WHITE PAPER



Training in EUS and ERCP: standardizing methods to assess competence



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Postgraduate interventional endoscopy fellowships were created in response to the burgeoning portfolio of therapeutic endoscopy. 1,2 Many programs recognized that comprehensive training in ERCP and EUS could not be achieved within the 3-year curriculum of an Accreditation Council for Graduate Medical Education (ACGME)-accredited fellowship in gastroenterology, hepatology, and nutrition. Although these postgraduate fellowships initially focused on ERCP and/or EUS, these postgraduate fellowships have evolved to include various combinations of training in ERCP and EUS, complex endoscopic resection (eg, large polyp EMR and endoscopic submucosal dissection [ESD]), endoluminal stent placement, advanced closure techniques, and bariatric endoscopy. Although the breadth of training has increased, the duration of these training programs has remained the same or been shortened. Given the myriad procedures that trainees must learn and the central role of EUS and ERCP in these training programs, assessing competence in these advanced endoscopic procedures is vital. To achieve this goal, the use of validated, task-specific, skills-assessment tools is of paramount importance. The goals of this American Society for Gastrointestinal Endoscopy (ASGE) document are to (1) present the rationale and methods to assess competence in performing EUS and ERCP, (2) describe an evidence-based tool for the assessment of competence in EUS and ERCP, and (3) outline a means of tracking and assessing procedures that align with the competency-based medical education ACGME guidelines.

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EARLY DAYS OF COMPETENCE ASSESSMENT: A NUMBERS GAME

Advanced endoscopy training traditionally has been based on an apprenticeship model. At the end of this training period, in lieu of a formal assessment of competence, volume is often used as a surrogate for competence. It is instructive to understand how the various volume thresholds (to ensure procedural competence) were established. Initially, minimum ERCP volume recommendations were determined by expert opinion. This resulted in early guidelines recommending as few as 35 supervised ERCPs for cognitive and technical competence.³ Two of the first studies that attempted to correlate volume with competence were published in 1996.^{4,5} In 1 study of 20 trainees,4 the authors found that, even after 100 procedures, trainees did not consistently achieve a cannulation rate of >85%. Thus, the authors concluded that >100 ERCPs were needed to achieve competence in diagnostic ERCP; this recommendation was echoed in the contemporaneous ASGE Gastroenterology Core Curriculum. In a second study, Jowell et al⁵ assessed competence in a variety of ERCP-related skills including cannulation, stent insertion, and sphincterotomy. The authors similarly found that deep biliary cannulation was not reliably achieved by all trainees, but the data suggested that trainees who performed at least 180 ERCPs achieved competence in this specific skill. Subsequent ASGE and National Institutes of Health consensus guidelines published in 2002 recommended that competence be assessed—but cannot be assured—after 200 ERCP procedures and 150 EUS procedures.^{6,7} No measure to assess competence was offered. A recent systematic review of the literature on ERCP training showed that trainee competence was achieved across a wide range of procedure volumes (overall, 70-400; selective duct cannulation, 79-300; common bile duct cannulation rate, 160-400; and native papilla common bile duct cannulation, 350-400).^{8,9} There is little information on ERCP training of trainees who are not gastroenterologists. 10 Based on recent quality indicators in ERCP that established a threshold of 90% for cannulation of ducts of interest in native papilla cases, 11 it should be noted that the benchmark used in

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previous studies to define success in terms of cannulation rates (80%) may have been set too low.

There are few historical data on volumes required for trainees to achieve EUS competence. Early volume recommendations appeared to be based on expert opinion. In part, this is most likely because of the inability to identify a universally applicable endpoint relevant to EUS. Because cannulation is central to all ERCP procedures, selective cannulation rate has always been an attractive primary endpoint. A comparable metric in EUS is less clear: successful identification and characterization of the lesion of interest? adequate cellularity from FNA or biopsy? Given the myriad indications and unique challenges associated with EUS for different pathologies, 1 or both of these questions cannot be assigned to EUS procedures unambiguously. These data highlight the fact that procedure volume thresholds—or a 1 size fits all metric-are inadequate to assure competence. Taskspecific, direct observational assessment tools with strong evidence of validity and reliability are needed.

FROM VOLUME TO MILESTONES: HOW DID WE GET HERE?

