

Appropriate Use Criteria for Gastrointestinal Transit Scintigraphy

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From the Newsline editor: Appropriate use criteria (AUC) are statements that contain indications describing when and how often an intervention should be performed under the optimal combination of scientific evidence, clinical judgment, and patient values while avoiding unnecessary provisions of services. SNMMI is a qualified provider-led entity under the Medicare Appropriate Use Criteria program for advanced diagnostic imaging, allowing referring physicians to use SNMMI AUC to fulfill the requirements of the 2014 Protecting Access to Medicare Act. SNMMI follows a balanced multidisciplinary approach to guidance development by including various stakeholders in the development process. For background and a detailed explanation of this development process, see <http://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=15665>. This Newsline article is a summary of the complete text of the AUC, which is available at www.snmmi.org/auc.

EXECUTIVE SUMMARY

The appropriate use of scintigraphy for studying gastrointestinal (GI) motility requires not only an understanding of the normal physiology and pathophysiology of the various disorders that can affect the GI tract but also an understanding of the numerous methods and associated technical details of the current clinically available modalities for studying GI motility. Developing recommendations on the appropriate use of GI transit scintigraphy requires input from experts in the fields of nuclear medicine, radiology, and gastroenterology. This document has therefore been prepared with input from representatives with this expertise from various professional societies (Appendix A). These experts reviewed the current literature with the methodology described below and established appropriateness ratings for a wide range of clinical scenarios experienced by patients who have symptoms associated with suspected abnormal GI function. The appropriate use criteria (AUC) delineated in this report are intended to assist referring medical practitioners in the diagnosis and management of patients with symptoms thought to arise from altered GI motility in the esophagus, stomach, small bowel, and colon.

INTRODUCTION

Direct measurement of GI motility is classically performed by a gastroenterologist by placing a tube or catheter-based probe within the GI tract to directly measure pressure changes within a lumen, electrical signals, or pH. Recently, less invasive

wireless motility capsules have been introduced (1,2). The advantages of scintigraphy for studying GI motility still remain valid despite the long time that has elapsed since the first application of a radiolabeled meal to measure gastric emptying (GE). Scintigraphy is noninvasive, does not disturb normal physiology, and can provide accurate quantification of the bulk transit of an orally administered radiolabeled solid or liquid meal. Compared with radiographic methods, scintigraphy involves low radiation exposure of the patient, is quantifiable, and uses commonly ingested foods rather than barium or nonphysiological radiopaque markers.

Gastroenterologists and primary care physicians are often faced with a wide range of symptoms in a patient, including early satiety, pain, nausea, vomiting, bloating, diarrhea, constipation, or difficulty passing a bowel movement. GI symptoms in patients often overlap and may or may not be associated with meal ingestion. It is difficult to assess whether a patient's symptoms are due to an underlying structural pathology or are functional. The authors of this AUC document recognize that management of these patients is complex and the decision to perform any diagnostic study must take into consideration the entire patient presentation. The recommendations in this document do not preclude the use of other testing. Referring health care providers should always consider the patient history, physical findings, and results of previously acquired tests before using GI scintigraphy studies. This AUC document is presented to assist health care practitioners in the appropriate use of GI scintigraphy in evaluating patients with GI tract symptoms. It is not intended to replace good clinical judgment.

As scintigraphy does not provide detailed anatomic images of the GI tract, it is particularly important to make sure an anatomic cause for the patient's symptoms has been excluded before assuming that the patient has a nonstructural primary motility disorder. This is typically performed by using radiographic imaging or endoscopic methods.

In reviewing the literature on GI transit scintigraphy, it is apparent that although some studies such as GE and esophageal transit have been available for over 50 y, the use of scintigraphy to image and quantify GI motility continues to undergo modernization and advancement. Methods such as esophageal transit scintigraphy (ETS) that were established many years ago have been replaced in many centers by more advanced manometric techniques, although they remain in limited use in select institutions where there is clinical expertise that is often not available in other institutions. GE studies continue to evolve with

advances that permit simultaneous measurement of other indices of gastric motility, such as accommodation and antral contractions (3–5). Because of such advancements, this AUC report may need to be updated as newer and more specialized techniques are developed.

As with many imaging studies, few multicenter studies have examined clinical outcomes. Our appropriateness ratings are influenced by the clinical experience of the expert panel, which included both imaging specialists and gastroenterologists who perform, order, and use these studies in the diagnosis and management of patients with a wide range of GI symptoms.

These AUC recommendations are intended to apply primarily to adults. Because no well-defined normal values for radiolabeled meals have been established in children (due to concerns about radiation exposure of children involved in research) and because established GI transit protocols require development of normal values, this committee felt that pooled data on normal values in children in the literature were insufficient to confirm the validity of GI transit studies in children. Many sites have, however, developed institutional experience that may be used to validate their local study procedures.

This document may also be useful for nuclear medicine physicians, radiologists, and technologists, as well as for developers of clinical decision support tools as guidance in validating requests for imaging patients with GI tract symptoms. Radiology benefit managers and other third-party payers may also use these AUC. It is our intention that the AUC be used to help ensure the appropriate ordering of GI motility scintigraphic testing in patients with GI symptoms who lack appropriate diagnosis and treatment.

ESOPHAGEAL TRANSIT SCINTIGRAPHY (ETS)

Introduction/Background

There are several tests of esophageal motor function. The decision about which diagnostic study to use for esophageal dysmotility depends on the patient's symptoms. If dysphagia is present, a barium swallow or endoscopy is usually performed first to exclude an anatomic lesion. Manometry is considered the gold standard for diagnosis of primary esophageal motility disorders, including achalasia, scleroderma, diffuse esophageal spasm, impaired lower esophageal sphincter (LES) relaxation, hypertensive LES, and non-specific esophageal motility disorders. Manometry, however, has limitations: it provides only an indirect measure of peristalsis, as the pressure waves recorded do not always correlate with the aboral forces applied to a solid or liquid bolus in the esophagus; the presence of a manometric tube itself may affect normal physiology; and quantification of the volume of retained solids or liquids in the esophagus is not possible.

