



Quality indicators for EUS

EUS has become integral to the diagnosis and staging of GI and mediastinal mass lesions and conditions. EUS-guided FNA (EUS-FNA) allows the endoscopist to obtain tissue or fluid for cytologic and chemical analysis, adding to the procedure's utility. Furthermore, the recent development of EUS-guided core biopsy techniques enables histologic sampling in selected cases and for obtaining tissue for molecular analysis in neoadjuvant and palliative settings. The clinical effectiveness of EUS and EUS-FNA depends on the judicious use of these techniques.

The quality of health care can be measured by comparing the performance of an individual or a group of individuals with an ideal or benchmark.¹ The particular parameter that is being used for comparison is termed a quality indicator. Quality indicators often are reported as ratios between the incidence of correct performance and the opportunity for correct performance or as the proportion of interventions that achieve a predefined goal.² Quality indicators can be divided into 3 categories: (1) structural measures—these assess characteristics of the entire health care environment (eg, availability and maintenance of endoscopy equipment at a hospital), (2) process measures—these assess performance during the delivery of care (eg, diagnostic rates of malignancy in patients undergoing EUS-FNA of pancreatic masses), (3) outcome measures: these assess the results of the care that was provided (eg, frequency of infection after EUS with FNA of cystic lesions).

METHODOLOGY

In 2006, the American Society for Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology (ACG) Task Force on Quality in Endoscopy published the first version of quality indicators for EUS.³ The present update integrates new data pertaining to previously proposed quality indicators and new quality indicators for performing EUS. We prioritized indicators that had wide-ranging clinical application, were associated with variation in practice and outcomes, and were validated in clinical studies. Clinical studies were identified through a computerized search of Medline followed by review of the bibliographies of all relevant articles. When such studies were absent,

indicators were chosen by expert consensus. Although feasibility of measurement was a consideration, we hope that inclusion of highly relevant, but not yet easily measurable, indicators will promote their eventual adoption. Although a comprehensive list of quality indicators is proposed, we recognize that, ultimately, only a small subset might be widely used for continuous quality improvement, benchmarking, or quality reporting. As in 2006, current the task force concentrated its attention on parameters related solely to endoscopic procedures. Although the quality of care delivered to patients is clearly influenced by many factors related to the facilities in which endoscopy is performed, characterization of unit-related quality indicators was not included in the scope of this effort.

The resultant quality indicators were graded on the strength of the supporting evidence (Table 1). Each quality indicator was classified as an outcome or a process measure. Although outcome quality indicators are preferred, some can be difficult to measure in routine clinical practice, because they need analysis of large amounts of data and long-term follow-up and may be confounded by other factors. In such cases, the task force deemed it reasonable to use process indicators as surrogate measures of high-quality endoscopy. The relative value of a process indicator hinges on the evidence that supports its association with a clinically relevant outcome, and such process measures were emphasized.

The quality indicators for this update were written in a manner that lends them to be developed as measures. Although they remain quality indicators and not measures, this document also contains a list of performance targets for each quality indicator. The task force selected performance targets from benchmarking data in the literature when available. When no data were available to support establishing a performance target level, "N/A" (not available) was listed. However, when expert consensus considers failure to perform a given indicator a "never event," such as monitoring vital signs during sedation, then the performance target was listed as >98%. It is important to emphasize that the performance targets listed do not necessarily reflect the standard of care but rather serve as specific goals to direct quality improvement efforts.

Quality indicators were divided into 3 time periods: pre-procedure, intraprocedure, and postprocedure. For each category, key relevant research questions were identified.

In order to guide continuous quality improvement efforts, the task force also recommended a high-priority subset of the indicators described, based on their clinical relevance and importance, evidence that performance

TABLE 1. Grades of recommendation*

Grade of recommendation	Clarity of benefit	Methodologic strength supporting evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Strong recommendation; likely to apply to most practice settings
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation; likely to change as data become available

*Adapted from Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action. Grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

varies significantly in clinical practice, and feasibility of measurement (a function of the number of procedures needed to obtain an accurate measurement with narrow confidence intervals [CI] and the ease of measurement). A useful approach for individual endoscopists is to first measure their performance with regard to these priority indicators. Quality improvement efforts would then move to different quality indicators if endoscopists are performing above recommended thresholds, or the employer and/or teaching center could institute corrective measures and remeasure performance of low-level performers.

Recognizing that certain quality indicators are common to all GI endoscopic procedures, such items are presented in detail in a separate document, similar to the process in 2006.⁴ The preprocedure, intraprocedure, and postprocedure indicators common to all endoscopy are listed in Table 2. Those common factors will be discussed in this document only insofar as the discussion needs to be modified specifically related to EUS.

Preprocedure quality indicators

The preprocedure period includes all contact between members of the endoscopy team with the patient before the administration of sedation. Common issues for all endoscopic procedures during this period include: appropriate indication, informed consent, risk assessment, formulation of a sedation plan, clinical decision making

with regard to prophylactic antibiotics and management of antithrombotic drugs, and timeliness of the procedure.⁵ Preprocedure quality indicators specific to performance of EUS include the following:

1. *Frequency with which EUS is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented*

Level of evidence: 1C

Performance target: >80%

Type of measure: process

The ASGE has published appropriate indications for EUS (Table 3).⁶ An appropriate indication should be documented for each procedure, and, when it is not a standard indication listed in the current ASGE Appropriate Use of GI Endoscopy guideline, it should be justified in the documentation.

