Quality, competency and endosonography

D. O. Faigel
Oregon Health & Science University, Portland

For all of us committed to the practice of medicine, the provision of high-quality patient care has been of paramount importance. This is particularly true of invasive procedures where patients place their trust in us to provide a safe, accurate, and technically successful procedure, and that we will use the information gained to advance their health and well being. These principles apply especially to technically complex procedures such as endoscopic ultrasonography (EUS), which is often done in ill patients suffering from cancer.

There are several consequences to an improperly or incompetently performed EUS. The most obvious is patient injury such as perforation from the stiff transducer end of the echoendoscope [1]. But there are other, more likely and equally harmful, consequences. If the procedure is incomplete it may have to be repeated. Repeating the procedure exposes the patient to a second round of procedure-associated risks, and also results in delay in establishing a diagnosis and instituting therapy. The staging information gained from EUS is often used in making critical patient care decisions [2]. For example, at our institution we use EUS to stage esophageal cancers and select patients for surgery, palliation or neoadjuvant protocols, a practice which is not only cost effective but cost saving [3]. However, this algorithm presupposes that an accurate EUS staging has been made. An inaccurate exam could result in patient mismanagement, the receipt of unneeded treatments, or even the erroneous denial of life-saving therapy. And finally, the less-than-competent endosonographer may not have the training to recognize and manage complications, or recognize the limitations of EUS in making recommendations.

It is obvious that as patient advocates we should care about quality. But there are selfish reasons to do so as well. Proving one's competency and provision of high quality services will go a long way towards defense of any allegations of malpractice. By creating a quality "Report Card" experts may be able to differentiate themselves from their less-skillful competition [4]. It is possible, and even likely, that in the near future payers (e.g., insurance companies) will publish these report cards on the internet so that their subscribers (patients) may use them to select a doctor.

In the United States, these discussions surrounding quality have taken on a new dimension with the advent of "Pay for Performance". Pay for performance, or "P4P" is the buzzword on nearly everybody's lips with a financial stake in clinical medicine. The idea is that payers (in the US this would primarily be Medicare and private insurance companies) would financially reward practitioners who provide high-quality service. How this would work in practice is still being determined. But it will likely apply to endoscopic procedures in general, and possibly to EUS in specific.

How can we ensure that only high quality EUS procedures are performed? As a recent Chair of both the Standards of Practice Committee and the Quality Assurance Taskforce of the American Society for Gastrointestinal Endoscopy (ASGE), I spent considerable time pondering this question. The first step, I believe, begins with adequate training. The next is to ensure that only competent endosonographers are credentialed and given privileges to perform EUS. The endosonographer then needs an adequate case volume and mix to maintain clinical skills. And quality assurance programs based on measurable quality endpoints need to be in place.

Training

Through training, the endosonographer gains the necessary technical and cognitive skills. The technical skills ensure that safe, accurate and technically successful procedures are performed. Cognitive skills take the information gained from the EUS, and place it in the appropriate clinical context so that accurate diagnoses are made. With an accurate diagnosis, needed therapy can be provided, whether that therapy is endoscopic, medical or surgical. Additional goals of training include ensuring that only indicated EUS procedures are performed, sedation and analgesia are given competently, patient risk factors are identified, and steps taken to minimize the risks [5].

Guidelines on training in EUS have previously been published by the ASGE [6]. While it is beyond the scope of this article to go through training requirements in detail, a few points should be highlighted.

EUS is an extension of endoscopy. Only individuals who have already mastered standard forward-viewing endoscopic techniques should train in EUS. For this reason, ASGE recommends that trainees have completed at least 24 months of a standard GI fellowship or equivalent training and have demonstrated competence in standard endoscopy before undertaking this training. The training program must have at least one endosonographer who is acknowledged as an expert by his/her peers and is committed to teaching EUS. And as previously stated, both procedural and cognitive skills need to be taught.

The precise curriculum, the intensity and length of training, and minimum number of procedures have not been defined. The trainee should perform an adequate number of EUS examinations for each established indication sufficient to reliably and consistently interpret most EUS findings correctly. Therefore, at the completion of his or her training, the trainee should be able to perform all endosonographic procedures, including staging of gastrointestinal malignancies, with an accuracy similar to that found in published reports. Self-study and short courses by themselves are inadequate to achieve competency in EUS.