Societal endoscopy credentialing guidelines have relied on the described limited available data to generate minimum procedure volumes wherein competence might be obtained (Tables 1 and 2). However, most current guidelines specify competence thresholds as opposed to absolute procedure volume requirements as a means to determine competence in EUS and ERCP, thresholds varying between guidelines. 12-18 A competence threshold is a minimum number of supervised procedures that a trainee is required to perform before competence can be assessed; an assessment of competence then requires direct observation and the use of objective criteria. The most recent document on privileging and credentialing in endoscopy by the ASGE suggests that at least 225 hands-on EUS cases and 200 supervised independent ERCP procedures (including 80 independent sphincterotomies and 60 biliary stent placements) should be performed before learner competence is assessed. 13 It should be noted that these guidelines are not validated, and these thresholds do not account for the variable rates at which trainees learn and acquire endoscopic skills. 19-21 Thus, these recommended volume thresholds generally have been accompanied by the caveat that a minimum volume of procedures cannot ensure competence. The thresholds remain valuable to guide training programs as to the minimum case volume they need to offer trainees and when they can realistically begin to make summative skill assessment of trainees based on objective criteria.

We recognize that reliance solely on minimum procedure volumes has a number of limitations because it would require several assumptions regarding training, specifically (1) all trainees learn at the same speed; (2) trainees learn all skills at the same speed; (3) all trainers are equivalent educators; (4) trainees are exposed to procedures of similar complexity and with comparable opportunities for supervised, hands-on learning; and (5) trainees acquire cognitive endoscopy skills at the same rate as technical skills. Because these assumptions are clearly unrealistic, it is imperative that we use more rigorous methodologies to assess competence.

Based on these limitations, there has been a greater emphasis on learning curves. One of the largest studies assessing competence in cannulation for 15 trainees was prospectively performed in the Netherlands.²² This demonstrated that trainees acquire competence in ERCP skills at variable rates based on the skill assessed. Specifically, this study recognized that trainees achieve competence in native papilla cannulation much later than other ERCP skills. Thus, competence assessment must account for the variable rates at which specific milestones are achieved. Results of a recent prospective multicenter study highlighted the learning curves in ERCP among advanced endoscopy trainees using a standardized assessment tool and cumulative sum (CUSUM) analysis. 19 This study demonstrated significant variability in the number of ERCPs performed during training and in the learning curves for cognitive and technical aspects of ERCP. We have previously demonstrated substantial variability in the number of procedures required to achieve competence in EUS and that a specific case load does not ensure trainee competence.²³

These findings parallel a growing movement in medical education. There is an increasing emphasis on standardizing competence assessments and demonstrating readiness for independent practice, as medical training in North America transitions from an apprenticeship model to competency-based medical education. The ACGME has replaced its reporting system with the Next Accreditation System, which is a continuous assessment reporting system focused on ensuring that specific milestones are reached throughout training, that competence is achieved by all trainees, and that these assessments are documented by training programs.

There has been an evolution in the definition of competence itself. ERCP competence traditionally has been defined as the ability to cannulate the duct of choice (selective cannulation). However, this important first step does not ensure procedural success and thus is an incomplete measure of competence. In contrast, successfully completing the entirety of a procedure is a more comprehensive measure of competence. Similarly, the trainer could use a global assessment of competence wherein he or she assesses trainee competence via a single question assessing technical and cognitive skill. Although these single composite competence measures are useful, their impact during training is limited, because they do not provide specific and directed feedback. Ideally, evaluation would assess performance on individual skills (eg,

TABLE 1. Guidelines for assessment of EUS competence*

	ASGE (United States)	FOCUS (Canada)	ESGE (Europe)	BSG (United Kingdom)
Year of publication	2017	2016	2012	2011
Total no. of supervised cases	225	250	NR	250
Pancreaticobiliary indication	NR	100	NR	150 (75 pancreatic cancer)
Luminal indication (mucosal)	NR	25 Rectal EUS	NR	80 (10 Rectal EUS)
Subepithelial lesion	NR	NR	NR	20
EUS-guided FNA	NR	50 (10 CPB, CPN)	50 (30 pancreatic)	75 (45 pancreatic)

ASGE, American Society for Gastrointestinal Endoscopy; FOCUS, Forum on Canadian Endoscopic Ultrasound; ESGE, European Society of Gastrointestinal Endoscopy; BSG, British Society of Gastroenterology; NR, not reported; CPB, celiac plexus block; CPN, celiac plexus neurolysis.