Early scintigraphy studies of esophageal transit demonstrated a high sensitivity for detecting a wide range of esophageal motility disorders but a low sensitivity for disorders

with intact peristalsis but high-amplitude contractions or isolated elevated pressures in the LES (6,7). The use of manometry potentially supplemented by ETS for equivocal manometry results will, in large part, be determined by local expertise and availability.

Summary of Recommendations

Clinical scenarios for esophageal transit (often performed with gastroesophageal reflux [GER] studies) are presented in Table 1. Esophageal manometry, barium swallow radiography, and pH monitoring are typically used for first-line evaluation of patients with suspected esophageal dysmotility and GER. Use of ETS is limited by the availability of local expertise with experience in the methodology, but, when available, such expertise is most commonly used when there are equivocal or nondiagnostic findings from first-line studies.

GE OF SOLIDS (SOLID NUTRIENT OR EQUIVALENT)

Introduction/Background

GE studies are usually ordered to confirm or exclude whether gastroparesis (delayed GE) is a cause of the patient's symptoms. Gastroparesis is usually associated with upper GI symptoms, which include nausea (92% of patients), vomiting (84%), abdominal fullness or distention (75%), and early satiety (60%) (8). Etiologies for gastroparesis include diabetes; postgastric surgical conditions; infections (especially postviral); neuromuscular, autoimmune, and connective tissue diseases; and idiopathic disease.

Patients often do not have well-defined GI symptoms and present with concerns about dyspepsia (symptoms of any pain or discomfort thought to originate in the upper GI tract). The goal of diagnosing delayed GE is to identify patients who will benefit from a prokinetic drug or other treatment to alleviate symptoms. A GE study is indicated for patients with suspected gastroparesis or dyspepsia after an anatomic cause for symptoms has been excluded. A GE study may also be indicated in the absence of dyspeptic symptoms, such as those with severe GER not responding to acid suppressants (to see whether delayed GE contributes to reflux), those requiring a workup to identify a diffuse GI motility disorder, and those who are diabetic and have poor glycemic control. GE studies can also be used to assess patients for dumping syndrome, in which GE is rapid. Classically, this occurs after surgery but is now being described in patients with autonomic dysfunction, cyclic vomiting syndrome, and functional dyspepsia.

Gastric emptying scintigraphy is currently the gold standard method for measuring GE and is the standard to which other diagnostic tests have been compared. It should be performed by using the currently accepted, standardized low-fat solid meal that is endorsed by the American Neurogastroenterology and Motility Society and SNMMI (9–11). Advantages of this test include good tolerability of the meal by the majority of patients, validated multicenter

TABLE 1
Clinical Scenarios for Esophageal Transit (Often Performed with Gastroesophageal Reflux Studies)

Scenario no.	Description	Appropriateness	Score
1	Dysphagia (e.g., symptoms of achalasia, scleroderma, diffuse esophageal spasm, hypertensive lower esophageal sphincter, nonspecific motility disorder, esophageal outflow obstruction)	Appropriate	7
2	Quantification of response to therapy (treatment for achalasia)	Appropriate	7
3	Aspiration	May be appropriate	4
4	Rumination	May be appropriate	4
5	Gastroesophageal reflux (e.g., symptoms of liquid or solid regurgitation, heartburn)	May be appropriate	5
6	Pre- and post-fundoplication	May be appropriate	5

normal values, and a reproducible methodology. Patients who cannot tolerate the current egg-based solid meal can be tested with the nutritional supplement Ensure PLUS (12,13). The advantages of this substitute meal are that it uses the same imaging protocol and that it has normal GE values that are similar to those of the solid egg-based meal. A rice-based solid meal substitute that is gluten free and vegan has documented normal values but may not be widely available (14). Although many variations of solid and liquid GE meals are used by some diagnostic facilities, they are not recommended until they have had sufficient validation in the literature.

Recently, a nonnutrient water-only GE test was compared with the standard solid meal and showed a delay in water GE in 32% of patients with normal solid GE (15,16). The potential advantages of a water-only meal are meal tolerability, a shorter acquisition time, and added sensitivity. Currently only single-center data support the use of a nonnutrient water meal.

To fully integrate the results of a GES test into patient management, it is important to document GI symptoms, prior surgical procedures, and all drugs in use (17). An abbreviated list of interfering medications includes the

TABLE 2
Clinical Scenarios for Gastric Emptying of Solids (Including Postinfectious Symptoms)

Scenario no.	Description	Appropriateness	Score
1	Symptoms of gastroparesis (e.g., symptoms of diabetic or idiopathic)	Appropriate	9
2	Functional dyspepsia (e.g., symptoms of upper abdominal pain/discomfort, early satiety, nausea, vomiting, bloating, postprandial fullness)	Appropriate	9
3	Postsurgical-induced symptoms of dyspepsia, questionable rapid gastric emptying (e.g., symptoms of postsurgical gastroparesis, postvagotomy gastroparesis)	Appropriate	9
4	Poorly controlled diabetes without dyspeptic symptoms	May be appropriate	5
5	Poorly controlled gastroesophageal reflux without dyspeptic symptoms	May be appropriate	6
6	Suspected generalized GI motility disorder (intestinal pseudoobstruction)	May be appropriate	6
7	Cyclic vomiting syndrome	May be appropriate	6
8	Anorexia nervosa	May be appropriate	5
9	Suspected impaired gastric accommodation (e.g., symptoms of early satiety, postprandial fullness, and/or abdominal pain)	Appropriate	7
10	Pre- and/or postbariatric surgery	May be appropriate	5
11	Postsurgical evaluation (for neurostimulator, pyloroplasty, pyloromyotomy, partial gastric resection)	May be appropriate	6
12	Postsurgical treatment	May be appropriate	6
13	Postsurgical neurostimulator placement	May be appropriate	6
14	Postsurgical pyloroplasty	May be appropriate	6
15	Following surgical or endoscopic pyloromyotomy	May be appropriate	6
16	Postsurgical partial gastric resection	May be appropriate	6