Correspondence: Douglas O. Faigel MD · Associate Professor of Medicine · Oregon Health & Science University · Physicians Pavilion Suite 310 · 3181 SW Sam Jackson Park Rd · Portland, OR, USA · 97239–3098 · Phone: 503-494-8577 · Fax: 503-494-7556 · E-mail: faigeld@ohsu.edu

Bibliography: Endoscopy 2006; 38 (S1): S65–S69 © Georg Thieme Verlag KG Stuttgart · New York · ISSN 0013-726X · DOI 10.1055/s-2006-946657

This document was downloaded for personal use only. Unauthorized distribution is strictly prohibited.

In the United States, the rigorous demands of EUS with expanding indications and new applications, has resulted in the establishment of a number of "third tier" training programs. These offer additional training beyond the standard 3-year GI fellowship. They may range in length from 3 – 12 months and may offer ERCP training as well. A major hurdle in establishing these programs is securing funding to pay the salary of the trainee (labor laws in the US generally do not allow "self-funding" by the trainee; i.e., no salary). I direct an EUS fellowship at our institution, Oregon Health & Science University. This is a 12-month intensive training program in EUS that is an additional (4th) year of training. EUS fellows perform 400 – 500 procedures and are trained in all aspects of diagnostic and interventional EUS.

Once training is completed, competency is assessed. When there are objective markers, such as surgical pathological staging of a tumor, these should be used. In centers that use neoadjuvant therapy, this may not be possible. In which case, trainee competence should be based on comparison of the endosonographic assessment of the instructor, when the instructor's level of competence is known, who should provide written support documenting the trainee's competency.

Ensuring competency through privileging

Competency is the minimal level of skill, knowledge, and/or expertise derived through training and experience that is required to safely and proficiently perform a task or procedure. When applied to EUS, this means that the endosonographer has gone through a period of training to develop the requisite skills and acquire the knowledge-base to safely perform, interpret, and correctly manage the findings of EUS procedures.

Privileging is the process by which local institutions authorize individuals to perform a specific procedure. Privileges for EUS should be determined separately from other endoscopic procedures such as EGD, colonoscopy and ERCP. Competence in one endoscopic procedure in no way ensures competence in another. Each institution should have specific guidelines regarding endoscopic privileging, and apply these guidelines uniformly to all applicants.

The ASGE has published detailed guidelines on privileging for endoscopic procedures including EUS [7,8]. The principles of EUS privileging developed by ASGE mandate that the trainee:

a) Must be able to integrate EUS into the overall clinical evaluation of the patient.
b) Should have sound general medical or surgical training.
c) Must have completed at least 24 months of a standard GI fellowship (or equivalent) and have documented competence in routine endoscopic procedures.
d) Must have a thorough understanding of the indications, contraindications, individual risk factors, and benefit-risk considerations for the individual patient.
e) Must be able to clearly describe the EUS procedure and obtain informed consent.
f) Must have knowledge of the gastrointestinal and surrounding anatomy as imaged by EUS, and of the technical features of the equipment, work station, and accessories.
g) Must be able to safely intubate the esophagus, pylorus, duodenum and colorectum, and obtain imaging of the desired organ or lesion.
h) Must be able to accurately identify and interpret EUS images and recognize normal and abnormal findings.
i) Must be able to perform imaging such as tumor staging in agreement with surgical findings or findings of the EUS trainer.
j) Must be able to document EUS findings and communicate with referring physicians.
k) Must competently perform those EUS procedures that were taught.

EUS is performed in several anatomic locations for various indications [9]. These include the evaluation and staging of mucosally based malignancies (esophagus, stomach, colon, rectum), evaluation of submucosal abnormalities, assessment of pathology involving the pancreas and bile ducts, and performance of EUS-guided FNA. It is recognized that a practitioner may be competent in one or more of these areas. ASGE has recommended that privileging should consider each of these areas separately. Training must be adequate for the major category for which privileges are sought. It is important to emphasize that performance of an arbitrary number of procedures does not guarantee competency. The number of supervised procedures necessary to obtain competency will vary between trainees. None-the-less, threshold numbers of procedures that should be performed before competency can be assessed have been proposed by the ASGE (Table **1**). It must be recognized that these are minimum numbers and that most trainees will require more, and never less, than this number to achieve competency. The numbers in Table **1** come from a review of the available literature and consensus of the ASGE Standards of Practice and Ad Hoc EUS Committees [7].