TABLE 2. Guidelines for assessment of competence in ERCP*

Society guidelines	Thresholds for assessment of competence
American Society for Gastrointestinal Endoscopy	200 supervised ERCPs; at least 80 independent sphincterotomies and 60 biliary stent placements
Gastroenterological Society of Australia and Canadian Association of Gastroenterology	200 unassisted ERCPs with native papillary sphincters, 80 independent sphincterotomies, and 60 stents
British Society of Gastroenterology	At least 300 ERCPs, with a cannulation rate of >80% (last 50 cases); must be competent in sphincterotomy, stone extraction, and stent placement

^{*}These numbers represent the minimum number of cases needed to be completed before competence can be assessed.

successful cannulation, stone extraction, stent placement) as well as the global assessment of competence.²⁴ Thus, the development of validated competence assessment tools is essential for both ERCP and EUS training.

In sum, a rigorous assessment of competence cannot rely on procedure volume. A minimum number of cases performed under supervision remains a necessary but insufficient step in the acquisition of competence. Instead, milestones such as native papilla cannulation success rates must be identified, assessment tools with strong validity evidence must be developed, and trainees must be assessed in a continuous fashion throughout fellowship. Furthermore, an ideal training program also would provide continuous feedback to trainees regarding which skills are lagging, so that trainees may seek additional educational opportunities.

THE STATUS OF TRAINING IN ADVANCED ENDOSCOPY IN THE UNITED STATES

ACGME requirements for advanced endoscopy training during an accredited 3-year fellowship are minimal: (1) there must be at least 1 key faculty member participating in advanced endoscopy procedures; (2) advanced endoscopy volumes must comply with ASGE guidelines; (3) fellows must receive adequate instruction in and exposure to these procedures so they can request them appropriately in clinical practice; and (4) hands-on exposure for fellows is not required (http://www.acgme.org/Portals/0/PDFs/FAQ/144 Gastroenterology FAQ.pdf). In contrast,

no similar criteria exist to define what must be present (ie, number of faculty members, numbers of advanced procedures performed) in a dedicated advanced endoscopy fellowship.

Data regarding the number of advanced endoscopy applicants, programs, and training content before 2012 are sparse. In an effort to standardize the process for applicants and programs, the ASGE established a match for advanced endoscopy fellowship programs in 2012 (www.asgematch.com). Since that time, the annual number of participating advanced endoscopy programs has been about 60, and the number of applicants has been about 110, resulting in program match rates of >90% and applicant match rates of <60%. Roughly 1 in 3 fellows graduating from an accredited ACGME fellowship program applies for an advanced endoscopy training position, despite the fact that these procedures comprise <10% of GI endoscopy practices.²⁵

In 2016, 97% and 100% of advanced fellowship programs included hands-on procedure volumes greater than the ASGE minimum for ERCP and EUS, respectively. In addition, all programs offered hands-on training in EMR and radiofrequency ablation. More than half of the programs also offered novel endoscopic interventions such as per-oral endoscopic myotomy, ESD, and bariatric endoscopy; however, the amount of hands-on exposure to these interventions is variable. Despite the broader spectrum of procedures offered in most U.S. advanced endoscopy programs, hands-on exposure to ERCP and EUS—usually considered the core disciplines in advanced

^{*}These numbers represent the minimum number of cases needed to be completed before competence can be assessed.

endoscopy—appears to exceed the ASGE guidelines. Still, the competence of graduates and the quality of care they provide after graduation remain poorly understood. Furthermore, little is known about the training composition for trainees intending to perform ERCP and/or EUS after a standard 3-year ACGME fellowship. Unlike in Australia and the United Kingdom, where societies attempt to tailor the number of trainees in ERCP and EUS to laborforce demands, no such processes have been attempted in the United States. For this reason, in many parts of the United States, advanced endoscopy services are not concentrated in high-volume facilities and with highvolume providers. 26,27 This is further reflected by lenient hospital guidelines for credentialing in ERCP: only 20% of U.S. hospitals required that a physician perform >200 ERCPs in order to receive credentials in their facilities.²⁸

Results from a recent, large, multicenter, prospective study showed that the median number of EUS examinations performed during advanced endoscopy training was 300 (range 155-650), with the vast majority of procedures being performed for pancreaticobiliary indications.²⁹ The median number of ERCP examinations performed per trainee was 350 (range 125-500), and the median number of ERCP examinations performed in patients with native papillae was 51 (range 32-79). The majority of examinations were performed for biliary indications and met the grade 1 ASGE degree of difficulty. The overall mean time allowed for cannulation in cases with a native papilla was 5.7 minutes, and for cases in which trainees failed cannulation it was 6.2 minutes. Overall, advanced endoscopy trainees have limited exposure to ERCPs for pancreatic indications, those requiring advanced cannulation techniques (eg, freehand needle-knife sphincterotomy) and interventional EUS procedures.