following: anticholinergics; calcium channel blockers; clonidine; proton pump inhibitors; tricyclic antidepressants; lithium; exenatide; liraglutide; pramlintide; dopamine agonists; progesterone-containing agents; nicotine by smoking and/or use of containing agents; medications containing opioids, octreotide, or other somatostatin analogs; and tetrahydrocannabinol by smoking and/or use of its ingestible derivatives. Interfering medications should be stopped for 3 d or 6–10 half-lives of the drug. Concealed use of an illicit drug can be an overlooked reason for GI symptoms and GE dysfunction. In patients with diabetes, blood glucose must be checked and documented immediately before the test to avoid slowing of GE due to hyperglycemia (18–21).

Summary of Recommendations

Clinical scenarios for gastric emptying of solids (including postinfectious symptoms) are presented in Table 2. GES remains the standard for measuring both solid and liquid GE. Recent advances in GES now permit additional measurements of gastric motility, including intragastric meal distribution, gastric accommodation response, and antral contraction frequency and amplitude. Although current treatments for gastroparesis are limited, it is anticipated that these newer measures of gastric dysmotility may lead to improved treatment.

GE OF LIQUIDS (NUTRIENT AND NONNUTRIENT/WATER MEALS)

Introduction/Background

Determination of GE rates of a nonnutrient water meal is not well established. Use of a water meal dates back to the early use of a saline load test for gastric outlet obstruction. There is limited evidence for the existence of a subset of patients with gastroparesis with normal solid GE but abnormal GE of water (15,16). Use of a water meal has not

been validated in multicenter studies. Because water by definition has no caloric value, it is clinically of greater pertinence to address the GE of a nutrient liquid meal. A nutrient liquid meal is indicated for patients referred for GES who have egg and/or gluten allergies or other reasons for intolerance of the standard solid meal. The GE characteristics of a validated liquid nutrient meal are similar to those of the standard solid meal but with a slightly faster emptying rate (12,13,22).

Summary of Recommendations

Clinical scenarios for gastric emptying of liquids (nonnutrient/water meal) are presented in Table 3. GES of solids remains the gold standard for measuring GE. There are limited data on the clinical value of liquid GE alone. Liquid GE is, however, typically combined with solids when additional small-bowel or colonic transit studies are needed. A substitute liquid meal can be of clinical value for patients who cannot tolerate the standard radiolabeled egg meal.

SMALL-BOWEL TRANSIT

Introduction/Background

The function of the small bowel is to transport food as it empties from the stomach and to mix it with bile and with pancreatic and intestinal secretions to facilitate absorption over the bowel mucosal surface. Measurement of small-bowel transit is complex because entry of a meal into the small intestine depends on GE and because small-bowel chyme spreads over a large distance as it progresses toward the colon. There is no simple small-bowel peristaltic pattern. Antegrade and retrograde movements of intestinal chyme occur in the jejunum and ileum, with some areas progressing rapidly and others slowly. Jejunal peristaltic activity is typically more rapid and intense, with slowing of peristalsis seen in the ileum (23).

TABLE 3
Clinical Scenarios for Gastric Emptying of Liquids (Nonnutrient/Water Meal)

Scenario no.	Description	Appropriateness	Score
1	Symptoms of gastroparesis (e.g., symptoms of diabetic vs. idiopathic) if solid emptying is normal	Appropriate	7
2	Functional dyspepsia (e.g., symptoms of upper abdominal pain/discomfort, early satiety, nausea, vomiting, bloating, postprandial fullness)	Appropriate	7
3	Poorly controlled diabetes without dyspeptic symptoms	May be appropriate	4
4	Poorly controlled gastroesophageal reflux without dyspeptic symptoms	Rarely appropriate	3
5	Suspected generalized GI motility disorder (intestinal pseudoobstruction)	Rarely appropriate	3
6	Cyclic vomiting syndrome	Rarely appropriate	3
7	Anorexia nervosa	May be appropriate	4
8	Gastrostomy evaluation	May be appropriate	5
9	Unable to tolerate solid meal	Appropriate	8
10	After a normal solid meal when symptoms suggest gastric motility disorder	Appropriate	8
11	Small-bowel transit study (when combined with liquid gastric emptying)	Appropriate	7

TABLE 4
Clinical Scenarios for Small-Bowel Transit

Scenario no.	Description	Appropriateness	Score
1	Symptoms of small bowel dysmotility (e.g., symptoms of nausea, vomiting, bloating, constipation, diarrhea, abdominal distention)	Appropriate	7
2	Suspected small intestinal bacterial overgrowth	May be appropriate	5
3	Suspected generalized gastrointestinal motility disorder (e.g., drug-induced, idiopathic, or genetic)	Appropriate	8
4	Suspected intestinal pseudoobstruction (e.g., unexplained small-bowel dilation)	Appropriate	8

The simplest approach to scintigraphic measurement of small-bowel transit is to measure orocecal transit time by imaging the leading edge of radiotracer transit through the bowel. Accurately defining the leading edge (the first visualized arrival of activity in the cecum), however, requires frequent (every 10–15 min) and prolonged imaging because of the stasis in the terminal ileum.