Discussion: Acceptable indications for EUS have been published recently.^{6,7} Although there are many instances in which EUS can be performed, the value of the procedure in the care of any particular patient depends on its impact on management, improvement in outcomes, and the superiority of EUS over other available imaging or surgical procedures. This implies a certain degree of clinical judgment in choosing when and if to perform EUS in relation to other procedures, making rigid indications impractical. Expert opinion

TABLE 2. Summary of proposed quality indicators common to all endoscopic procedures^{a,b}

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
Preprocedure			
1. Frequency with which endoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented	1C+	Process	> 80
2. Frequency with which informed consent is obtained and fully documented	3	Process	> 98
3. Frequency with which preprocedure history and directed physical examination are performed and documented	3	Process	> 98
4. Frequency with which risk for adverse events is assessed and documented before sedation is started	3	Process	> 98
5. Frequency with which prophylactic antibiotics are administered for appropriate indication	Varies	Process	> 98
6. Frequency with which a sedation plan is documented	Varies	Process	> 98
7. Frequency with which management of antithrombotic therapy is formulated and documented before the procedure	3	Process	N/A
8. Frequency with which a team pause is conducted and documented	3	Process	> 98
9. Frequency with which endoscopy is performed by an individual who is fully trained and credentialed to perform that particular procedure	3	Process	> 98
Intraprocedure			
10. Frequency with which photodocumentation is performed	3	Process	N/A
11. Frequency with which patient monitoring during sedation is performed and documented	3	Process	> 98
12. Frequency with which the doses and routes of administration of all medications used during the procedure are documented	3	Process	> 98
13. Frequency with which use of reversal agents is documented	3	Process	> 98
14. Frequency with which procedure interruption and premature termination because of sedation-related issues is documented	3	Process	> 98
Postprocedure			
15. Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented	3	Process	> 98
16. Frequency with which patient instructions are provided	3	Process	> 98
17. Frequency with which the plan for pathology follow-up is specified and documented	3	Process	> 98
18. Frequency with which a complete procedure report is created	3	Process	> 98

TABLE 2. Continued

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
19. Frequency with which adverse events are documented	3	Process	> 98
20. Frequency with which adverse events occur	3	Outcome	N/A
21. Frequency with which postprocedure and late adverse events occur and are documented	3	Outcome	N/A
22. Frequency with which patient satisfaction data are obtained	3	Process	N/A
23. Frequency with which communication with referring providers is documented	3	Process	N/A

N/A, Not available.

*This list of potential quality indicators is meant to be a comprehensive list of measurable endpoints. It is not the intention of the task force that all endpoints be measures in every practice setting. In most cases, validation may be required before a given endpoint may be adopted universally.

has identified specific clinical situations for which EUS is deemed an appropriate diagnostic or therapeutic procedure (Table 3).⁶ EUS generally is not indicated for staging of tumors shown to be metastatic by other imaging methods (unless the results are the basis for therapeutic decisions or unless the procedure is performed to confirm a diagnosis by tissue sampling). It is fully expected that certain indications may change with time. In addition, the appropriate use of EUS also depends, in part, on the availability of other imaging methods, because not all patients will have reasonable access to alternatives to EUS. For this reason, 100% compliance with predetermined indications is considered restrictive.

The inclusion of an indication in the procedure documentation for all cases is a useful quality measure for two reasons. First, it provides a justification for the procedure and serves as a means of tracking compliance with accepted indications. Second, the indication places the remainder of the procedure report in a specific context wherein certain endosonographic landmarks and finding characteristics logically should follow. For example, detailed descriptions of the pancreas may not be necessary when the indication for EUS is esophageal cancer staging. However, once esophageal cancer staging is provided as the indication, certain components of the examination, such as tumor (T) and node (N) staging, including celiac axis visualization (except in cases when the tumor cannot be safely traversed), are expected and their subsequent inclusion would reflect a thorough EUS.

2. *Frequency with which consent is obtained, including specific discussions of risks associated with EUS, and fully documented*

Level of evidence: 3

Performance target: > 98%

Type of measure: process

The consent should address the relevant and substantial adverse events pertaining to each specific EUS procedure in addition to the risks associated with all endoscopic procedures.

Discussion: EUS and EUS-FNA present risks of unique adverse events beyond those associated with standard endoscopy. A review of the adverse events specific to EUS have been published previously and are detailed in the following section.^{8,9} In most instances, EUS requires passage of large echoendoscopes or endoscopes with relatively rigid portions. Although EUS is associated with an increased risk of perforation, this adverse event is rare. Esophageal or duodenal perforations are rare adverse events associated with EUS.⁸⁻¹⁵ The incidence of cervical esophageal perforation during intubation ranges from 0.03% to 0.06%.^{11,12} Perforation risk also may be higher when staging esophageal cancer, particularly in the setting of before-EUS dilation of an obstructing malignancy (range 0%-24%).^{14,16-18} Perforation related to dilation of malignant esophageal strictures for complete EUS examination is rare when the procedure is performed cautiously by experienced operators.¹⁶ Dilation of esophageal cancer, advanced patient age, difficult esophageal intubation, and lack of operator experience have been identified as risk factors for esophageal perforation.^{8,11,14} FNA introduces an increased risk of bleeding (0.5%), infection (<1%),^{8-10,13-15,19-22} and pancreatitis ($\leq 2\%$ and greater for cystic lesions compared with solid lesions).^{8-10,19,21,23-26} Tumor seeding along the FNA tract has been reported in very rare circumstances.²⁷⁻³² Routine performance of bile duct EUS-FNA for primary tumor diagnosis (cholangiocarcinoma) is not recommended in surgical candidates because of the small risk of tumor seeding and negative impact on transplant