BACKGROUND ON TOOLS TO ASSESS COMPETENCE IN EUS AND ERCP

Given the technical complexity of ERCP, EUS, and other advanced endoscopic procedures, training has typically focused on technical aspects, such as cannulation and the diagnostic yield of FNA. Conceptually, competence in advanced endoscopy should be considered in 3 broad competence domains: (1) technical (psychomotor), (2) cognitive (knowledge and recognition), and (3) integrative (expertise and behavior).³⁰ Until recently, no instrument designed for ERCP, EUS, or any other advanced endoscopic procedure had incorporated all of these competence domains. In the United Kingdom, the Joint Advisory Group (JAG) has developed the direct observation of procedural skills (DOPS) program in colonoscopy and upper endoscopy. For colonoscopy, the DOPS instrument is used to assess performance in four domains: (1) assessment, consent, and communication; (2) safety and sedation; (3) endoscopic skills during insertion and withdrawal (the principal domain for assessing technical competence); and (4) diagnostic and therapeutic ability. These concepts can be transferred easily to ERCP and EUS, although these procedures are highly variable in their spectrum of indications and required maneuvers. EUS is particularly hampered by its poor interobserver variability, even among experts. Finally, the risks of ERCP often preclude adequate (even this requires definition) hands-on time—especially during cannulation.

Competence does not happen; it develops over time. As such, the ACGME Next Accreditation System requires training programs to continuously monitor trainee development from not yet assessable to ready for unsupervised practice (the target) or beyond (aspirational). There is a critical need for instruments specific to ERCP and EUS that incorporate the core competencies of the ACGME and include key technical aspects for each procedure. Additionally, endoscopy trainers must learn how to perform these assessments systematically and consistently. Given the risks specific to ERCP, EUS-guided FNA (EUS-FNA), and EUS-directed therapies, additional considerations include the use of simulators and careful patient triage throughout the training process (for example, a trainee's first attempt to cannulate a native papilla should not be a patient with complete pancreas divisum requiring minor papillary access).

ASSESSMENT OF COMPETENCE IN EUS AND ERCP BY USING A TASK-SPECIFIC TOOL WITH STRONG VALIDITY EVIDENCE

The ASGE recommends that advanced endoscopy programs consider using the EUS and ERCP Skills Assessment Tool (TEESAT) (Fig. 1), a competence assessment tool for EUS and ERCP with strong validity evidence. 19,23,24,29,31 This tool facilitates assessment and grading of technical and cognitive skills and development of global assessments in a balanced manner. It should be used in a continuous fashion throughout fellowship training but not consecutive examinations. This tool uses a 4-point scoring system: (1) (novice) unable to complete the task and requiring the trainer to take over, (2) (intermediate) achieves the task with multiple verbal instructions or hands-on assistance, (3) (advanced) achieves the task with minimal verbal instruction, and (4) (superior) achieves the task independently. Setting these anchors for specific skills and behaviors is critical to ensure that the grading process is reproducible from one assessor to the next. In addition, this tool includes a global rating scale (4-point scale) used to provide an overall assessment of the trainee: (1) learning basic technical and cognitive aspects but requires significant assistance and coaching, (2) acquired basic technical and cognitive skills but requires limited hands-on

<u>EUS</u>

□Radial □Linear □Both

Indication for EUS (mark all that apply):

□Pancreatic Mass	□Biliary dilation	□Abdominal/Mediastinal lymphadenopath;
□Possible subepithelial lesion	□Pancreatic Cyst	□Pancreatic Duct Dilation
□Luminal GI cancer staging		□Abdominal pain
□Rule Out CBD Stones	□Rule Out Chronic Pancreatitis	
□Other:		

ANCHORS

1(novice) = unable to complete requiring trainer to take over 2(intermediate) = achieves with multiple verbal instruction or hands on assistance 3(advanced) = achieves with minimal verbal instruction 4 (superior) = achieves independently N/T= not attempted for reasons other than trainee skill N/A= not applicable

EUS: Technical Aspects: If possible, trainee to receive one minute per station prior to first verbal instruction.