An alternative scintigraphic method of measuring small-bowel transit does not attempt to characterize the complex temporal or spatial peristaltic small-bowel patterns or leading-edge transit but simply measures the overall bulk movement of radiotracer as it progresses distally into the terminal ileum. Typically, the radiolabeled meal collects in a terminal ileal reservoir. This region is also referred to as the ileocolonic junction. The recent SNMMI/European Association of Nuclear Medicine guideline on small-bowel transit recommends use of the percentage of administered liquid meal that has accumulated in the terminal ileum at 6 h after meal ingestion as a simple index of small-bowel transit (24). Small-bowel transit is considered normal if >40% of administered activity has progressed into the terminal ileum or passed into the cecum and ascending colon at 6 h. Small-bowel transit is delayed if activity persists in multiple loops of small bowel at 6 h and if little activity (<40%) arrives in the terminal ileum reservoir. The amount of colon filling at 6 h has also been used as an index of small-bowel transit. The wireless motility capsule has been shown to correlate well with scintigraphy for measuring small-bowel transit (1).

Indications for small-bowel transit testing have been proposed in prior consensus publications. Authors of a review article by the American and European Neurogastroenterology

and Motility societies proposed that small-bowel transit testing should be considered for those with unexplained nausea, vomiting, bloating, distention, or other manifestations of small intestinal bacterial overgrowth (SIBO) or dysmotility (2). The authors of an older review commented that symptoms of small-bowel dysmotility are similar to those of gastroparesis and that small-bowel transit testing could be considered for those patients with persistent symptoms despite normal GE rates (25).

Summary of Recommendations

Clinical scenarios for small-bowel transit are presented in Table 4. The investigations cited in this systematic review support the endorsement of the panel for use of small-bowel scintigraphy as an appropriate diagnostic test in patients with symptoms of small-bowel dysmotility and SIBO. The available data suggest that a subset of patients with symptoms of presumed upper and/or lower gut origin will exhibit delayed small-bowel transit. However, there is not yet convincing literature that specifically documents that small-bowel transit delays will influence additional management decisions or affect outcomes of any treatments for patients with functional GI disorders.

COLON TRANSIT

Introduction/Background

Colonic motility regulates slow mixing and movement of its contents so that the colon can absorb water and electrolytes and transform liquid chyme into semisolids or solids in the sigmoid colon. Rhythmic phasic contractions aided by tonic contractions cause slow distal propulsion and mixing of colonic contents. In addition, infrequent high-amplitude

TABLE 5
Clinical Scenarios for Colon Transit

Scenario no.	Description	Appropriateness	Score
1	Symptoms of large-bowel (colon) dysmotility (e.g., symptoms of constipation, bloating, abdominal pain, non-diarrhea-dominant irritable bowel syndrome)	Appropriate	8
2	Suspected generalized gastrointestinal motility disorder	Appropriate	8
3	Suspected intestinal pseudoobstruction (e.g., unexplained megacolon)	Appropriate	8

TABLE 6
Clinical Scenarios for Whole-Gut Transit

Scenario no.	Description	Appropriateness	Score
1	Suspected pan-gastrointestinal motility disorder (e.g., unable to differentiate upper from lower gastrointestinal motility disorder)	Appropriate	8
2	Presurgical evaluation of colonic inertia	Appropriate	8

(>100 mm Hg) propagating contractions produce mass movements that deliver a large column of stool into the rectum. Thereafter, in healthy individuals, controlled evacuation of stool normally occurs between once in 3 d and up to 2 to 3 times a day. A key question in patients with chronic constipation is to identify whether there is colonic inertia, generalized slow colon transit, pelvic floor dysfunction, functional outlet obstruction, or irritable bowel syndrome (IBS) (26). Colonic motility and transit time are tested to determine whether a patient with symptoms of constipation has abnormal colonic transit and whether a specific area of the colon is involved.

Colon transit can be imaged by using serial radiographs after ingestion of radiopaque markers with a meal.

Radiographs are obtained for several days (up to 7) to count the number of markers remaining in segments of the colon (right, left, and rectosigmoid regions) or throughout the colon. The radiopaque marker test is not physiological, however, for the assessment of transit of intestinal chime. In contrast, 2 scintigraphic methods that have been most commonly applied to provide a more dynamic assessment of colonic transit use oral ¹¹¹In-diethylenetriamine pentaacetic acid (¹¹¹In-DTPA). These methods are described in detail in a consensus practice guideline (27). The wireless motility capsule is a newer technique that has been shown to correlate well with scintigraphy and radiopaque markers for measuring colon transit (1).

Summary of Recommendations

Clinical scenarios for colon transit are presented in Table 5. Colonic transit scintigraphy can be used to distinguish motility disorders that affect colonic transit from those that affect the whole gut. Disorders of colonic transit that cause constipation can be further differentiated into slow-intestinal-transit and normal-transit constipation. In addition, this test may identify patients who have intestinal pseudoobstruction and distal colonic disorders, such as delayed rectosigmoid transit or dysfunction and disorders of the pelvic floor.

WHOLE-GUT TRANSIT

Introduction/Background

Whole-gut transit scintigraphy (WGTS) refers to a combined study that includes measurement of GE, small-bowel, and colonic transit after administration of a dual-isotope, solid-liquid meal (28–30). These studies are helpful for

evaluating patients whose symptoms cannot be classified as either upper or lower GI in origin or where a functional and not an organic cause is suspected (31). The wireless motility capsule has been shown to correlate well with scintigraphy for measuring whole-gut transit (1).

Summary of Recommendations

Clinical scenarios for whole-gut transit are presented in Table 6. Substantial evidence exists that WGTS helps in localizing a site or sites of abnormal GI motility, thus helping yield a diagnosis and directing therapy in patients with a wide range of both upper and lower GI tract symptoms.

