMMI continues to develop a comprehensive library of AUC for high-value nuclear medicine procedures. The Guidance Oversight Committee and the Procedure Standards Committee have also undertaken a thorough review of the procedure standard development process in light of the more rigorous development process demanded for AUC. Since AUC are primarily based on the systematic review of the evidence, it is logical to use the AUC literature review for the development of a procedure standard on the same topic. The SNMMI Procedure Standards Committee is also evaluating the document revision time frame, investigating the identification of new topics, exploring the issues behind adjudication of conflicts of interests, and considering how to improve the composition of writing groups for procedure standard development. The Society is particularly interested in evaluating the inclusion of patients and/or patient advocates where feasible, emphasizing their rights and autonomy and the importance of their participation for the delivery of optimal care.

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