For those seeking privileges for mucosal lesions, a minimum of 75 cases is recommended. Accurate EUS imaging begins with being able to intubate the organ of interest and identify landmarks. In a prospective study, competent intubation of the upper GI tract was achieved in 1 to 23 procedures (median 1 – 2), with visualization of the gastric or esophageal wall in 1 to 47 procedures

Table **1** Minimum number of EUS procedures before competency can be assessed

Site/lesion	*No. of cases required*
Mucosal tumors (cancers of esophagus, stomach, rectum)	75
Submucosal abnormalities	40
Pancreaticobiliary	75
EUS-guided FNA Nonpancreatic*	25
Pancreatic†	25

For competence in imaging both mucosal and submucosal abnormalities, a minimum of 125 supervised cases is recommended.

For comprehensive competence in all aspects of EUS, a minimum of 150 supervised cases, of which 75 should be pancreaticobiliary and 50 EUS-guided FNA, is recommended.

* Intramural lesions or lymph nodes. Must be competent to perform mucosal EUS.

† Must be competent to perform pancreaticobiliary EUS.

Reprinted from Eisen GM, Dominitz JA, Faigel DO et al. Guidelines for credentialing and granting privileges for endoscopic ultrasound. Gastrointest Endosc 2001; 54:811 – 814, with permission from the American Society for Gastrointestinal Endoscopy.

This document was downloaded for personal use only. Unauthorized distribution is strictly prohibited.

(median 10–15). Evaluation of the celiac axis required 8 to 36 procedures (median 25) [10]. Studies on the learning curve for esophageal cancer staging have been reported. Fockens et al. [11] found that adequate staging accuracy was achieved only after 100 examinations, and Schlick et al. [12] found 75 cases to be the minimum to attain 89.5% T stage accuracy.

Evaluation of submucosal lesions may be done with echoendoscopes or through-the-scope catheter probes. Recognizing that some practitioners may wish only to be privileged for submucosal evaluation (such as with probes) the Standards of Practice committee set the threshold at 40 procedures, based on expert opinion [7].

The most challenging aspects of EUS are the evaluation of the pancreas and bile ducts and the performance of EUS guided FNA. In a prospective study, adequate imaging of the pancreas required 15 to 74 cases (median 34), and imaging of the bile and pancreatic ducts required 13 to 135 cases (median 55) [10]. A survey of the American Endosonography Club found that although technical competence in pancreaticobiliary imaging could be achieved in 94 cases, interpretive competence required 121 [13], whereas other expert opinion suggested 150 cases were needed for interpretative competence [14]. Given these complexities, ASGE recommends 75 pancreaticobiliary cases as the minimum.

For FNA, the targeted site may be pancreatic or non-pancreatic (lymph nodes or intramural masses). In general, pancreatic FNA is more difficult and is among the most challenging tasks in EUS. The ASGE recommendations of 50 EUS FNA (25 pancreatic and 25 non-pancreatic) has been recently assessed by one endosonographer and found to accurately reflect his training experience [15].

Comprehensive competence means that an endosonographer is proficient in all aspects of EUS. The ASGE recommends that individuals wishing comprehensive EUS privileges have completed a minimum 150 supervised procedures, of which 75 should be pancreaticobiliary, and 50 EUSguided FNA, at least 25 of which were of the pancreas. It is again important to emphasize that these are minimal threshold numbers that need to be completed before competency can be assessed. Completing this, or any threshold number, should not be taken to mean that the individual is competent to perform EUS. In most cases the trainee will need to have completed a number greatly in excess of the published thresholds. In my training program, I would not feel comfortable assessing competence in a trainee who had done fewer than 350–400 procedures.