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Marta Cremonesi, PhD, 2020 Loevinger–Berman Award Recipient

The SNMMI Medical Internal Radiation Dose (MIRD) Committee announced on January 8 the selection of Marta Cremonesi, PhD, as the 2020 Loevinger–Berman Awardee, recognizing a lifetime of achievements and contributions to medical internal dosimetry. “Marta Cremonesi is an authority in the field of internal dosimetry and one of the pioneers of the initial applications of radiopeptides, in a career that began over 20 years ago. Over time, she has passionately continued her work in all fields of radionuclide therapy, exhibiting both meticulous scientific rigor and extraordinary productivity,” said Lisa Bodei, MD, PhD, a long-time colleague and collaborator. “Her contributions to the definition of the renal impact and tolerability of peptide-receptor radionuclide therapy are considered to constitute the standard of care for anyone involved in this treatment. Marta has defined the field both with her scientific skills and the generosity with which she has shared her knowledge and experience.”

Cremonesi is a medical physicist based in Italy and has served as the Director of the Radiation Research Unit of the European Institute of Oncology of Milan since 2014. Her career shows a dedicated commitment to internal dosimetry for radiopharmaceuticals in general and targeted radionuclide therapy in particular, including several Good Clinical Practice clinical trials using radiopharmaceuticals for diagnosis and therapy. Respected as an authority in the field, she

has presented more than 40 sessions and more than 180 communications and posters at meetings worldwide and has been an author on more than 100 publications, including 11 books.

Cremonesi will be the 21st recipient of the Loevinger–Berman Award since its conception in 1999. The award will be presented at the SNMMI 2020 Annual Meeting in New Orleans, LA, during the Loevinger–Berman Award continuing education session.

This award, sponsored by the Education and Research Foundation for Nuclear Medicine and Molecular Imaging, was established in 1999 by the MIRD Committee in honor of Robert Loevinger, PhD, and Mones Berman, PhD, internal dosimetry pioneers who formulated the MIRD schema for internal dose calculations. The Loevinger–Berman award recognizes innovation and excellence in the nuclear medicine subspecialty of internal radiation dosimetry through research and development, significant publication contributions, or advancement of the understanding of internal dosimetry in relationship to risk and therapeutic efficacy.

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**Marta Cremonesi,
PhD**

Improving Nuclear Medicine Practice with UEMS/EBNM Committees

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Nuclear medicine is one of the most dynamic fields in medicine. It is defined in the Accreditation Council for Graduate Medical Education program requirements as follows: “Nuclear medicine is the medical specialty that uses the Tracer Principle, most often with radiopharmaceuticals, to evaluate molecular, metabolic, physiologic, and pathologic conditions of the body for the purposes of diagnosis, therapy, and research” (1)

Nuclear medicine training in most European countries comprises a period of 4–6 years, and the spectrum of investigations, particularly in the fields of PET and therapy with radionuclides, has progressed dramatically in recent years. In particular, PET/CT is now an indispensable part of the multidisciplinary decision-making process, first with ^{18}F -FDG and, increasingly, with new tracers such as prostate-specific membrane antigen ligands in prostate cancer and (most probably in the near future) ^{18}F -fibroblast-activated protein inhibitors (2).

A high-quality standard is necessary to implement and translate such scientific dynamism into the clinical routine in a proper way. General certification audits, without clinical background, do not specifically cover medical and technical advances, because this specific clinical knowledge is not part of the general audit instruments. To overcome these shortcomings, several committees have been instituted in the Nuclear Medicine Section of the European Union of Medical Specialists (UEMS; www.uems.net), which has existed for more than 50 years in close cooperation with the European Board for Nuclear Medicine (EBNM) and is the political representative organization for medical specialists in the European Union and associated countries.

UEMS was given the task of defining the basic principles in the field of training of European medical specialists to ensure a comparably high level of competence across Europe and thus allow free movement of specialists among member countries. The training requirements for nuclear medicine as a separate medical specialty, achieved by Desmond Craft in 1989 (3,4), were updated in 2017 by the Education and Syllabus Committee of UEMS/EBNM (5). The document is not limited to trainees; it also describes the requirements for trainers and training centers. In collaboration with the European Association of Nuclear Medicine (EANM), the committee has also prepared a European Nuclear Medicine Guide that is freely available to everyone in the field (<https://www.eanm.org/publications/european-nuclear-medicine-guide/>).

The UEMS/EBNM Fellowship Examination Committee is responsible for setting up a “Nuclear Board Examination” to award the title of “Fellow of the EBNM,” with the

acronym FEBNM. To be awarded a Certificate of Fellowship of the EBNM, candidates must pass the full fellowship examination (written and oral exams) and be specialists in nuclear medicine approved by their national health authorities. The European Board Certificate in Nuclear Medicine proves that the candidate’s knowledge and ability in nuclear medicine satisfy European standards independently from the origin of training. Although this quality recognition is optional and does not interfere with national requirements for specialization in nuclear medicine, it has already proven to be helpful in the careers of young nuclear medicine physicians. The first EBNM fellowship examination took place in 1996 in Copenhagen (Denmark) during the EANM Congress. Since that time, hundreds of colleagues from countries all over the world have obtained the title of FEBNM. This examination is open to all nuclear medicine physicians and residents in their final year of training in compliance with the training syllabus. It is a 2-step examination with a written multichoice question (MCQ) exam and an oral exam. The written exam must be passed in order to proceed to the oral exam. The MCQ exam includes 140 type A questions covering the entire range of basic and clinical nuclear medicine. It has now evolved toward an online format, with the first such session introduced in May 2019. This was a major step forward, providing a digital and flexible platform for any applicant connecting from her/his home without traveling to the examination center. The oral exam is organized during the Annual EANM Congress, and a preparation session is offered to candidates on the same day. This exam aims to test the ability of the candidates to evaluate and manage common clinical cases in everyday practice. Successful candidates are invited to a certificate handover during the EANM Annual Congress.