TABLE 3. Appropriate indications for EUS³⁷

Staging of tumors of the GI tract, pancreas, bile ducts, and mediastinum including lung cancer
Evaluating abnormalities of the GI tract wall or adjacent structures
Tissue sampling of lesions within, or adjacent to, the wall of the GI tract
Evaluation of abnormalities of the pancreas, including masses, pseudocysts, and chronic pancreatitis
Evaluation of abnormalities of the biliary tree
Placement of radiologic (fiducial) markers into tumors within or adjacent to the wall of the GI tract
Treatment of symptomatic pseudocysts by creating an enteral-cyst communication
Providing access into the bile ducts or pancreatic duct, either independently or as an adjunct to ERCP
Evaluation for perianal and perirectal disorders (anal sphincter injuries, fistulae, abscesses)
Evaluation of patients at increased risk of pancreatic cancer
Celiac plexus block or neurolysis

candidacy or outcomes after resection for patients with resectable disease.³³ Celiac plexus neurolysis or celiac plexus block carry unique risks of transient hypotension (1%) and diarrhea (4%-15%), in addition to standard risks.⁸ The consent form used by the endosonographer should be comprehensive enough to include these adverse events.

3. *Frequency with which appropriate antibiotics are administered in the setting of FNA of cystic lesions*

Level of evidence: 2C

Performance target: N/A

Type of measure: process

Discussion: There have been no randomized trials conducted to determine the need for prophylactic antibiotics in the setting of EUS-FNA. The risk of bacteremia after EUS-FNA is low (0%-6%) and comparable with that of diagnostic endoscopy.^{22,34-36} This holds true for patients undergoing EUS-FNA of the rectum and perirectal space. In a prospective study of 100 patients who underwent EUS-FNA for lower GI tract lesions, the incidence of bacteremia was 2%.²² In general, the risk of clinically significant infectious adverse events after EUS-FNA of solid lesions is very low (range 0%-0.6%).^{13-15,19-22} Infectious adverse events were reported in 0.04% of patients undergoing EUS-FNA in a recent systematic review.¹⁰ The rate of infection related to EUS-FNA of pancreatic cysts was relatively low (0.5%) as well and was attributed to the routine use of prophylactic antibiotics.¹⁰ On the other hand, EUS-FNA of mediastinal cysts is associated with high rates of infectious adverse events including life-threatening mediastinitis.⁸ The recommendation of administering antibiotics before EUS-FNA of pancreatic cysts has been challenged in a retrospective study that showed no protective effect from periprocedural prophylactic antibiotics in patients undergoing EUS-FNA of pancreatic cysts.³⁷ The ASGE

suggests antibiotics before EUS-FNA of mediastinal cysts and advises against administration of prophylactic antibiotics before EUS-FNA of pancreatic and peripancreatic cystic lesions.³⁸ Prophylaxis, when deemed necessary, involves administration of an antibiotic such as a fluoroquinolone administered before the procedure and continued for 3 to 5 days postprocedure. Administration of prophylactic antibiotics for lower GI tract lesions should be made on a case-by-case basis. ASGE advises against antibiotic prophylaxis before diagnostic EUS or EUS-FNA of solid lesions in the lower GI tract.^{38,39}

4. *Frequency with which EUS examinations are performed by trained endosonographers*

Level of evidence: 3

Performance target: >98%

Type of measure: process

Discussion: Although it is beyond the scope of this article to discuss training requirements and competency assessment, a trained endosonographer is defined as one who has undergone formal training and gained the necessary technical and cognitive skills. Training in EUS requires the development of technical and cognitive skills beyond that required for standard endoscopic procedures. The value of EUS in provision of patient care is directly proportional to the training, skill, and experience of the endosonographer. Recognizing the specialized nature of EUS and EUS-FNA, ASGE has published specific criteria for the training of, and the granting of clinical privileges for, individuals who want to perform these procedures.⁴⁰⁻⁴² These guidelines have not been validated and do not account for different rates at which people learn. Unfortunately, there is a dearth of data on the intensity and length of training, the requisite curriculum and extent of theoretical learning, and minimum number of procedures required to ensure competency. Given the variability in

diagnostic yield associated with relative experience and training in this procedure, it is a reasonable expectation that the likelihood of a high-quality procedure is increased by having a fully trained endosonographer perform the examination.

Preprocedure research questions

1. Does EUS impact patient management decisions for each specific indication?
2. Does EUS improve patient outcomes for each specific indication?
3. What is the absolute impact of prophylactic antibiotics on the risk of infection after FNA of cystic lesions?
4. How often is EUS performed for nonstandard indications in clinical practice?
5. Is there a difference in findings or outcomes when EUS is performed for non-standard indications?
6. How much training is required for individuals performing EUS before they can achieve staging accuracy and diagnostic FNA yields comparable to those of published literature?