Ensuring continued competence in EUS is the goal of recredentialling and renewal of privileges. Each institution should have policies on renewing privileges for EUS. Factors to consider include an adequate case volume, technical success and/or accuracy, complications, and participation in ongoing educational activities [16]. While the minimum number that represents an "adequate case volume" has not been defined, I feel that this should be no fewer than 50/year.

Quality Assurance

Quality assurance is a patient-centered process that seeks to provide patients with the best possible care. A high-quality EUS ensures that the patient receives an indicated procedure, that correct and clinically relevant diagnoses are made (or excluded), that therapy is properly performed, and that all these are accomplished with minimum risk.

The ASGE previously published a guideline on quality assessment in EUS [17]. More recently, I co-chaired with Irving Pike MD an ASGE/ACG Quality Assurance Taskforce. The taskforce was charged with creating measurable quality endpoints that could be used in quality assurance programs. Five documents were prepared, one of which specific to EUS, and will be published in Spring 2006.

A variety of EUS indicators were considered by the taskforce. Ultimately, 7 categories were selected based on literature review and expert consensus (Table **2**) [18]. Acceptable indications for EUS are in Table **3**. The strength of the literature supporting these indicators was graded as per Table **4**.

In a separate document, we considered endpoints common to all endoscopic procedures. These endpoints include patient risk stratification, performance of a preprocedure history and physi-

Table **2** Summary of ASGE/ACG proposed quality indicators for endoscopic ultrasound*

Quality Indicator	*Grade of Recommendation*
1. Proper indication (see Table **3.**)	3
2. Proper consent.	3
3. Prophylactic antibiotics for FNA of cystic lesions.	2C
4. Visualization of structures: A. In EUS for non-obstructing esophageal cancer, visualization of the celiac axis. B. In EUS for evaluation of suspected pancreatic disease, visualization of the entire pancreas.	3
5. Description of abnormalities: A. Gastrointestinal cancers should be staged with the TNM staging system. B. Pancreatic mass measurements should be documented. C. The wall layers involved by sub-epithelial masses should be documented.	3
6. When celiac axis lymph nodes are seen during EUS staging of a thoracic esophageal cancer, FNA is performed.	2C
7. The incidence of pancreatitis after EUS-FNA of the pancreas is measured.	1C

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

Reprinted from Jacobson BC, Chak A, Hoffman B et al. Quality indicators for endoscopic ultrasound. Gastrointest Endosc 2006;63 (4 part 2):S35-S38, with permission from the American Society for Gastrointestinal Endoscopy.

This document was downloaded for personal use only. Unauthorized distribution is strictly prohibited.

Table **3** Acceptable Indications for EUS

1. Staging of tumors of the GI tract, pancreas, bile ducts and mediastinum.
2. Evaluating abnormalities of the GI tract wall or adjacent structures.
3. Tissue sampling of lesions within, or adjacent to, the wall of the gastrointestinal tract.
4. Evaluation of abnormalities of the pancreas, including masses, pseudocysts and chronic pancreatitis.
5. Evaluation of abnormalities of the biliary tree.
6. Providing endoscopic therapy under ultrasonographic guidance.

Reprinted from Jacobson BC, Chak A, Hoffman B et al. Quality indicators for endoscopic ultrasound. Gastrointest Endosc 2006;63 (4 part 2):S35 – S38, with permission from the American Society for Gastrointestinal Endoscopy.

cal, plans to manage anticoagulants, and patient follow-up after the procedure [19]. A detailed consideration of these endpoints is beyond the scope of this paper.

These indicators represent endpoints that could be measured as part of a quality assurance program. Note that most are based on expert opinion. Thus validation may be required before a specific endpoint is adopted. Additional endpoints have been suggested by others, which may be worth considering [4,18].

Conclusion

As physicians, we have an obligation to provide for the health and well being of our patients. As patient advocates, we have an obligation to ensure that only high-quality and effective interventions are performed. EUS is a technically challenging procedure but one that offers substantial clinical benefits. However, in order to provide these benefits, EUS must be performed by competent expert endoscopists in an atmosphere that values high-quality services.

In this paper I have outlined the key principles to ensure high-quality EUS. These are adequate training to achieve competency, insurance of competency through privileging, and quality assurance through measurement of specific quality indicators. By adopting these principles, we can assure that our patients receive the high-quality and efficacious care they deserve.