Many applicants come from outside Europe, mainly from South Asia. In 2014, the UEMS/EBNM Fellowship Examination Committee was invited by the Asian Nuclear Medicine Board (ANMB) to act as external auditors for the setup of the first fellowship examination of the ANMB. The Fellowship Examination Committee has achieved a significant level of experience in these examinations, and a collaboration with the European School of Multimodality Imaging and Therapy (ESMIT) was set up in 2017 to prepare high-quality questions for ESMIT training assessment.

The Continuing Medical Education (CME) Committee of UEMS/EBNM was established in 1999 as a scientific and technical body devoted to the evaluation and accreditation of CME activities in the field of nuclear medicine

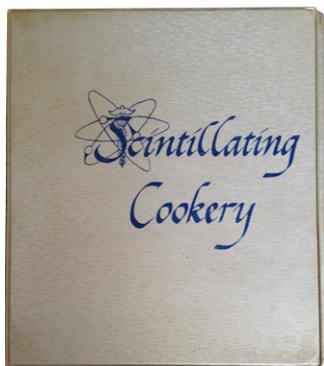
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The Nuclear Medicine Community: From 1970s Cookbook to 2020 Global Influence

Vasken Dilsizian, MD, SNMMI President

Nuclear medicine is a global community with a mission and expertise unique in medicine, and SNMMI works in myriad ways to maintain and enhance the connections that sustain that community. In the United States, the numbers of nuclear medicine physicians, physicists, technologists, and scientists have grown rapidly over the last half century.

I was reminded recently of the extent of these changes when a colleague gave me a small silver binder with the title *Scintillating Cookery*. Published in 1979 to mark the silver anniversary of the Society of Nuclear Medicine (SNM), the loose-leaf book was the product of coordinated efforts among all SNM chapters to produce a nuclear medicine version of the community-contributed recipe collections popular at that time. The effort was begun in 1976 by Mitzi Blahd, whose husband, William Blahd, MD, later served as 1977–1978 president of SNM. One focus of his presidency was reinvigorating the Education and Research Foundation (ERF). Ms. Blahd, described by a contemporary as a “nuclear medicine activist,” financed and directed the collection of recipes from chapters across the United States, selling more than 2,000 copies and contributing the proceeds to the ERF. The result is a book that contains familiar recipes for home cooking but with attributions to many of the famous names in our field: Wagner, Ter-Pogossian, Anger, Kuhl, and many others. When Ms. Blahd gave my colleague the book, she commented, “It was a real effort to pull this together, but the fact that all the families in the field knew all the other families made it easier.” I was touched by this glimpse of a time when nuclear medicine was a much smaller enterprise—but reminded that even today, we continue many of the traditions that bring us together.



***Scintillating Cookery* was published in 1979 as part of a nuclear medicine community fundraising effort.**

SNMMI global community-building efforts are essential to many of our most visible activities. Our worldwide membership includes physicians, physicists, technologists, chemists, radiopharmacists, students, and industry representatives from more than 84 countries around the world. At its Annual Meeting, SNMMI brings together more than 6,000 members and visitors, with representatives from industry and government agencies, to discuss groundbreaking new research and look ahead to near- and long-term innovations. At each Annual Meeting, the society collaborates closely with a featured country in educational and other activities designed to enhance shared understanding of that country’s nuclear medicine research and practice. The international response continues to be overwhelmingly positive at the Annual Meeting, with attendees representing more than 65 countries and more than 60% of submitted abstracts coming from outside the United States.



Vasken Dilsizian

One of my foci as SNMMI president is to expand and enhance the society’s international outreach and project participation in ways that cross geographic and political boundaries. We are building on a strong base of past accomplishments in this area. Each year, the SNMMI collaborates with international organizations to continue the exchange of ideas, education, and knowledge. As an example, leaders from the SNMMI and international nuclear medicine societies and agencies cooperate in the Nuclear Medicine Global Initiative, dedicated to identifying and working together to resolve global challenges in nuclear medicine. SNMMI also works actively with the International Atomic Energy Agency to expand its mission in making the benefits of nuclear and molecular medicine available to more individuals, particularly those in resource-challenged countries. Conferences such as the Targeted Radionuclide Therapy Conference bring together stakeholders, including regulators, legislators, industry, members and others to address real-world solutions to shared challenges.

The *Journal of Nuclear Medicine* remains the premier journal in the field precisely because it publishes the most innovative and significant work of accomplished contributors representing diverse countries and practice outlooks. The result is a powerful platform respected and trusted

by the broadest spectrum of nuclear medicine practitioners throughout the world.

SNMMI also supports the nuclear medicine community by involving professionals in councils, centers, and committees to work together to advance scientific and professional activities and connects them through social networks and continuous updates on news and information.

These activities—and others still in the planning stages—have different missions and different target groups. But they share the extraordinary benefit of continuing to build our modern nuclear medicine community. In the United States,

our field was once so small that many members knew one another simply through connections in training, practice, and professional meetings—small enough to produce a community cookbook. Today, this community is exponentially larger, spanning the globe. This brings the potential for enhanced visibility, a more powerful voice in the broader field of medicine, and successful collaborative efforts to advance the benefits of nuclear medicine to more patients. Our success depends on our dedication to maintaining both the spirit of and commitment to a global community in our field.

