Reexamining Compliance with Gastric Emptying Scintigraphy Guidelines: An Updated Analysis of the Intersocietal Accreditation Commission Database

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Many variables can influence the results of gastric emptying scintigraphy (GES). A lack of standardization causes variability, limits comparisons, and decreases the credibility of the study. To increase standardization, in 2009 the Society of Nuclear Medicine and Molecular Imaging (SNMMI) published a guideline for a standardized, validated GES protocol for adults based on a 2008 consensus document. Laboratories must closely follow the consensus guideline to provide valid and standardized results as an incentive to achieve consistency in patient care. As part of the accreditation process, the Intersocietal Accreditation Commission (IAC) evaluates compliance with such guidelines. The rate of compliance with the SNMMI guideline was assessed in 2016 and showed a substantial degree of noncompliance. The aim of this study was to reassess compliance with the standardized protocol across the same cohort of laboratories, looking for changes and trends. Methods: The IAC nuclear/PET database was used to extract GES protocols from all laboratories applying for accreditation from 2018 to 2021, 5 y after the initial assessment. The number of labs was 118 (vs. 127 in the initial assessment). Each protocol was again evaluated for compliance with the methods described in the SNMMI guideline. The same 14 variables were assessed in a binary fashion: patient preparation (4 variablestypes of medications withheld, withholding of these medication for 48 h, blood glucose \leq 200 mg/dL, blood glucose recorded), meal (5 variables-use of consensus meal, nothing by mouth for 4 h or more, meal consumed within 10 min, documentation of percentage of meal consumed, meal labeled with 18.5-37 MBq [0.5-1.0 mCi]), acquisition (2 variables-anterior and posterior projections obtained, imaging each hour out to 4 h), and processing (3 variables-use of the geometric mean, decay correction of data, and measurement of percentage retention). Results: Protocols from the 118 labs demonstrated that compliance is improving in some key areas but remains suboptimal in others. Overall, labs were compliant with an average of 8 of the 14 variables, with a low of 1-variable compliance at 1 site, and only 4 sites compliant with all 14 variables. Nineteen sites met an 80% threshold for compliance (11+ variables). The variable with the highest compliance was the patient's taking nothing by mouth for 4 h or more before the exam (97%). The variable with the lowest compliance was the recording of blood glucose values (3%). Notable areas of improvement include the use of the consensus meal, now 62%

versus previously only 30% of labs. Greater compliance was also noted with measurement of retention percentages (instead of emptying percentages or half-times), with compliance by 65% of sites versus only 35% 5 y prior. **Conclusion:** Almost 13 y after the publication of the SNMMI GES guidelines, there is improving but still suboptimal protocol adherence among laboratories applying for IAC accreditation. Persistent variation in the performance of GES protocols may significantly affect patient management, as results may be unreliable. Using the standardized GES protocol permits interpretation of results in a consistent manner that allows interlaboratory comparisons and fosters acceptance of the test validity by referring clinicians.

Key Words: gastric emptying scintigraphy; guidelines; accreditation; protocols; standardization

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Since its inception in 1966, nuclear medicine gastric emptying scintigraphy (GES) has evolved to demonstrate significant interinstitutional protocol variation (1,2). Lack of protocol consistency across institutions limits the ability to compare studies across hospitals and laboratories and can affect clinical management. GES studies are perhaps particularly prone to a lack of standardization because of the numerous parameters intrinsic to the exam, which can potentially affect study credibility among both imagers and referring clinicians. Principally, these parameters include variation in image acquisition, meal components/composition, and factors involving patient preparation. The American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) published a consensus statement in 2008 addressing the need for standardization (3). SNMMI, in 2009, summarized key points of these recommendations in its publication Procedure Guideline for Adult Solid-Meal Gastric-Emptying Study 3.0 (4). Providing a standardized GES protocol allowed for a reproducible and reliable exam that better supports the needs of clinicians and their patients. Parameters addressed in the guideline include meal labeling and composition, patient preparation, and image acquisition and interpretation criteria.