Intubation	1	2	3	4	N/T	N/A
AP window	1	2	3	4	N/T	N/A
Body of pancreas	1	2	3	4	N/T	N/A
Tail of pancreas	1	2	3	4	N/T	N/A
Head/neck of pancreas	1	2	3	4	N/T	N/A
Uncinate	1	2	3	4	N/T	N/A
Ampulla	1	2	3	4	N/T	N/A
Gallbladder	1	2	3	4	N/T	N/A
CBD/CHD (Trace CBD from hilum to ampulla)	1	2	3	4	N/T	N/A
Portosplenic confluence	1	2	3	4	N/T	N/A
Celiac axis	1	2	3	4	N/T	N/A

EUS: Technical Aspects:

Achieve FNA	1	2	3	4	N/T	N/A
Achieve celiac plexus block/ neurolysis	1	2	3	4	N/T	N/A

**Reasons for disqualification-e.g. obstructive esophageal mass, rectal EUS, intended limited exam (celiac plexus block/neurolysis)

Figure 1. The EUS and ERCP Skills Assessment Tool (TEESAT).

assistance and/or significant coaching, (3) able to perform independently with limited coaching and/or requires additional time to compete, and (4) competent to perform the procedure independently.

With regard to ERCP, TEESAT allows for documentation of the indication and the grade of difficulty by using the ASGE ERCP degree of difficulty grading system.³¹ The trainee is graded for basic maneuvers and all relevant technical and cognitive aspects of ERCP. Relevant

technical endpoints included the ability to perform deep cannulation of the desired duct, sphincterotomy, stone clearance, stent insertion, and advanced cannulation techniques (double-wire technique, placement of a pancreatic duct stent, precut sphincterotomy). The time allowed for the trainee to attempt cannulation is recorded. A clear distinction is made for grading of procedures for biliary versus pancreatic indications. Examples of cognitive endpoints include demonstration

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ANCHORS

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EUS: Cognitive Aspects

Identify lesion of interest or appropriately ruled out	1	2	3	4	N/T	N/A
Appropriate TNM stage	1	2	3	4	N/T	N/A
Characterize subepitheial lesion (wall layers)	1	2	3	4	N/T	N/A
Appropriate differential diagnosis	1	2	3	4	N/T	N/A
Appropriate management plan (FNA, refer to surgery, surveillance or no surveillance)	1	2	3	4	N/T	N/A

Global Overall Assessment:

Global Overall Assessment (subjective)								
1	4							
Novice: Learning basic technical & cognitive aspects, requires significant assistance & coaching	Acquired basic technical & cognitive skills but requires limited hands-on assistance and/or significant coaching	Able to perform independently with limited coaching and/or requires additional time to complete	Competent to perform procedure independently					

Immediate Post-Procedure Complications:

Procedure done in ambulatory setting?	□Yes	□No		
Patient admitted post-procedure?	□Yes If yes, □Pain re □Pancre	□No equiring hospita	alization	
	□ Bleedi	□ Mild ina	□Moderate	□ Severe
	□Perfora	pulmonary con	□Delayed nplications	

Recommendations for next procedure:

Figure 1. Continued.

of clear understanding of the indication, appropriate use of fluoroscopy, and a logical plan based on findings on cholangiography or pancreatography. With regard to EUS, trainees are graded based on all relevant cognitive and technical aspects. Technical aspects include clear identification of important landmarks at various EUS stations and performance of FNA. Cognitive aspects

include identification of the lesion of interest; appropriate tumor, node, metastases staging; development of an appropriate differential diagnosis; and a management plan. Immediate after-procedure adverse events are documented (Fig. 1A and B). The endpoints used in this tool parallel the key quality indicators established for EUS and ERCP.

ERCP

Indication for ERCP(mark all that apply):

