## **Supplementary Text**

# Competency-Assessment Tool and Grading Protocol

For ERCP, relevant technical end points included ability to perform deep cannulation of the desired duct, sphincterotomy, stone clearance, stent insertion, and advanced cannulation techniques (double-wire technique, placement of pancreatic duct, precut sphincterotomy). Examples of cognitive end points included demonstration of clear understanding of indication, appropriate use of fluoroscopy, and logical plan that was based on cholangiogram/pancreatogram findings.

For EUS, technical aspects included clear identification of important landmarks at various EUS stations and performance of FNA. Cognitive aspects included identification of lesion of interest, appropriate TNM (tumor, node, metastases) stage, and appropriate differential diagnosis and management plan.

# Comprehensive Data Collection and Reporting System

This centralized database was stored at the University of Colorado's instance of REDCap (Research Electronic Data Capture, Vanderbilt University, Nashville, TN) that resided on a local secure server. Data regarding grading of EUS and ERCP exams were entered by research coordinators at all participating centers into the REDCap database. By using a combination of an Application Programming Interface, REDCap, and SAS (v.9.3; SAS Institute, Cary, NC), graphic representations of overall and individual end point learning curves were generated by using CUSUM on demand. Access to these data was controlled by a custom module that determined authentication and role-based levels of access.

## Statistical Analysis

By continuously studying the control charts, the performance of each individual trainee was compared with a predetermined standard, allowing for the detection of negative trends and enabling earlier feedback (which consisted of either re-training or continued observation) This approach to assess competence has been widely described in healthcare and specifically in the field of endoscopic procedure learning (upper endoscopy, colonoscopy, EUS, ERCP, and advanced imaging techniques).<sup>1-11</sup> Bolsin and Colson<sup>11</sup> published a summary of CUSUM analysis, which is summarized as follows. Successful procedures are given a score of s, and failed procedures are given a score of 1 - s. These values are based on pre-specified acceptable failure rates (p0, level of inherent error if procedures are performed competently) and unacceptable failures rates (p1, where

p1-p0 represents the maximum acceptable level of human error). For this study, we used p0 = 0.1 and p1 = 0.3. CUSUM scores were then calculated by using the following formulas:  $P = \ln (p1/p0)$ ;  $Q = \ln [(1-p1)/p0]$ (1-p0); and s = Q/(P+Q) = 0.15, and 1- s = 0.85. The CUSUM curve was created by plotting the cumulative sum after each case against the index number of that case, and Cn is the sum of all individual outcome scores. The CUSUM graph was designed to signal when Cn crosses predetermined limits. These limits are displayed as horizontal lines of the graph and calculated on the basis of the risk for type I ( $\alpha$ ) and type II ( $\beta$ ) error, which was set at 0.1 for this analysis. The formulae for H0 and H1 are as follows: H1 = a / (P+Q) and H0 = -b / (P+Q), where  $a = \ln[(1 - \beta)/\alpha]$  and  $b = \ln[(1 - \alpha)/\beta]$ . If the CUSUM plot fell below the acceptable line, the performance was acceptable with the predetermined type II error; if the CUSUM plot rose above the unacceptable line, the performance was considered unacceptable; if the plot stayed between the 2 boundary lines, no conclusion could be drawn, and further training was recommended.

The strength of rater agreement was categorized by using criteria proposed by Landis and Koch<sup>12</sup>: 0.00–0.20, slight; 0.21–0.40, fair; 0.41–0.60, moderate; 0.61–0.80, substantial; 0.81–1.00, almost perfect.

## **Results**

## Sensitivity Analyses

A smaller proportion of AETs achieved competence in the overall technical and cognitive aspects of EUS and ERCP and individual end points. Similar results were noted when learning curves were analyzed by using a more stringent acceptable failure rate of 5% and unacceptable failure rates of 10%–20% (data not shown).

## Discussion

Approximately 50% of AETs planned to practice at academic medical centers. This appears to be in line with results from a recent study surveying recent advanced endoscopy fellowship graduates, which found that slightly more than half were in academic practices. With regard to ERCP volume, 39% of those in private practice and 65% of those in academic practice were performing >200 ERCPs/year. This study also found that there was a strong perception that the job market was saturated for AETs, with most programs having difficulty placing their AETs in advanced endoscopy positions.<sup>13</sup> This raises into question the potential lack of career options for AETs, the ability to attain the volume of cases needed in the first year to grow skills, and whether there are currently too many advanced endoscopy training programs.

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questionnaire.