References

1 Jacobson BC, Adler DG, Davila RE, Hirota WK, Leighton JA, Qureshi WA, Rejan E, Zuckerman MJU, Fanelli RD, Baron TH, Faigel DO. ASGE guideline: Complications of EUS. Gastrointest Endosc 2005; 61 (1): 8 – 12

2 Jacobson BC, Hirota W, Baron TH, Leighton JA, Faigel DO. The role of endoscopy in the assessment and treatment of esophageal cancer. Gastrointestinal Endoscopy 2003; 57 (7): 817 – 822

3 Shumaker DA, de Garmo P, Faigel DO. Potential impact of preoperative endoscopic ultrasound on esophageal cancer management and cost. Gastrointestinal Endoscopy 2002; 56: 391 – 396

4 Cotton PB, Hawes RH, Barkun A et al. Excellence in endoscopy: toward practical metrics. Gastrointest Endosc 2006; 63: 286 – 291

5 Faigel DO, Baron TH, Lewis B et al. Ensuring competence in Endoscopy. ASGE, 2005: Available at www.asge.org

6 Van Dam J, brady PG, Freeman M et al. Guidelines for training in endoscopic ultrasound. Gastrointest Endosc 1999; 49: 829 – 833

7 Eisen GM, Dominitz JA, Faigel DO et al. Guidelines for credentialing and granting privileges for endoscopic ultrasound. Gastrointest Endosc 2001; 54: 811 – 814

8 Eisen GM, Baron TH, Dominitz JA, Faigel DO et al. Methods of granting hospital privileges to perform gastrointestinal endoscopy. Gastrointest Endosc 2002; 55: 780 – 783

9 Chak A, Cooper GS. Procedure-specific outcomes assessment for endoscopic ultrasonography. Gastrointest Endosc Clin North Am 1999; 9: 649 – 656

10 Hoffman B, Wallace MB, Eloubeidi MA, Sahai AV, Chak A, van Velse A et al. How many supervised procedures does it take to become competent in EUS? Results of a multicenter three year study. Gastrointest Endosc 2000; 51: AB139

11 Fockens P, van den Brande JHM, van Dullemen HM, van Lanschot JJB, Tytgat GNJ. Endosonographic T-staging of esophageal carcinoma: a learning curve. Gastrointest Endosc 1996; 44: 58 – 62

12 Schlick T, Heintz A, Junginger T. The examiner's learning effect and its influence on the quality of endoscopic ultrasonography in carcinoma of the esophagus and gastric cardia. Surg Endosc 1999; 13: 894 – 898

Table **4** 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 methodolgic 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 methodolgic 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 becomes available.

* Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. Moving from evidence to action. Grading recommendations-a qualitative approach. In: Guyatt G, Rennie D eds. *Users' Guides to the Medical Literature*. Chicago: AMA press;2002. p. 599 – 608.

This document was downloaded for personal use only. Unauthorized distribution is strictly prohibited.

[13] Hoffman BJ, Hawes RH. Endoscopic ultrasound and clinical competence. Gastrointest Endosc Clin North Am 1995; 5: 879 – 884
[14] Boyce HW. Training in endoscopic ultrasonography. Gastrointest Endosc 1996; 43: S12 – 15
[15] Eloubeidi MA, Tamhane A, Wilcox CM. Endoscopic Ultrasound-guided Fine needle aspiration of solid pancreatic masses: a learning curve. Gastrointest Endosc 2004; 59: P231
[16] ASGE Guideline. Reneval of privileges. Gastrointest Endosc 1999; 49: 823 – 825
[17] Johanson JF, Cooper G, Eisen GM et al. Quality assessment of endoscopic ultrasound. Gastrointest Endosc 2002; 55: 798 – 801
[18] Jacobson BC, Chak A, Hoffman B et al. Quality indicators for endscopic ultrasonography. Gastrointest Endosc 2006; 63 (4 part 2): S35 – 38
[19] Faigel DO, Pike IM, Baron TH et al. Quality indicators for gastrointestinal endoscopic procedures: an introduction. Gastrointest Endosc 2006; 63 (4 part 2): S3 – 9

This document was downloaded for personal use only. Unauthorized distribution is strictly prohibited.