Intraprocedure quality indicators

The intraprocedure period extends from the administration of sedation to the removal of the endoscope. This period includes all the technical aspects of the procedure including completion of the examination and of therapeutic maneuvers. Common to most endoscopic procedures is the provision of sedation and need for patient monitoring. Intraprocedure quality indicators specific to performance of EUS include the following:

5. *Frequency with which the appearance of relevant structures, specific to the indication for the EUS, is documented*

Level of evidence: 3

Performance target: >98%

Type of measure: process

Documentation for each of the following indications should include the following items:

1. In the setting of esophageal cancer staging without obstruction, location of the gastroesophageal junction and visualization of the celiac axis and left lobe of the liver (to rule out metastatic disease) should be documented.
2. In the setting of evaluating for the presence of pancreaticobiliary disease, visualization of the entire pancreas (describing features of chronic pancreatitis and pancreatic cysts when present) along with evaluation of the pancreatic duct should be documented. Description of biliary abnormalities (eg, stones, dilation) should be documented.
3. In the setting of EUS for lower GI tract indications such as rectal cancer, location of the tumor and visualization of surrounding structures such as iliac vessels, genitourinary structures, and sphincter

apparatus and evaluation for lymphadenopathy should be documented.

Discussion: To maximize clinical efficacy, EUS should provide all pertinent information relevant to the procedure's indication. The endosonographer must visualize specific structures depending on the disease process being investigated and should subsequently document these findings in writing or with photographic documentation.

- 6a. *Frequency with which all GI cancers are staged with the American Joint Committee on Cancer (AJCC)/Union for International Cancer Control (UICC) TNM staging system^{43,44} (priority indicator)*

Level of evidence: 3

Performance target: >98%

Type of measure: process

- 6b. *Frequency with which pancreatic mass measurements are documented along with evaluation for vascular involvement, lymphadenopathy, and distant metastases*

Level of evidence: 3

Performance target: >98%

Type of measure: process

- 6c. *Frequency with which EUS wall layers involved by subepithelial masses are documented*

Level of evidence: 3

Performance target: >98%

Type of measure: process

Discussion: A diagnosis based on EUS findings, with or without cytology from FNA, requires not only an accurate localization and description of sonographic findings but also an accurate interpretation of these findings within the individual patient's clinical context. Currently, the AJCC/UICC TNM (tumor, node, metastasis) systems are the most widely used methods for staging GI malignancies.^{43,44} Therefore, to maximize the utility of EUS in the setting of cancer staging, the elements necessary to assign both T and N stages should be obtained during the procedure and documented in writing and with saved images. This includes measurements of the mass, because T staging may depend on tumor size as in pancreatic cancer. Examination should include evaluation of vascular involvement (eg, portal vein/superior mesenteric vein and celiac axis, hepatic artery and superior mesenteric artery involvement in pancreatic cancer) and distant metastasis, which also impacts the T stage and candidacy for resectability. In the setting of subepithelial lesions, the differential diagnosis is based on wall layer of origin, echo characteristics, and size of lesion. Therefore, these findings should be documented in every report.

Several recent reports have described the accuracy of T and N staging with EUS in relation to cancers of the pancreas, esophagus, stomach, and rectum. Accurate staging of pancreatic cancer plays an integral role in the initial decision making process for patients

with pancreatic cancer. In pancreatic cancer, results from contemporary studies have reported accuracy of T staging ranging from 62% to 67%,⁴⁵⁻⁴⁸ with earlier studies reporting higher accuracy rates (85%-94%).⁴⁹⁻⁵¹ In the absence of distant metastasis, the presence and degree of contact between the tumor and the peripancreatic vessels is of paramount importance in determining surgical resectability. In a meta-analysis, the sensitivity and specificity of EUS in diagnosing vascular invasion was 73% (95% CI, 68.8-76.9) and 90% (95% CI, 87.9-92.2).⁵² Results from available data with regard to accuracy of EUS in predicting vascular invasion are variable, with a wide range suggesting the operator dependency and variability. The task force acknowledges this and hence does not make accuracy of vascular invasion as a quality indicator but recommends documentation of vascular invasion as a quality indicator. Similarly, variable rates of accuracy for N staging have been reported in pancreatic cancer (range 40%-85%).^{45,47,48,50,51,53,54} In esophageal cancer, sensitivity and specificity of EUS for T staging has ranged from 81% to 92% and 94% to 99%, respectively.⁵⁵ Although the role of EUS has been questioned in the setting of Barrett's-esophagus-related neoplasia (high-grade dysplasia and intramucosal cancer),^{56,57} EUS has moderate accuracy rates in differentiating mucosal (T1a) versus submucosal (T1b) esophageal cancer, although this is largely being supplanted by EMR and/or endoscopic submucosal dissection and direct pathology staging.⁵⁸ Sensitivity and specificity of EUS for N staging was 80% (95% CI, 75-84) and 70% (95% CI, 65-75) in a meta-analysis.⁵⁹ In gastric cancer, a recent meta-analysis reported high accuracy rates in differentiating T1-2 from T3-4 disease (sensitivity 86% [95% CI, 81-90] and specificity 91% [95% CI, 89-93]). EUS for lymph node status was less reliable sensitivity 69% [95% CI, 63-74] and specificity 84% [95% CI, 81-88]).⁶⁰ The sensitivity and specificity for T staging in rectal cancer was 88% and 98% for T1, 81% and 96% for T2, 96% and 91% for T3, and 95% and 98% for T4 cancer, respectively.⁶¹ However, recent studies have questioned these high accuracy rates and have suggested that magnetic resonance imaging may have similar accuracy rates in the T and N staging of rectal cancer.^{62,63}