As part of its mission, the Intersocietal Accreditation Commission (IAC) evaluates the quality of care being provided by

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nuclear medicine laboratories. The IAC does this through assessment of evaluation protocols, staff qualifications, and quality of imaging, among other factors. Specifically, protocol compliance and reporting are evaluated on the basis of accepted practices, to include published professional society guidelines such as those provided in the 2009 SNMMI GES publication. In 2016, an evaluation of protocol adherence noted a substantial degree of noncompliance across institutions seeking accreditation. This low adherence pointed to the need for greater education on consensus efforts for the standardization of GES studies. Subsequently, a separate group of researchers performed an in-depth survey of 121 sites performing GES, using 51 metrics derived from the consensus recommendations (5). These sites included both academic and nonacademic facilities, and similar results were revealed, with sites self-reporting compliance with less than two thirds of the measured metrics and no sites 100% compliant. Now, 13 y since the original guideline publication, this study aimed to reassess protocol adherence across the same cohort of laboratories undergoing IAC accreditation.

MATERIALS AND METHODS

Laboratories applying for general nuclear medicine accreditation from April 2018 to October 2022 were reviewed, and their respective GES protocols were examined, with corresponding deidentified facility information extracted from the IAC database. No patient data were collected or used. An Institutional Review Board waiver was obtained. From the IAC database, 7 demographic variables were recorded, which included lab or facility type (hospital vs. nonhospital), accreditation cycle (first time vs. reaccreditation), annual gastrointestinal-study volume, annual general nuclear medicine-study volume (excluding nuclear cardiology and PET), number of physicians, number of technologists, and number of γ -cameras (Table 1). On the basis of the SNMMI GES procedure guideline, 14 variables were selected for assessment (4). Compliance with these variables was considered the minimum needed for optimally accurate and reproducible performance of GES by laboratories. The 14 variables were divided into 4 categories: patient preparation, meal content, image acquisition, and image processing (Table 2). Meals administered were further categorized into 5 subgroups based on content (Table 3). Scores were computed on the basis of compliance with and adherence with the 14 variables. For example, a score of 14 constituted full compliance with all 14 variables. Associations were investigated to see if the 14 adherence variations were related in any way to the demographic variables. The total number of correct variables was also correlated with the demographic variables.

The data were cleaned and examined for outliers, normality of distribution, and correlations. Frequency and percentage compliance were reported for the 14 compliance variables, meal subgroup, and categoric demographic variables. Mean, median, and range were reported for the continuous demographic variables.

RESULTS

In total, 128 laboratories applied for general nuclear medicine accreditation from 2018 to 2022. Of these laboratories, 118 applied for gastrointestinal imaging accreditation, submitting GES protocols that were evaluated. The remaining laboratories did not provide GES protocols because they either did not perform GES or submitted other types of gastrointestinal imaging protocols for evaluation.

Demographics

Demographic frequency distributions are listed in Table 1. Most laboratories were hospital-based (69%). Laboratories performed a mean of 1,623 general nuclear medicine studies annually, with a median of 1,180. Laboratories performed a mean of 426 gastrointestinal nuclear medicine studies annually, with a median of 306. Most laboratories had been through the accreditation process more than once, with only 3% of labs undergoing their initial accreditation.

Guideline Adherence

Of the 4 variable categories (patient preparation, meal, acquisition, and processing/reporting), laboratories were most compliant with the variables related to patient preparation and meal delivery (Fig. 1). Specifically, the areas of greatest compliance were having instructions for patients to fast a minimum of 4 h (97%), using an appropriate radiotracer dose of 18.5–37 MBq (0.5–1.0 mCi) (77%), and having the patient consume the test meal in 10 min or less (73%). The areas of lowest compliance were having instructions for blood glucose testing before meal ingestion (97%) and, relatedly, having instructions for documenting the patient blood glucose level (92%).

Variable	Category	Frequency (n)	%
Laboratory type	Hospital-based	82	69.5
	Nonhospital	36	30.5
First time vs. reaccreditation application	First time	3	2.5
	Reaccredited	115	97.5
	Mean	Median	Range
Gastrointestinal study annual volume	426	306	6–1,736
General nuclear medicine annual volume	1,623	1,180	45-9,077
Number of medical staff	12	9.5	1–77
Number of technical staff	6.8	7	1–31
Number of γ -cameras	3.6	2	0–20

TABLE 1Laboratory Demographic Data (n = 118)