Billary:		<u>Pancreatic:</u>
□Stent removal/change		□Stricture
□Suspected/established CBD stones		□Leak/fistula
□Post-transplant stricture		□Recurrent acute pancreatitis
Stricture		□Stent removal/change
□Benign □Malignant □	Indeterminate	□Suspected SOD
	Bismuth III □Bismuth IV	□Stone
□Bile leak		
Suspected sphincter of Oddi dysfund	etion	□Other:
Other:		
ASG	E ERCP Degree of Difficulty G	ade:
	Biliary:	
	<u>Dinary.</u>	
Grade 1	Grade 2	Grade 3
□Diagnostic cholangiogram	□Diagnostic cholangiogram with BII	□SOM
□Biliary brush cytology	anatomy	□Cholangioscopy
□Standard sphincterotomy	□Removal of CBD stones >10mm□	□Any therapy altered anatomy
□+/- removal of stones < 10mm	□Stricture dilation/stent for hilar	□Removal of intrahepatic stones with
☐Stricture dilation/stent for benign	tumors or benign intrahepatic	lithotripsy
extrahepatic stricture or bile leak	stricture or bile leak	
	Pancreatic:	
Grade 1	Grade 2	Grade 3
□Diagnostic pancreatogram	□Diagnostic pancreatogram with BII	SOM
□Pancreatic cytology	anatomy	□Pancreatoscopy
	☐Minor papilla cannulation	□Any therapy altered anatomy
		□All pancreatic therapy including
		pseudocyst drainage

ANCHORS

1(novice) = unable to complete requiring trainer to take over achieves with multiple verbal instruction or hands on assistance 3(advanced) = achieves with minimal verbal instruction 4 (superior) = achieves independently N/T = not attempted for reasons other than trainee skill N/A = not applicable

Maneuvers (ALL ERCPs):

Intubation	1	2	3	4	N/T	N/A
Achieving the short position	1	2	3	4	N/T	N/A
Identifying the papilla	1	2	3	4	N/T	N/A
Native papilla?		у	es		no	
Prior biliary sphincterotomy?		у	es		no	
Prior pancreatic sphincterotomy?		у	es		no	

**Reasons for disqualification-e.g. unable to perform due to medical instability or unable to reach papilla.

Figure 1. Continued.

ASSESSMENT SCHEDULE AND DATA COLLECTION

Assessments made by using this tool should be recorded immediately after completion of the procedure or as soon as reasonably possible and in a continuous fashion throughout training. The ASGE does not recommend grading every EUS and ERCP procedure but rather assessing

trainees periodically to ensure evaluation of at least 20% of the trainee's procedures, distributed throughout the training period. A variety of assessment schedules may be used: (1) after every fifth EUS and ERCP examination, (2) several consecutive assessments after completion of a set threshold of EUS and ERCP examinations (eg, evaluation of 5 consecutive cases after completion of 25 EUS and ERCP procedures), or (3) all procedures performed on a

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BILIARY ERCP ANCHORS

1(novice) = unable to complete requiring trainer to take over 2(intermediate) = achieves with multiple verbal instruction or hands on assistance 3(advanced) = achieves with minimal verbal instruction 4 (superior) = achieves independently N/T= not attempted for reasons other than trainee skill N/A= not applicable

Technical Aspects

Stent removal?		yes		no
Evaluate stent removal if performed by trainee:	1	2 3	4	
Did trainee attempt cannulation?		yes		no
Time to attempt cannulation of first duct of interest for trainee				
(To start when cannulating device out of duodenoscope)? (in minutes)				
Cannulation achieved? (Achieved deep cannulation with contrast visualization)		yes		no
Evaluate cannulation if performed by trainee:	1	2 3	4	
Inadvertent cannulation of pancreatic duct by trainee?		yes		no
Sphincterotomy performed during procedure?		yes		no
Evaluate sphincterotomy if performed by trainee:	1	2 3	4	

Advanced Cannulation Techniques

(Double-wire, PD Stent placement, Pre-cut sphinceteromy)

Double-wire used to cannulate bile duct	□ yes □ no
Wire placed in pancreatic duct?	1 2 3 4 N/T N/A
Cannulation of CBD achieved?	□ yes □ no
PD stent placed to facilitate BD cannulation?	□ yes □ no
Wire placed in PD?	1 2 3 4 N/T N/A
PD stent placement?	1 2 3 4 N/T N/A
Cannulation of CBD achieved?	□ yes □ no
Pre-cut sphinceterotomy?	□ yes □ no
Evaluate pre-cut sphinceterotomy if performed by trainee:	1 2 3 4 N/T N/A

Technical Aspects

Wire placement in desired location in the bile duct?		уe	es	I	□ no	
(e.g. desired liver segment, cystic duct) Evaluate wire placement if performed by trainee:	1	2	3	4	N/T	N/A
Balloon sweep	1	2	3	4	N/T	N/A
Use of basket	1	2	3	4	N/T	N/A
Mechanical lithotripsy	1	2	3	4	N/T	N/A
Stone clearance	1	2	3	4	N/T	N/A
Stricture dilation	1	2	3	4	N/T	N/A
Stent insertion	1	2	3	4	N/T	N/A