- 7a. *Percentage of patients with distant metastasis, ascites, and lymphadenopathy undergoing EUS-guided FNA who have tissue sampling of both the primary tumor and lesions outside of the primary field when this would alter patient management*

Level of evidence: 1C

Performance target: >98%

Type of measure: process

- 7b. *Diagnostic rate of adequate sample in all solid lesions undergoing EUS-FNA (adequate sample is defined by the presence of cells and/or tissue from the representative lesion in question)*

Level of evidence: 3

Performance target: $\geq 85\%$

Type of measure: outcome

- 7c. *Diagnostic rates and sensitivity for malignancy in patients undergoing EUS-FNA of pancreatic masses (priority indicator)*

Level of evidence: 1C

Performance target: Diagnostic rate of malignancy in patients undergoing EUS-FNA of all pancreatic masses, $\geq 70\%$ and sensitivity of malignancy among patients with pancreatic cancer, $\geq 85\%$

Type of measure: outcome

Discussion: The additional clinical information obtained from FNA can increase the diagnostic accuracy of EUS significantly by confirming a pathologic diagnosis, by obtaining more accurate nodal staging in malignancy, and by yielding fluid for various analyses, including chemical analyses, tumor markers, and bacterial and/or fungal stains or culture. FNA is not feasible or appropriate in all conditions. Sampling a lymph node by traversing the primary tumor with the FNA needle should be avoided, because this may result in a false-positive lymph node cytology result and can potentially seed a previously benign lymph node with malignant cells from the primary tumor. The need for pretreatment FNA of pancreas tumors is variable. The primary value of FNA is to confirm malignancy, particularly when chemoradiotherapy is considered prior to or in lieu of surgery or to exclude lesions such as metastases to the pancreas, mass-forming pancreatitis, non-adenocarcinoma histology, and lymphoma. However, when FNA is appropriate, the endosonographer should make every effort to obtain adequate cytologic material to confirm a diagnosis.

Accuracy of EUS-FNA has been evaluated in several studies in patients with cancers of the pancreas, esophagus, stomach, bile duct, and rectum. Data from these studies provide a benchmark for quality performance measurement in EUS. A multicenter, retrospective study that included 1075 patients who underwent EUS-FNA of solid pancreatic masses at 21 centers (81% academic) with 41 endosonographers reported an overall diagnostic rate of malignancy of 71% (95% CI, 69-74).⁶⁴ Sensitivity and specificity that uses the criterion standard of either surgical pathology or long-term follow-up are ideal benchmarks for pancreatic EUS-FNA performance. A recent meta-analysis that included studies that met this criterion reported a pooled sensitivity of 85% (95% CI, 84-86) and specificity of 98% (95% CI, 97-99), with higher accuracy of EUS-FNA reported in prospective, multicenter studies.⁶⁵

In the setting of esophageal cancer in the thoracic esophagus, malignant celiac axis lymph nodes no longer confer M1a status and, per the new staging system, a regional lymph node has been redefined to include any paraesophageal node extending from

cervical nodes to celiac nodes.⁶⁶ EUS-FNA for lymph node staging in esophageal cancer is an accurate staging modality with sensitivity of 83% (95% CI, 70-93), specificity of 93% (95% CI, 77%-99%), and accuracy of 87% (95% CI, 77-94) as reported in a prospective study that included 76 consecutive patients with pathologic evaluation of resected lymph nodes.⁶⁷ Retrospective studies that focused primarily on celiac lymph nodes reported sensitivity of 88% to 100%, specificity of 100%, and accuracy rates ranging from 87% to 100% for detection of lymph node metastases.⁶⁸⁻⁷¹

Several studies have reported the use of EUS-FNA for the diagnosis of cholangiocarcinoma in the setting of indeterminate extrahepatic strictures. Reported sensitivity ranges from 29% to 89%⁷²⁻⁷⁷ with a higher sensitivity reported for distal compared with proximal strictures (81% vs 59%; $P = .04$) in a single study.⁷⁷ The conventional criteria for malignant lymph nodes at EUS (size > 1 cm, round, hypoechoic, and homogeneous) have a poor predictive value in malignant lymphadenopathy associated with cholangiocarcinoma.⁷⁸ Hence, given the potential for avoiding unnecessary neoadjuvant therapy and staging laparotomy, a low threshold for sampling lymphadenopathy in this situation should be maintained. EUS-FNA should be performed only when results are likely to alter decision making (primary surgical resection or definitive or neoadjuvant chemoradiation). EUS-FNA also should be performed in patients with suspected distant metastases, given the potential to significantly change patient management.