## The EUS and ERCP Skills Assessment Tool (TEESAT)

Institu	ntion <u>:</u> Assigned Code: Advanced Endoscopy Trainee Baseline Questionnaire	
1.	<u>When and where did you complete your general GI fellowship?</u>	
2.	Did you receive any formal training on the cognitive aspects for EUS? $\bigcirc$ yes $\square$ no	
	If yes, <u>please elaborate</u> :	
3.	Did you perform any EUS exams with <u>hands on experience during your general GI fellowship?</u>	
	O yes □ no If yes, <u>how many</u> EUS exams did you perform during your general GI fellowship?	
4.	Did you receive any formal training on the cognitive aspects for ERCP?	
	O yes □ no If yes, <u>please elaborate</u> :	
	□Lectures □Consult Service □Clinic □ Conferences	
5.	Did you perform any ERCP exams with <u>hands on experience during your general</u> GI fellowship?	
	O yes □ no	
	If yes, <u>how many</u> ERCP exams did you perform during your general GI fellowship?	Supplementary Figure 1. Baseline

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## Post Study Assessment

#### Advanced Endoscopy Fellowship Year:

- 1. How many EUS procedures did you perform during your fellowship?
- 2. How many ERCP procedures did you perform during your fellowship?
- 3. I feel comfortable with independently performing ERCP at the end of my advanced endoscopy training (please circle an answer below)
  - □ strongly agree □ tend to agree □ neutral □ tend to disagree □ strongly disagree
    - a. How comfortable do you feel with performing sphincterotomy?
       a. strongly agree 
       a tend to agree 
       a neutral 
       bend to disagree 
       beta strongly disagree
    - b. How comfortable do you feel with stone clearance (<1cm)?</li>
       strongly agree 
       tend to agree 
       neutral 
       tend to disagree 
       strongly disagree
    - c. How comfortable do you feel with placement of biliary stents?
      strongly agree 
      tend to agree 
      neutral
      tend to disagree
      strongly disagree
    - d. How comfortable do you feel with placement of pancreatic stents?
      - □ strongly agree □ tend to agree □ neutral □ tend to disagree □ strongly disagree
- 4. I feel comfortable with independently performing EUS as the end of my advanced endoscopy training (please circle an answer below)

□strongly agree □ tend to agree □ neutral □ tend to disagree □ strongly disagree

- a. How comfortable do you feel in performing EUS-FNA?
- □ strongly agree □ tend to agree □ neutral □ tend to disagree □ strongly disagree
- b. How comfortable do you feel in performing CPB/CPN?
- □ strongly agree □ tend to agree □ neutral □ tend to disagree □ strongly disagree
- c. How comfortable do you feel in placement of fiducials?
- □ strongly agree □ tend to agree □ neutral □ tend to disagree □ strongly disagree
- 5. Did the learning curves provided by this study enhance your advanced endoscopy

fellowship (please circle an answer below)?

□strongly agree □ tend to agree □ neutral □ tend to disagree □ strongly disagree Comments:

#### First Year of Independent Practice:

- 1. What type of environment will you be practicing in (circle one)?
  - a. Academic
  - b. Private
  - c. Combination of academic and private practice
- Will you be joining a practice with a senior partner who performs high volume ERCP and/or EUS?

#### Yes or No

3. What % of your job will be "advanced" endoscopy?

0%, 1-25%, 26-50%, 51-75%, >75%

- 4. How many EUS procedures do you estimate you will perform in the first year of independent practice?
- 5. How many ERCP procedures do you estimate you will perform in the first year of independent practice?

**Supplementary Figure 2.** Post-study questionnaire.

## EUS

#### Assigned Code:\_ **Indication for EUS (mark all that apply):**

□Other:

□Radial □Linear

□Panc Mass □Panc Cyst □Abdominal pain

□PD Dilation Luminal GI cancer

Biliary dilation Abdominal/Mediastinal lymphadenopathy Possible subepithelial lesion Mediastinal mass

### **EUS: Technical Aspects:**

1(superior) = achieves without instruction 2(advanced) = achieves with minimal verbal cues 3(intermediate) = achieves with multiple verbal cues or hands on assistance 4 (novice) = unable to complete N/T = not attempted N/A = not applicable

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

#### **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 subepithelial 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

## The EUS and ERCP Skills Assessment Tool (TEESAT)

#### **Overall Assessment:**

Overall Assessment (subjective)											
1	2	3	4	5	6	7	8	9	10		
Below a	verage for	· level of	Average	for level o	f training	Above a	verage for	r level of	Superior for level of		
	training						training		training		

#### **Immediate Post-Procedure Complications:**

Procedure done in ambulatory setting? **□**Yes ∎No

Patient admitted post-procedure? Yes □No

> If yes, □Pain requiring hospitalization Pancreatitis □ Mild □Moderate Severe Bleeding □Immediate Delayed Perforation Cardiopulmonary complications □ Mortality DOther:

Supplementary Figure 3. The EUS and ERCP Skills Assessment Tool (TEESAT).