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and molecular imaging. The purpose of the UEMS/EBNM CME Committee is to guarantee high-quality CME programs of scientific and educational excellence that are free of influence from the health care industry. The roles of this committee include: evaluation and accreditation of nuclear medicine CME activities in Europe, monitoring CME activities relating to nuclear medicine in Europe, and, in agreement with the European Accreditation Council for Continuing Medical Education (EACCME; <https://eaccme.uems.eu/home.aspx>), ensuring full reciprocity of credits within most European countries and beyond. The EACCME has signed agreements with the American Medical Association and the Royal College of Physicians and Surgeons of Canada that ensure full recognition of CME credits for participants who attend CME events in European countries. The committee is also dedicated to assuring and guaranteeing the high quality of the scientific and educational content of CME in nuclear medicine and ensuring, in compliance with EBNM/EACCME guidelines, the transparency and independence of CME activities. In addition, the committee facilitates and accredits all types of CME modalities in nuclear medicine and promotes the application of new CME technologies (e.g., webinars).

The UEMS/EBNM CME Committee accredits through EACCME major events of international status and importance in the field of nuclear medicine in Europe and beyond. Smaller but high-quality educational events in Europe are accredited in the same way. Meanwhile, CME activities have been expanded, especially in collaboration with the International Atomic Energy Agency, to promote nuclear medicine in non-European countries.

The Committees of Accreditation of Nuclear Medicine Departments and Training Centers were joined in recent years.

Accredited centers (35 centers as of January 2020) must fulfill certain objective criteria concerning staff, equipment, number, and spectra of diagnostic and therapeutic procedures, teaching, and quality control. To obtain accreditation as training centers (14 centers as of January 2020), sites must be accredited as nuclear medicine departments and follow the training requirements for the nuclear medicine specialty edited by the Education and Syllabus Committee of UEMS/EBNM (5). Accreditation is currently provided by questionnaire and clinical protocol examination, not by visitation. Visits could be performed in the future, if travel costs were covered by applicant centers.

In order to harmonize nuclear medicine with high-quality standards, it would be beneficial for the specialty to enhance synergistic efforts in a global manner. UEMS/EBNM committees are open and would appreciate global cooperation with other non-EU nuclear medicine organizations in the different efforts described here.

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FDA Compounding Quality Center of Excellence

On December 19, 2019, the U.S. Food and Drug Administration (FDA) announced the creation of its Compounding Quality Center of Excellence, an initiative designed “to enhance collaboration among and provide educational programs for outsourcing facilities aimed at improving the overall quality of compounded medicines.” The Center of Excellence, supported by a contract awarded by the FDA to Deloitte (New York, NY), will have 3 main areas of focus: in-person and online education and training; a conference to provide outsourcing facilities, stakeholders, and FDA opportunities to exchange ideas and best practices; and market research to help inform the FDA on key issues faced by outsourcing facilities.

In-person training will target registered outsourcing facilities—and, as space allows, pharmacies that are considering becoming outsourcing facilities—by focusing on key aspects of current good manufacturing practice (CGMP) and FDA policies. Courses will be scheduled throughout 2020 and beyond. Participants may earn continuing education credits while enhancing their understanding of necessary procedures and guidelines. Topics for in-person trainings will include sterile compounding, environmental monitoring, investigating quality issues, initiating corrective and preventive actions, and proper cleanroom design and practices. Portions of this training will be in a laboratory environment to enhance hands-on learning. Training will be offered in small settings with free registration for outsourcing facility personnel.

Online education programs will also focus on key aspects of CGMP, as well as other facets of drug compounding. These courses will be free for participants and will provide continuing education credits. As part of this new initiative, the FDA will also host a Center of Excellence Conference in September 2020 in Dallas, TX, as a forum in which outsourcing facilities and related stakeholders can offer feedback on policies and regulatory issues.

Market research will be another key area of the Center of Excellence. With this information, the agency will be able to better understand possible barriers and opportunities outsourcing facilities may encounter in several areas, such as: business growth and viability, adherence to CGMP regulations, and interactions with the FDA. This research will provide a better analysis of the outsourcing facility sector, so the agency can enhance the Center of Excellence to make it as valuable as possible for all stakeholders.

“By providing comprehensive, accessible learning tools, we will support outsourcing facilities in reliably producing high-quality compounded products that meet FDA’s standards. While engagement is voluntary, this initiative will provide an increased awareness and understanding of common issues and provide innovative ways to address challenges outsourcing facilities may face,” said Janet Woodcock, MD, director of the FDA Center for Drug Evaluation and Research. “The FDA looks forward to ongoing engagement with outsourcing facilities.” Additional information is available at: <https://www.fda.gov/drugs/human-drug-compounding/compounding-quality-center-excellence>.

U.S. Food and Drug Administration

DOE Delays Ban on Highly Enriched Uranium Export

On January 2, 1 day before the expiration of a previously set deadline, the U.S. Department of Energy (DOE) issued a letter to the U.S. House Committee on Energy and Commerce certifying that the current global supply of ^{90}Mo produced without the use of highly enriched uranium (HEU) is not sufficient to meet needs in the United States. Therefore, the January 3, 2020, deadline for implementation of a ban on HEU export from the United States will be extended for a minimum of 2 years, with the potential for another 4-y extension. The purpose of the extension is to ensure adequate domestic supply of $^{99\text{m}}\text{Tc}$ in the United States.

The American Medical Isotopes Production Act (AMIPA) of 2012 strongly encouraged a move to low-enriched uranium (LEU) for medical isotope production by 2020. On December 23, SNMMI submitted comments, noting that “on multiple occasions over the past several years, members throughout the United States reported limited supplies of $^{99\text{m}}\text{Tc}$ for clinical imaging because of disruptions in the production of ^{99}Mo ” and that “the supply of non-HEU ^{99}Mo needs to be significantly more robust before we feel confident that the supply is reliable enough to meet day-to-day patient-care needs.”