TABLE 2 Standard Protocol Variables

Category	Variable	Definition
Patient preparation	Medication withholding	Prokinetic agents: metoclopramide, tegaserod (Zelnorm; Alfasigma USA, Inc.), domperidone, erythromycin, and cisapride; opiates; anticholinergic and antispasmodic agents; atropine, nifedipine, progesterone, octreotide, theophylline, benzodiazepine, and phentolamine
	Withholding time	Two days
	Blood glucose	Testing of blood glucose level before study to ensure level is <200 mg/dL
	Blood glucose recording	Recording of blood glucose level and including it in final report
Meal	Consensus meal	Proper preparation of meal with all 4 listed ingredients and no other ingredients (e.g., no butter or juice): 118 mL (4 oz) of liquid egg whites, 120 mL of water, 2 slices of toast, 30 g of jam or jelly
	Nothing by mouth	No food or water by mouth for minimum of 4 h
	Meal ingestion time	Consumption of meal as quickly as possible and in less than 10 min
	Partial meal	Instructions in cases of vomiting or if patient ingests only a portion of meal
	Radiopharmaceutical dose	18.5–37 MBq (0.5–1.0 mCi) of ^{99m} Tc sulfur colloid
Acquisition	Image projections	Acquisition of both anterior and posterior images
	Image frequency	Acquisition of images immediately on meal completion and hourly until 4 h
Processing	Geometric mean	Calculation of geometric mean using anterior and posterior projections (geometric mean = $\sqrt{(anterior counts \times posterior counts)}$
	Decay-corrected	Decay correction of counts in region of interest
	Percentage retention	Reporting of final measurements as percentage gastric retention at each time point

Compliance with the Consensus Meal

Thirty-eight percent of laboratories were not compliant with the consensus meal, with 62% of laboratories using the exact meal content of 2 egg whites, 2 slices of white toast, jelly, and 120 mL of water as recommended in the guidelines (Table 4). Incorrect ingredients were used in place of the 2 egg whites in 23% of laboratories. These included a variety of similar, but invalid, ingredients ranging from a single whole egg to powdered eggs and water. Additional ingredients not recommended in the guidelines were used by 6% of the laboratories. For example, added ingredients included butter, peaches, or additional water. Also, oatmeal was still inappropriately being used as an alternative meal by 8 laboratories. Approximately 3% of laboratories used highly unusual GES meals. These included tuna sandwiches, peanut butter and jelly sandwiches, beef stew, and the patient's favorite meal.

Variable Compliance and Changes Since 2016

Overall, labs were compliant with an average of 7.9 of the 14 variables, with a low of single-variable compliance at

Meal Content Subgroups			
Meal type	Ingredients		
Full consensus Partial	Egg white, white toast, jelly, and water Partial components of consensus meal		
Consensus plus	Consensus meal with addition of nonstandard ingredients such as egg yolk (whole eggs)		
Oatmeal	Oatmeal alone or with other ingredients		
Other	Unusual meals such as burrito or peanut butter sandwich		

TABLE 3Meal Content Subgroups

1 site and a high of 14-variable compliance at 1 site (Fig. 2). Previously, the average was compliance with 4.8 variables, with a low of zero variables at 2 sites, but 4 sites were compliant with all 14 variables. The variable with the highest compliance included instructing the patient to take nothing by mouth for 4 h (97%), similar to the 95% compliance found in 2016. The variable with the lowest compliance was the assessment of blood glucose levels at 3%, previously 13%. This value increases to 24% if looking only at sites that check blood glucose levels in patients with known diabetes. Since 2016, notable areas of improvement include use of the consensus meal, now in 62% of labs versus previously in only 31%, as well as measurement of retention percentages instead of emptying percentages or half-times by 65% of sites versus only 35% 5 y prior.

DISCUSSION

Practice guidelines have been shown to improve the quality of patient care through evidence-based protocol standardization and serve to reduce variability in patient care (6-8). SNMMI published *Procedure Guideline for Adult Solid-Meal Gastric-Emptying Study 3.0* in 2009, which provided standardized guidance on performing GES (4). GES studies have previously been shown especially prone to protocol variability, with a wide range of meals administered to patients across institutions (2,5). The 2009 GES consensus guideline, therefore, was developed to reduce the GESrelated variations between nuclear medicine laboratories and represented a consensus across different professional societies. The data presented in this study, obtained from laboratories applying for IAC accreditation, have shown areas of improved compliance since the previous analysis

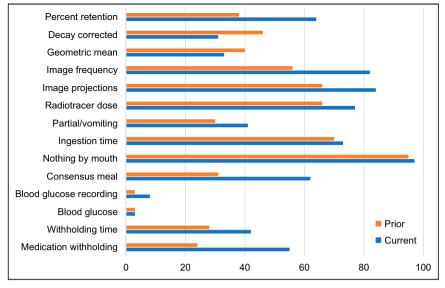


FIGURE 1. Comparison of prior survey vs. current survey results: compliance with 14 individual protocol variables from prior study (2) and current evaluation. Highest-compliance variables in current study included instructions on taking nothing by mouth for 4 h before procedure at 97%, and variable with lowest compliance was provision of blood glucose instructions at 3%. Overall average of compliance across all variables increased from 43% in 2017 to 54% currently.

of data in 2016. However, whereas there has been increased compliance with regard to guideline adherence since 2016 with specific variables, there is still, overall, a relatively low rate of compliance with the guideline GES protocol in the current study group of 118 laboratories.