## **ERCP**

Assigned Code:\_\_\_\_

## Indication for ERCP(mark all that apply):

<u>Biliary:</u>			<u>Pancreatic:</u>					
□ Stent remova	l/change				□Stricture			
□ Suspected/es	tablished C	BD stones			□Leak/fistula			
Dest-transpla	nt stricture				Recurrent acute pancreatitis			
□ Stricture					■Stent removal/change			
∎Beni	gn	∎Malignant	□Indeterminate		□Suspected SOD			
∎Bism	nuth I	<b>□</b> Bismuth II	<b>□</b> Bismuth III	<b>□</b> Bismuth IV	□Stone			
<b>□</b> Bile leak					Minor papilla endotherapy			
□ Cholangioscop	рy				■Pancreatoscopy			
□Suspected sph	incter of Oc	ldi dysfunction			□Other:			
□Other:								
<b>FAILED ERCP from outside center?</b> DYes  No								

**<u>FAILED ERCP</u>** from outside center? **D**Yes

If yes, **D**Biliary **D**Pancreatic

## **ASGE ERCP Degree of Difficulty Grade:**

## **Biliary:**

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
$\Box$ +/- 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	DSOM
Pancreatic cytology	anatomy	Pancreatoscopy
	Minor papilla cannulation	Any therapy altered anatomy
		All pancreatic therapy including
		pseudocyst drainage

## Maneuvers (ALL ERCPs):

1(superior) =achieves without instruction 2(advanced) =achieves with minimal verbal cues 3(intermediate) = achieves with multiple verbal cues or hands on assistance 4 (novice) = unable to complete

## **N/T**= not attempted **N/A**= not applicable

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?	🗖 yes 🗖 no
Prior biliary sphincterotomy?	🗖 yes 🗖 no
Prior pancreatic sphincterotomy?	🗖 yes 🗖 no

### Supplementary Figure 3. Continued

## **BILIARY ERCP**

## **Technical Aspects**

1(superior) = achieves without instruction2(advanced) = achieves with minimal verbal cues3(intermediate) = achieves with multiple verbal cues or hands on assistance4 (novice) = unable to completeN/T= not attemptedN/A= not applicable

Stent removal	1 2 3 4 N/T N/A
Cannulation- Contrast visualization of bile duct	1 2 3 4 N/T N/A
Inadvertent cannulation of pancreatic duct	🗖 yes 🗖 no
Sphincterotomy	🗖 yes 🗖 no
<u>If yes</u>	1 2 3 4 N/T N/A
Wire placement in desired (biliary) duct?	🗖 yes 🗖 no
<u>If yes</u>	1 2 3 4 N/T N/A
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
Cannulation of CBD?	1 2 3 4 N/T N/A
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
Cannulation of CBD?	1 2 3 4 N/T N/A
Pre-cut sphincterotomy?	1 2 3 4 N/T N/A

Time to attempt cannulation of first duct of interest for trainee (To start when cannulating device out of

duodenoscope)? \_\_\_\_\_\_(in minutes)

If trainee cannulation failed, did supervisor succeed? 🗖 yes 🗖 no

Time for attending to achieve cannulation?\_\_\_\_\_\_ (in minutes)

Technique used to achieve cannulation?

□Regular cannulation □Double-wire □PD Stent placement

□Pre-cut sphincteromy

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**

1(superior) = appropriate knowledge, requires no instruction2(advanced) = achieves with minimal verbal cues3(intermediate) = achieves with multiple verbal cues4 (novice) = poor knowledge unable to achieve endpointN/T = not attemptedN/A = not applicable

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

#### Supplementary Figure 3. Continued

## PANCREATIC ERCP

### **Technical Aspects**

1(superior) =achieves without instruction 2(advanced) =achieves with minimal verbal cues
 3(intermediate) = achieves with multiple verbal cues or hands on assistance
 4 (novice) =unable to complete N/T= not attempted N/A= not applicable

Stent removal	1 2 3 4 N/T N/A
Cannulation-contrast visualization of pancreatic duct?	🗖 yes 🗖 no
Cannulation	1 2 3 4 N/T N/A
Sphincterotomy	🗖 yes 🗖 no
<u>If yes</u>	1 2 3 4 N/T N/A
Wire placement in desired (pancreatic) duct?	🗖 yes 🗖 no
lfyes	1 2 3 4 N/T N/A

Time to attempt cannulation of first duct of interest for trainee (To start when cannulating device out of

#### duodenoscope)? \_\_\_\_\_(in minutes)

If trainee cannulation failed, did supervisor succeed? 
yes no

Time for attending to achieve cannulation?\_\_\_\_\_\_ (in minutes)

Technique used to achieve cannulation?