*U.S. Department of Energy
SNMMI*

Increasing Brown Fat Activity in Healthy Women

In an article e-published on January 21 ahead of print in the *Journal of Clinical Investigation*, researchers from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) (Bethesda, MD) reported that chronic treatment with mirabegron, a β -adrenergic receptor (β 3-AR) agonist approved only for treatment of overactive bladder, activated brown fat (BAT) in a small group of healthy women and had several other beneficial metabolic effects. The research was led by Aaron Cypess, MD, PhD, at NIDDK. The study included 14 healthy women of diverse ethnicity (ages, 27.5 ± 1.1 y; body mass index, 25.4 ± 1.2 kg/m²) who received 100 mg mirabegron (Myrbetriq extended-release tablet; Astellas Pharma, Tokyo, Japan) for 4 wk. ^{18}F -FDG PET/CT identification of changes in BAT metabolic activity over this period was the primary study endpoint. Secondary endpoints included resting energy expenditure (REE), plasma metabolites, and glucose and insulin metabolism as assessed by repeat sampled intravenous glucose tolerance tests.

At 4 wk, participants’ brown fat activity had more than doubled, although their body weight and body mass remained

the same. Other changes included: increased resting energy expenditure; higher levels of high-density lipoprotein cholesterol and bile acids; and improved processing and regulation of blood glucose. Adiponectin, a white adipose tissue-derived hormone with antidiabetic and antiinflammatory capabilities, increased with acute treatment and was 35% higher at study completion.

Doses in this study were higher than those currently approved by the FDA for overactive bladder treatment. Higher doses have been linked to cardiovascular risk, and participants in this study experienced increased heart rates and blood pressure that normalized after treatment ended.

The authors concluded that their findings indicate “that human BAT metabolic activity can be increased after chronic pharmacological stimulation with mirabegron and support the investigation of β -AR agonists as a treatment for metabolic disease.”

*National Institutes of Health
Journal of Clinical Investigation*

SNMMI/NCI Third Targeted Radionuclide Therapy Conference

SNMMI and the National Cancer Institute (NCI) held the Third Targeted Radionuclide Therapy Conference on December 16, 2019. Invited attendees, representing the major stakeholders in theranostics, including the U.S. Food and Drug Administration, NCI, academicians, clinical physicians, and pharmaceutical company executives, met at NCI Shady Grove (Rockville, MD) for a full day of in-depth discussions on maximizing dose to tumor while sparing normal tissue, the current state of the science, state-of-the-art clinical trial design, and strategies for achieving response.

This year’s conference included a global representation of 33 speakers from 3 continents, representing government agencies, academia, and industry. The program focused on 4 comprehensive sessions around the central topic of “What is the goal of radionuclide therapies: Palliative, curative, or adju-

vant treatment?” Complete PowerPoint presentations are available at: https://s3.amazonaws.com/rdcms-snmimi/files/production/public/FileDownloads/Meetings/_NCI_SNMMI_3TRT_Workshop_12-16-19.pdf.

In an online summary, SNMMI recognized the cochairs of this year’s meeting from SNMMI, including Daniel Lee, MD (Therapy Center of Excellence), John Sunderland, PhD (Clinical Trials Network), and Jon McConathy, MD, PhD (Clinical Trials Network); and from NCI, including Janet Eary, MD (Associate Director Cancer Imaging Program, NCI), Lalitha Shankar, MD, PhD (NCI), and Michael McDonald, MD, PhD (NCI). SNMMI also acknowledged the 2019 conference sponsors: Progenics; Actinium Pharmaceuticals; Advanced Accelerator Applications, A Novartis Company; Blue Earth Diagnostics; Hermes Medical Solutions; and Lucerno Dynamics.

SNMMI

New Nuclear Physics Facility to Be Built at Brookhaven

The U.S. Department of Energy (DOE) announced on January 9 the selection of Brookhaven National Laboratory (BNL; Upton, NY) as the site for a planned major nuclear physics research facility. The Electron Ion Collider (EIC), to be designed and constructed over 10 years at an estimated cost of \$1.6–\$2.6 billion, will produce protons and heavier atomic nuclei in what the DOE termed “an effort to penetrate the mysteries of the ‘strong force’ that binds the atomic nucleus together.” “The EIC promises to keep America in the forefront of nuclear physics research and particle accelerator technology, critical components of overall U.S. leadership in science,” said U.S. Secretary of Energy Dan Brouillette. “This facility will deepen our understanding of nature and is expected to be the source of insights ultimately leading to new technology and innovation.”

Design and construction of the EIC was recommended by the National Research Council of the National Academies of Science, which noted that such

a facility “would maintain U.S. leadership in nuclear physics” and “help to maintain scientific leadership more broadly.” Plans for an EIC were also endorsed by the federal Nuclear Science Advisory Committee. The Thomas Jefferson National Accelerator Facility (Newport News, VA) will be a major partner in realizing the EIC, and several other DOE laboratories are expected to contribute to EIC construction and to the groundbreaking nuclear physics research program at BNL. The EIC will include 2 intersecting accelerators, 1 producing an intense beam of electrons, the other a high-energy beam of protons or heavier atomic nuclei, which are steered into head-on collisions. These collisions will produce “freeze frame” tomographic 3D images of gluons in the nuclei, illuminating the ways in which gluons and quarks bind to form the particles that constitute most visible matter in the universe.

In its release announcing the project, the DOE stated that “the EIC will be a game-changing resource for the international nuclear physics community.” American researchers have benefited from DOE participation in international collaborations, such as CERN, and the international community is currently contributing to U.S. construction of the Long Baseline Neutrino Facility and the Deep Underground Neutrino Experiment. Among the benefits of the EIC cited by BNL was the long-term potential for “sparking scientific discoveries in a new frontier of fundamental physics” with advances that could lead to energy-efficient accelerators, thereby dramatically shrinking the size and operating costs of future accelerators used across science and industry to: make and test computer chips, treat cancer cells, design solar cells and batteries, develop drugs and medical treatments, and produce radioisotopes for diagnosis and treatment.

Funding for the EIC is subject to annual appropriations by Congress.

U.S. Department of Energy