The involvement of an on-site cytopathologist during EUS-FNA may help limit the number of FNA passes taken and increase the overall diagnostic accuracy of the procedure, although data are inconclusive.^{9,79-85} The impact of on-site cytopathology evaluation in terms of diagnostic yield, number of passes, repeat procedures, and procedure time has not been studied in a randomized, controlled trial. However, it is recognized that not all endosonographers will have access to this degree of service. Therefore, for situations in which an on-site cytopathologist or cytotechnologist is not available, 5 to 7 FNA passes for pancreas masses and 2 to 4 passes for lymph nodes or suspected liver metastases are advised.⁸⁶⁻⁸⁸ Other methods to increase cytologic adequacy and accuracy have not been definitively shown to be superior. EUS-FNA can be performed by using 25-gauge, 22-gauge, or 19-gauge needles. Randomized, controlled trials comparing 25-gauge and 22-gauge needles demonstrated no difference in diagnostic accuracy between the two groups.⁸⁹⁻⁹¹ A recent meta-analysis of 8 studies involving 1292 patients undergoing EUS-FNA (25-gauge, 565 patients and 22-gauge, 799 patients) showed that a 25-gauge needle was more sensitive than a 22-gauge needle for diagnosing pancreatic ma-

lignancy (pooled sensitivity, 25-gauge: 0.93 [95% CI, 0.91-0.96] vs 22-gauge: 0.85 [95% CI, 0.82-0.88]).⁹² A randomized, controlled trial comparing 19-gauge and 22-gauge needle systems in patients undergoing EUS-FNA of pancreatic masses demonstrated a higher diagnostic accuracy rate and the presence of superior cellular material by using the 19-gauge needle. However, a significantly lower technical success rate was reported by using the 19-gauge needle system.⁹³ Large needle gauges (19-gauge) provide a larger specimen but are limited to transgastric biopsy in most cases and for EUS-guided interventions such as pseudocyst drainage. Few randomized, controlled trials have demonstrated no advantage in the routine use of a stylet during EUS-FNA.⁹⁴⁻⁹⁶ In recent years, the technique of performing EUS-FNA passes without the use of a stylet has gained popularity but has not been adopted by all endosonographers. Use of traditional true-cut biopsy has not been shown to be superior to FNA and is associated with a high failure rate in transduodenal puncture.⁹ Recent availability of small-gauge core biopsy needles (25-gauge and 22-gauge) and flexible 19-gauge needles offers an opportunity for research.

Intraprocedure research questions

1. What are the thresholds for accurate T and N staging of GI malignancies?
2. How do community practices compare with academic centers with regard to EUS staging and EUS-FNA accuracy?
3. Under what circumstances does FNA change patient management?
4. What is the optimal technique for performing EUS-FNA, and what are the variables that impact obtaining adequate specimens?
5. How does on-site cytopathology evaluation during EUS-FNA impact diagnostic yield, number of passes, repeat procedures, and procedure time?
6. What are the optimal methods for tissue processing of FNA specimens?

Postprocedure quality indicators

The postprocedure period extends from the time the endoscope is removed to subsequent follow-up. Postprocedure activities include providing instructions to the patient, documentation of the procedure, recognition and documentation of adverse events, pathology follow-up, communication with referring physicians, and assessing patient satisfaction.⁵ Postprocedure quality indicators specific to performance of EUS include the following:

8. *Frequency with which the incidence of adverse events after EUS-FNA (acute pancreatitis, bleeding, perforation, and infection) is documented*

Level of evidence: 3

Performance target: >98%

Type of measure: process

9. Incidence of adverse events after EUS-FNA (acute pancreatitis, bleeding, perforation, and infection) (priority indicator)

Level of evidence: 1C

Performance target: acute pancreatitis <2%, perforation <0.5%, clinically significant bleeding <1%

Type of measure: outcome

Discussion

A. Overall and specific adverse event rates. The overall safety of EUS-FNA is well-established, with a low overall adverse event rate. The main adverse events include acute pancreatitis, bleeding, and infection. Two other adverse events that merit mention include tumor seeding and false-positive EUS-FNA cytology results.

Variable rates of morbidity related to EUS-FNA have been reported, ranging from 0% to 2.5%.^{13-15,19-21} A recent systematic review that included 10,941 patients reported an overall EUS-FNA specific morbidity rate of 0.98% (107/10,941) and mortality rate of 0.02% (2/10,941).¹⁰ Patients undergoing EUS-FNA of the pancreas for evaluation of pancreatic masses, cystic lesions, or lesions of the pancreatic duct are at risk of developing pancreatitis, likely as a result of direct tissue injury as the needle traverses pancreatic tissue. The incidence of pancreatitis in this setting, including data from prospective series, has ranged between 0% and 2%.^{19,21,23-26} The rate of pancreatitis was 0.44% (36/8246) in a systematic review, mild-moderate severity in most patients.¹⁰ Acute clinically significant bleeding related to EUS-FNA is a rare adverse event, and incidence has ranged from 0 to 0.5%.^{10,13-15,19-21} Mild intraluminal bleeding has been reported in up to 4% of cases,⁹⁷ extraluminal bleeding in 1.3% to 2.6% of cases,^{26,98} and intracystic bleeding in up to 6% of cases during EUS-FNA of pancreatic cysts.⁹⁹ The risk of clinically significant infectious adverse events after EUS-FNA of solid lesions is very low (range 0%-0.6%).^{13-15,19-22} Infectious adverse events were reported in 5 of 10,941 (0.04%) patients in a recent systematic review.¹⁰ The rate of infection related to EUS-FNA of pancreatic cysts is relatively low (0.5%) and is attributed to the routine use of prophylactic antibiotics.¹⁰ On the other hand, EUS-FNA of mediastinal cysts is associated with high rates of infectious adverse events including life-threatening mediastinitis.⁸