Cognitive Aspects

Fellow demonstrated clear understanding of indication of procedure?				4	N/T	N/A
Cholangiogram Appropriate use of fluoroscopy?	1	2	3	4	N/T	N/A
Proficient use of real time cholangiogram interpretation and ability to identity nature of pathology (stone, stricture, leak, etc.)?	1	2	3	4	N/T	N/A
Logical plan based on cholangiogram findings?	1	2	3	4	N/T	N/A
Fellow demonstrated clear understanding for appropriate use of rectal indomethacin?	1	2	3	4	N/T	N/A

Figure 1. Continued.

specific day of the week. It makes intuitive sense that the precision of the assessments will increase with more evaluations, thereby helping identify trainees surpassing, meeting, or lagging behind expected milestones.³² Such a process would help programs tailor the latter phases of training to address deficiencies among those requiring

remediation. The program director should ensure that all trainers and trainees are familiar with TEESAT's specific assessment parameters and score definitions. Past experience suggests that, once trainers are familiar with this assessment tool, completing this form requires less than 2 minutes.

PANCREATIC ERCP ANCHORS

1(novice) = unable to complete requiring trainer to take over 2(intermediate) = achieves with multiple verbal instruction or hands on assistance 3(advanced) = achieves with minimal verbal instruction 4 (superior) = achieves independently N/T= not attempted for reasons other than trainee skill N/A= not applicable

Technical Aspects

Stent removal?		ye	s		no	l
Evaluate stent removal if performed by trainee:	1	2	3	4		
Did trainee attempt cannulation?		ye	s		no	
Time to attempt cannulation of first duct of interest for trainee						
(To start when cannulating device out of duodenoscope)? (in minutes)						
Cannulation achieved? (Achieved deep cannulation with contrast visualization)		ye	s		no	
Evaluate cannulation if performed by trainee:	1	2	3	4		
Sphincterotomy performed during procedure?		ye	s		no	I
Evaluate sphinceterotomy if performed by trainee:	1	2	3	4	N/T	N/A
Balloon sweep	1	2	3	4	N/T	N/A
Use of basket	1	2	3	4	N/T	N/A
Stone clearance	1	2	3	4	N/T	N/A
Stricture dilation	1	2	3	4	N/T	N/A
Stent insertion?		ye	s			no
Evaluate stent insertion if performed by trainee:	1	2	3	4		

Cognitive Aspects

Fellow demonstrated clear understanding of indication of procedure	1	2	3	4	N/T	N/A
Pancreatogram Appropriate use of fluoroscopy	1	2	3	4	N/T	N/A
Ability to identity nature of pathology (stone, stricture, leak, etc.)	1	2	3	4	N/T	N/A
Logical plan based on pancreatogram findings	1	2	3	4	N/T	N/A
Fellow demonstrated clear understanding for appropriate use of rectal indomethacin?	1	2	3	4	N/T	N/A

Figure 1. Continued.

CUSUM analysis has been applied to create learning curves with regard to overall and individual technical and cognitive endpoints in EUS and ERCP for each trainee. By continuously studying the control charts, the performance of each trainee is compared to a predetermined standard, allowing for the detection of negative trends and enabling earlier feedback (ie, retraining or continued observation). 19,23 This approach to assessing competence has been described widely in healthcare and specifically in the field of endoscopic procedure learning (upper endoscopy, colonoscopy, EUS, ERCP, and advanced imaging techniques). 19,23,24,33-39 A rating of 3 (minimal verbal cues) or 4 (no assistance) for individual endpoints is considered a success, whereas a rating of 1 or 2 is considered a failure. For the 4-point global rating scale, success is defined as a score of 3 or 4. The overall scores for the entire ERCP and EUS procedures are calculated as the

median performance for all endpoints. This results in 3 possible scenarios: (1) if the CUSUM plot falls below the acceptable line of failure rate, the trainee has achieved competence; (2) if the CUSUM plot rises above the unacceptable line, the performance is considered unacceptable, and remediation is recommended; and (3) if the plot stays between the 2 boundary lines, no conclusion can be drawn, and further training is recommended. In addition to overall EUS and ERCP performance, comprehensive learning curves may be created for individual technical and cognitive endpoints.