GES Variability

Patient Preparation. Patient preparation is especially important in gastrointestinal nuclear medicine studies because of the physiologic sources of error that can be introduced. Approximately 55% of laboratories were compliant with providing medication-withholding instructions, an improvement from a prior compliance rate of 26% in 2016 and the 31%–35% reported in 2021 by Wise et al. (2,5). A variety of drugs, including those known for their prokinetic properties, should be withheld for approximately 48 h before a procedure (Table 2). Different nuclear medicine studies can have their own list of medications that need to be withheld before a procedure (such as an ¹²³I-MIBG study or a hepatobiliary scan). As such, providing lists of medications in respective study protocols is an optimal way of educating

TABLE 4Meal Component Variation (n = 118)

Meal type	Frequency (n)	%
Full consensus	74	62.7%
Partial	27	22.8%
Consensus plus	6	5.1%
Oatmeal	10	8.5%
Other	3	2.5%

nuclear medicine technologists on appropriate patient preparation. Considering the well-described effects of drugs such as opiates and anticholinergics on gastric emptying, even in small doses, compliance with specific medication discontinuation before a GES study is paramount to assess gastric motility under ideal physiologic conditions (9, 10).

Compared with 2016, a suboptimal level of compliance was again noted vis-à-vis instructions for measuring the patient's blood glucose level before the exam, with only 24% of laboratories checking it in known diabetics and 8% of labs assessing it in all patients. This is in line with Wise's results of only 16% of facilities measuring blood glucose in diabetic patients (5). Considering that hyperglycemia is an understood cause of delayed gastric emptying. results should be interpreted in the setting of this known physiologic derangement (11). As such, annotating glucose levels (and ensuring that levels were

<200 mg/dL) was considered an important variable in our study. Some of the lack of compliance may arise from a small but significant variation between the original 2008 consensus document and subsequent SNMMI guidelines on solid gastric emptying (3,4). The consensus document used 275 mg/dL as the upper limit for an acceptable blood glucose level before GES, but that number was revised down to 200 in the SNMMI guidelines and in the American College of Radiology practice parameter (12).

Meal Content and Preparation. Previously, the composition and preparation of meals were noted to be a source of major variability (2). A variable meal composition can affect the reliability of a GES study, considering that carbohydrates empty more quickly than fatty and protein-rich foods and that liquids empty more quickly than semisolids, which empty more quickly than solids (13). Food volume and resulting gastric wall stress are also known factors that affect emptying (14). A nonstandardized meal with a varying nutrient composition and volume can therefore lead to spurious study interpretation if there are no published normal values for the specific meal administered. The consensus meal consists of 2 slices of white toast, 30 g of strawberry jelly, 120 mL of water, and 120 g of liquid egg white (Egg Beaters [Post Holdings] or generic) scrambled with 18.5-37 MBq (0.5-1.0 mCi) of ^{99m}Tc-sulfur colloid (4). Consensus meal adherence has reassuringly improved since 2016, with compliance now being at 62% versus the previous 31% (2).

A few labs have continued to include nonstandard meals such as tuna sandwiches and beef stew, which would be doubtful to have a comparable emptying rate to the known rate for a standard consensus meal. Cooking the liquid egg

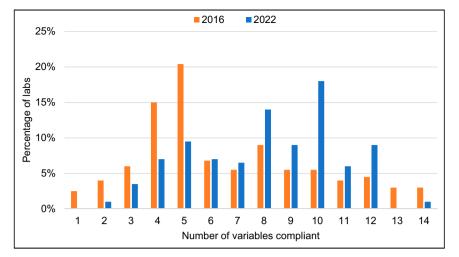


FIGURE 2. Number of variables compliant with guidelines per laboratory in current and previous 2016 studies. Smaller percentage of laboratories was compliant with all 14 variables. However, greater percentage of laboratories was compliant with more guideline variables.