B. Tumor seeding after EUS-FNA. Needle track seeding or implantation metastasis has been reported after EUS-FNA and deserves special mention. This adverse event has been described as case reports.²⁷⁻³¹ However, the true incidence of this adverse event is difficult to assess because of the high mortality of patients ineligible for potentially curable therapy. In addition, tumor seeding may occur at sites that are outside the field of primary resection. In a prospective study of 140 patients undergoing EUS, which included patients with cancer and benign lesions, the luminal fluid aspirated through the accessory channel before and after FNA was submitted for cytologic analysis. Cytology examination of the luminal fluid showed positive results for malignancy in 48% of patients and 10%

in patients with extraluminal cancer. Post-FNA luminal fluid cytology was unexpectedly positive in 3 of 26 pancreatic cancer patients. This suggests that EUS-FNA may withdraw malignant cells from the tumor into the GI lumen and potentially cause seeding from the target organ.³² Another retrospective study demonstrated a higher rate of peritoneal carcinomatosis related to pancreatic cancer in patients undergoing percutaneously guided FNA compared with EUS-FNA (16.3% vs 2.2%; $P < .025$).¹⁰⁰ The concern for tumor seeding is of greatest relevance in patients with suspected cholangiocarcinoma and EUS-FNA of the primary tumor and is considered as a contraindication to liver transplantation for cholangiocarcinoma. A recent study evaluated the incidence of tumor seeding in 191 patients with locally unresectable hilar cholangiocarcinoma undergoing liver transplant evaluation. There were 16 patients who underwent transperitoneal FNA (16 percutaneous, 3 EUS)—6 were positive for malignancy, 9 negative, and 1 had equivocal results. During operative staging, peritoneal metastasis was seen in 5 of 6 (83%) patients with positive FNA versus 0 of 9 (0%) with negative FNA. Peritoneal metastasis was significantly higher in patients with positive preoperative FNA compared with those not undergoing transperitoneal sampling (5/6 [83%] vs 14/175 [8%]; $P = .009$).³³

C. False-positive EUS-FNA cytology results. The incidence of false-positive EUS-FNA cytology results ranges from 1.1% to 5.3%.¹⁰¹⁻¹⁰³ In a study that matched 377 EUS-FNA cytology results of positive or suspicious with surgical specimens in patients who had not received any neoadjuvant chemoradiation, a false-positive rate of 5.3% (increased to 7.2% if false-suspicious included) was reported. The false positive rate was higher in non-pancreatic FNA compared with pancreatic FNA (15% vs 2.2%; $P = .0001$). Discordant results were then blindly assessed by 3 cytopathologists, and reasons for false-positive results included epithelial cell contamination and pathology misinterpretation.¹⁰¹ Another retrospective study that involved 367 patients with solid pancreatic lesions in whom EUS-FNA cytology results were positive or suspicious for malignancy resulting in surgical resection, the false positive rate was 1.1% (3.8% if false-suspicious included). These false-positive results were attributed to pathology misinterpretation in the setting of chronic pancreatitis.¹⁰²

D. Risk factors for adverse events related to EUS-FNA. Given the rarity of EUS-FNA-related adverse events, studies assessing predictors for adverse events are hampered by the lack of power to evaluate risk factors. Prospective studies report a higher cumulative FNA-related morbidity rate compared with retrospective studies (59/3426 [1.72%] vs 48/7515 [0.64%]). These findings hold true for FNA-related adverse events of pancreatic lesions (mass and cystic lesion).¹⁰ EUS-FNA of cystic lesions in the pancreas is associated with a higher rate of adverse events compared with EUS-FNA of solid lesions, although it is still quite low.^{10,13} The number of passes is not associated with the risk of adverse events.⁹ Similarly, needle

TABLE 4. Summary of proposed quality indicators for EUS*

Quality indicator	Grade of recommendation	Type of measure	Performance target (%)
Preprocedure			
1. Frequency with which EUS is performed for an indication that is included in a published standard list of appropriate indications and the indication is documented	1C	Process	> 80
2. Frequency with which consent is obtained, including specific discussions of risks associated with EUS, and fully documented	3	Process	> 98
3. Frequency with which appropriate antibiotics are administered in the setting of FNA of cystic lesions	2C	Process	N/A
4. Frequency with which EUS exams are performed by trained endosonographers	3	Process	> 98
Intraprocedure			
5. Frequency with which the appearance of relevant structures, specific to the indication for the EUS, is documented	3	Process	> 98
6a. Frequency with which all gastrointestinal cancers are staged with the American Joint Committee on Cancer (AJCC)/Union for International Cancer Control (UICC) TNM staging system (priority indicator)	3	Process	> 98
6b. Frequency with which pancreatic mass measurements are documented along with evaluation for vascular involvement, lymphadenopathy and distant metastases	3	Process	> 98
6c. Frequency with which EUS wall layers involved by subepithelial masses are documented	3	Process	> 98
7a. Percentage of patients with distant metastasis, ascites, and lymphadenopathy undergoing EUS-guided FNA who have tissue sampling of both the primary tumor diagnosis and lesions outside of the primary field when this would alter patient management	1C	Process	> 98
7b. Diagnostic rate of adequate sample in all solid lesions undergoing EUS-FNA (adequate sample is defined by the presence of cells/tissue from the representative lesion in question)	3	Outcome	≥ 85
7c. Diagnostic rates and sensitivity for malignancy in patients undergoing EUS-FNA of pancreatic masses (priority indicator)	1C	Outcome	Diagnostic rate: ≥ 70 Sensitivity: ≥ 85
Postprocedure			
8. Frequency with which the incidence of adverse events after EUS-FNA (acute pancreatitis, bleeding, perforation and infection) is documented	3	Process	> 98
9. Incidence of adverse events after EUS-FNA (acute pancreatitis, bleeding, perforation and infection) (priority indicator)	1C	Outcome	Acute pancreatitis: < 2% Perforation: < 0.5% Clinically significant bleeding: < 1%