An integrated, comprehensive system has been created that demonstrates the feasibility of data collection and addresses the reporting needs of this project, which include streamlining data collection from training programs and applying CUSUM analysis.²⁹ A combination of an application programming interface, REDCap,⁴⁰ and SAS

Global Overall Assessment:

Global Overall Assessment (subjective)							
1	2	3	4				
Novice: Learning basic technical & cognitive aspects, requires significant assistance & coaching	Acquired basic technical & cognitive skills but requires limited hands-on assistance and/or significant coaching	Able to perform independently with limited coaching and/or requires additional time to complete	Competent to perform procedure independently				

Immediate Post-Procedure Complications:

Procedure done in ambulatory setting?	□Yes	□No		
Patient admitted post-procedure?		□No equiring hospit	alization	
	□ Pancr	□ Mild	□Moderate	□ Severe
	□Perfor □Cardio □Mortal □Other:	opulmonary co lity	□Delayed mplications	

Recommendations for next procedure:

Figure 1. Continued.

(v. 9.3, SAS Institute, Cary, NC) can be used to generate graphic representations of overall and individual endpoint learning curves by using CUSUM analysis on demand. Access to these data is controlled by a custom module that determines authentication and role-based levels of access. All users of the site can have unique logins and, based on their logins, program directors and trainees can then view individual learning curves and compare results with reference standards. This infrastructure could be used by all advanced endoscopy training programs in the future.

Validation data

In a recent multicenter prospective study assessing learning curves in EUS and ERCP, using the earlier described novel comprehensive data collection and reporting system, we demonstrated the feasibility of creating a national centralized database that allows for continuous monitoring and reporting of individualized learning curves on demand.²⁹ The results of this study also confirmed the

substantial variability in learning curves among trainees in EUS and ERCP, thus validating the shift from use of volume thresholds to use of well-defined and validated performance metrics for determination of competence.

This infrastructure has the potential to help program directors and trainers identify specific skill deficiencies among trainees, thus facilitating development of tailored, individual remediation. Documenting milestones and competence benchmarks will facilitate the ability of training programs to ultimately demonstrate that trainees have attained the technical and cognitive skills required for safe and effective unsupervised practice in EUS and ERCP.²⁹ Importantly, health systems could rely on quantitative data to inform decisions regarding initial credentialing.

Future directions

In order to allow for widespread adoption of this tool, creating a centralized national database that provides learning curves to program directors and trainees on demand or on a periodic basis (quarterly) would be ideal.

Moving forward, there is a need to establish a standardized advanced endoscopy training curriculum and minimum standards for advanced endoscopy training programs (structure, process, and outcomes measures). Minimum standards should help ensure adequate training in advanced endoscopy and, in theory, facilitate the process of trainee assessment through competency-based milestones. The role of simulators in EUS and ERCP training needs to be clarified by future randomized controlled trials assessing whether their use can "bend" learning curves and lead to a reduction in the number of procedures required to achieve competence (and potentially a reduction in adverse events) or perhaps be used as objective measures of skill or competence. The impact of structured feedback on trainee learning curves and quality indicators in EUS and ERCP^{11,41} during the first year of independent practice for trainees has not been evaluated. This is an important component of construct validity for the proposed evaluation tool and a novel Web-based comprehensive data collection and reporting system. Addressing this priority research question along with validation of described results are the primary aims of an ongoing prospective multicenter trial (RATES 2-clinicaltrials.gov NCT02509416). An ongoing multicenter study (clinicaltrials.gov NCT02476279) also will address the association between trainee participation and after-procedure adverse events assessed at a 30-day follow-up period. Future studies need to establish training pathways, learning curves, and competence thresholds in advanced EUS and ERCP procedures.

TEESAT is a part of the ASGE's effort to standardize assessment of competence in EUS and ERCP. Widespread implementation of this standardized approach to assessing competence has the potential to allow us to ensure that trainees attain the skills necessary for independent practice.

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Abbreviations: ACGME, Accreditation Council for Graduate Medical Education; ASGE, American Society for Gastrointestinal Endoscopy; CUSUM, cumulative sum; ESD, endoscopic submucosal dissection; EUS-FNA, EUS-guided FNA; TEESAT, The EUS and ERCP Skills Assessment Tool.

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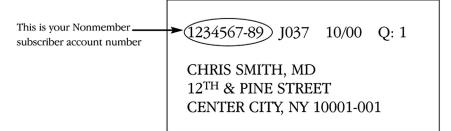
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