whites with the sulfur colloid allows for bond formation and appropriate labeling of the egg whites with the radiotracer. Otherwise, the radiotracer can separate from the egg protein component, resulting in a potentially early transit of a radiotracer-predominant emulsion. Some labs were noted to diverge from the concomitant cooking of the egg whites and the sulfur colloid. For example, at least 1 lab injected sulfur colloid into a single hard-boiled egg, a meal often administered in the past, but now antiquated and likely resulting in inaccurate exam results. Many labs continued to use whole eggs, a problematic divergence considering that ^{99m}Tc-sulfur colloid binds to the albumin in the egg white and not to the egg yolk. Egg yolk also contains a higher fat content, which can artifactually delay transit compared with the liquid egg whites in the consensus meal.

Acquisition and Processing. Since 2016, there was an improvement in protocol compliance with respect to image acquisition. Approximately 85% of laboratories were compliant with imaging in both the anterior and the posterior views, whereas the previously compliance was 65% in 2016 (2). Images were acquired at the appropriate frequency by 83% of laboratories, an improvement from 55% compliance in 2016. Guidelines recommend that both anterior and posterior images be acquired, not only to assist with proper quantification of meal retention but also to serve as an added interpretation tool in the setting of potential artifacts and abnormal anatomy. The consensus protocol also recommends imaging immediately on meal completion and at 1, 2, 3, and 4 h afterward, as this timing provides information on transit dynamics. Greater than 10% administered meal retention at 4 h constitutes an abnormal exam result, and hence protocol omission of this data point can result in a false-negative interpretation in up to 30% of cases (15). Greater compliance with reporting percentage retention was also noted in the current study, constituting 65% of laboratories, an increase from the 35% in the 2016 study (2). Fewer labs are reporting the half-time of emptying for assessment, an encouraging trend considering the limitations in reporting half-time in patients due to the data's being collected at hourly intervals and the potential need for data extrapolation (3). Similar poor adherence was noted with regard to calculating retention using the geometrics of anterior and posterior projections and decay correcting the counts in the region of interest, constituting 33% and 31% compliance, respectively.

Guideline Implementation

Overall, there has been a trend toward greater guideline adherence since 2016. Although some aspects of the consensus guidelines remain to be widely adopted, compliance with the standardized meal

and with providing instructions to withhold interfering medications have improved, as have some variables concerning the imaging-and-processing portion of the exam and the reporting of meal percentage retention at each time point. The fact that other variables have continued to demonstrate low rates of implementation in laboratory protocols suggests a need for continued education on the consensus guidelines with attention to these particular variables. Specifically, these include testing blood glucose before the exam to ensure a level below 200 mg/dL, recording this level in the final report, calculating the geometric mean (using the anterior and posterior projections), and using decay correction for the counts in the region of interest.

Limitations

This study was a retrospective evaluation of application materials submitted to the IAC for accreditation. The IAC database was designed for management of accreditation and not for observational research purposes. It is possible that laboratories are following the guidelines but that actual practice is not documented in the protocol. Such a possibility is unlikely, however, given the similar findings of Wise et al. in a study of GES guideline compliance using a survey technique (5). A final limitation is that adherence with guidelines was chosen as a surrogate for quality because measuring direct patient outcomes in diagnostic medicine is complicated.

CONCLUSION

Since the publication of the SNMMI GES guidelines, there has been a gradual increase in protocol adherence among laboratories applying for IAC nuclear/PET accreditation. Certain specific recommendations in the guidelines have gained greater acceptance, whereas lack of adherence with other practice variables persists. Greater efforts on disseminating the specific gaps in guideline adherence would likely be helpful.

DISCLOSURE

Mary Beth Farrell is an employee of the IAC. The views expressed are those of the authors and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, the Department of Defense, or the U.S. government. No other potential conflict of interest relevant to this article was reported.

KEY POINTS

QUESTION: What is the degree of laboratory protocol adherence with the GES guideline published in 2009, and has adherence improved since it was assessed in 2016?

PERTINENT FINDINGS: Protocol adherence with the guidelines was examined for 118 laboratories, and adherence has improved in some areas since 2016 but remains suboptimal in others. Overall, labs complied with an average of 8 of the 14 variables, and only 19 laboratories met an 80% threshold for compliance (11+ variables).

IMPLICATIONS FOR PATIENT CARE: Persistent variation in the performance of GES protocols may significantly affect patient management, as results may be unreliable.

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