N/A, Not available.

*This list of potential quality indicators was meant to be a comprehensive listing of measurable endpoints. It is not the intention of the task force that all endpoints be measured in every practice setting. In most cases, validation may be required before a given endpoint may be universally adopted.

TABLE 5. Priority quality indicators for endoscopic ultrasound*

Frequency with which all GI cancers are staged with the AJCC/UICC TNM staging system

Diagnostic rates and sensitivity for malignancy in patients undergoing EUS-guided FNA of pancreatic masses

The incidence of adverse events after EUS-guided FNA (acute pancreatitis, bleeding, perforation, and infection)

AJCC, American Joint Committee on Cancer; UICC, Union for International Cancer Control; TNM, tumor, node, metastasis.

*See text for specific targets and discussion.

gauge does not appear to increase the risk of adverse events, although these studies were not powered to detect a difference in this endpoint.^{91,93} EUS-guided true-cut biopsies appear to have a similar safety profile compared with standard EUS-FNA.¹⁰⁴⁻¹⁰⁶ However, EUS-guided true-cut biopsies are not routinely performed transduodenally and for lesions <2 cm. The safety of a core biopsy needle was described in a recent randomized, controlled trial comparing a 22-gauge EUS-FNA needle to a 22-gauge EUS-fine needle biopsy needle.¹⁰⁷

Postprocedure research questions

1. What are the estimates of adverse events related to EUS-FNA in community practices?
2. What are the true estimate and clinical significance of tumor seeding and false positive rates after EUS-FNA?
3. What is the incidence of the adverse events of EUS-guided core biopsies, and do such biopsies improve outcomes over standard FNA sampling?
4. Is it feasible to incorporate data regarding surgical pathology and long-term follow-up in patients undergoing EUS?
5. How can the diagnostic yield of EUS-FNA be improved?
6. What is the frequency with which EUS alters patient management and long-term outcomes?¹⁰⁸⁻¹¹¹

Priority indicators for EUS

For EUS, the recommended priority indicators among all the proposed indicators (Table 4) are:

1. Frequency with which all GI cancers are staged with the AJCC/UICC TNM staging system
 2. Diagnostic rates of malignancy and sensitivity in patients undergoing EUS-FNA of pancreatic masses
 3. The incidence of adverse events after EUS-FNA (bleeding, perforation, and acute pancreatitis) (Table 5)
- For each of these indicators, reaching the recommended performance target is considered strongly associated with important clinical outcomes. These indicators can be measured readily in a manageable number of examinations, and for each there is evidence of substantial variation in performance.^{112,113}
- There is evidence that simple educational and corrective measures can improve endoscopist performance. The primary purpose of measuring quality indicators is to improve patient care by identifying poor performers and retraining them so that they might be able to meet

the performance targets for these important aspects of the procedure.

Conclusion

The quality indicators proposed in this document were selected, in part, because of their ease of implementation, monitoring, and reporting (Table 4). The task force has attempted to create a comprehensive list of potential quality indicators. We recognize that not every indicator will be applicable to every practice setting. Facilities should select the subset most appropriate to their individual needs. We recognize that the field of EUS continues to expand, with the possible appearance of new indications and adverse events. Therefore, these quality indicators should be updated as the need arises. With the increasing demand for EUS, the number of physicians performing this complex procedure will continue to grow. It is the hope of the ACG, ASGE, and AGA that these measures and targets not only guide practicing endoscopists who perform EUS but also that they be incorporated into the training of new endosonographers to ensure that all patients receive the highest quality care possible.

DISCLOSURES

Dr Wallace received research grant support from Olympus, BSCI, Ninepoint Medical, and US Endoscopy. Dr Shabeen, received research grant support from Covidien Medical, CSA Medical, and Takeda Pharmaceuticals. All other authors disclosed no financial relationships relevant to this publication.

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Abbreviations: ACG, American College of Gastroenterology; AJCC, American Joint Committee on Cancer; ASGE, American Society for Gastrointestinal Endoscopy; EUS-FNA, EUS-guided FNA; TNM, tumor, node, metastasis; UICC, Union for International Cancer Control.

This document is a product of the ASGE/ACG Task Force on Quality in Endoscopy. This document was reviewed and approved by the Governing Boards of the American Society for Gastrointestinal Endoscopy and the American College of Gastroenterology. It appears simultaneously in *Gastrointestinal Endoscopy* and the *American Journal of Gastroenterology*.



This document was reviewed and endorsed by the American Gastroenterological Association Institute.



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