□Regular cannulation □Double-wire □PD Stent placement □Pre-cut sphincteromy

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?		у	es			no
<u>If yes</u>	1	2	3	4	N/T	N/A

## **Cognitive Aspects**

 1(superior) = appropriate knowledge, requires no instruction
 2(advanced) = achieves with minimal verbal cues

 3(intermediate) = achieves with multiple verbal cues 4 (novice) = poor knowledge unable to achieve endpoint

 N/T= not attempted
 N/A= not applicable

Fellow demonstrated clear understanding of indication of procedure	1	2	3	4	N/T	N/A
Pancreatogram	1	2	3	4	N/T	N/A
Appropriate use of fluoroscopy						2
Ability to identify 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	1	2	3	4	N/T	N/A
indomethacin?						

### The EUS and ERCP Skills Assessment Tool (TEESAT)

#### **Overall Assessment:**

Overall Assessment (subjective)									
1	2	3	4	5	6	7	8	9	10
Below average for level of		Average for level of training			Above average for level of			Superior for level of	
training						training		training	

### **Immediate Post-Procedure Complications:**

Procedure done in ambulatory setting? Yes No

Patient admitted post-procedure?

∎Yes ∎No

If yes, Pain requiring hospitalization Pancreatitis Mild Moderate Severe Bleeding Immediate Delayed Perforation Cardiopulmonary complications Mortality Other:\_\_\_\_\_\_

Supplementary Figure 3. Continued



Supplementary Figure 4. Cannulation rates with time.



**Supplementary Figure 5.** Scatter plot demonstrating no change in the time allowed for the advanced endoscopy trainee to cannulate cases with a native papilla during the 1-year training period.

#### Supplementary Table 1. List of Participating Advanced Endoscopy Training Programs

Institution	Location
University Hospitals Cleveland Medical Center	Cleveland, Ohio
Carolinas Medical Center	Charlotte, North Carolina
University of Virginia Health System	Charlottesville, Virginia
Icahn School of Medicine Mount Sinai	New York, New York
Henry Ford Hospital	Detroit, Michigan
Moffitt Cancer Center	Tampa, Florida
Washington University School of Medicine	St Louis, Missouri
Geisinger Medical Center	Danville, Pennsylvania
Indiana University	Indianapolis, Indiana
University of Texas Southwestern	Dallas, Texas
Northwestern University	Chicago, Illinois
University of Colorado	Aurora, Colorado
Vanderbilt University	Nashville, Tennessee
University of Wisconsin	Madison, Wisconsin
University of California, Los Angeles	Los Angeles, California
Digestive Diseases Institute at Virginia Mason Medical Center	Seattle, Washington
Dartmouth Hitchcock Medical Center	Lebanon, New Hampshire
University of Kansas	Kansas City, Kansas
Brigham and Women's Hospital	Boston, Massachusetts
The University of Texas Health Science Center at San Antonio	San Antonio, Texas

## Supplementary Table 2. Comparison of Competence in EUS and ERCP by Using TEESAT and a Global Rating Scale

Stu	No. of AETs meeting inclusion criteria	No. of evaluations	No. of AETs achieving competence (%), primary analysis <sup>a</sup>	No. of AETs achieving competence (%), sensitivity analysis <sup>b</sup>
EUS				
Overall technical	17	1070	14 (82.3)	11 (64.7)
Overall cognitive	17	1061	13 (76.4)	8 (47)
Global rating scale	17	1066	10 (58.8)	0 (0)
ERCP biliary				
Overall technical	20	2259	12 (60)	5 (25)
Overall cognitive	20	2268	20 (100)	17 (85)
Global rating scale	20	2263	10 (50)	1 (5)

<sup>a</sup>Primary analysis: success defined as score of 1 or 2 (no assistance/minimal verbal cues); acceptable failure rate, p0 = 0.1 and unacceptable failure rate, p1 = 0.3. Global rating scale: success defined as score of 7–10.

<sup>b</sup>Sensitivity analysis: success defined as score of 1 (stringent definition of success); global rating scale: success defined as score of 10.

Supplementary Table 3. Results	of the Post-Study Questic	onnaire Assessing	Comfort Level in	n EUS and ERCP	After
Comple	tion of Advanced Endosco	py Training			

Post-training questions	Strongly agree, % (n)	Tend to agree (n)	Neutral, % (n)	Tend to disagree, % (n)	Strongly disagree, % (n)
I feel comfortable independently performing ERCP	53.8 (7)	46.2 (6)	0 (0)	0 (0)	0 (0)
I feel comfortable with deep cannulation of duct of interest	53.8 (7)	38.5 (5)	7.7 (1)	0 (0)	0 (0)
I feel comfortable performing sphincterotomy	61.5 (8)	23.1 (3)	7.7 (1)	7.7 (1)	0 (0)
I feel comfortable with stone clearance	76.9 (10)	15.4 (2)	7.7 (1)	0 (0)	0 (0)
I feel comfortable with placement of biliary stents	84.6 (11)	15.4 (2)	0 (0)	0 (0)	0 (0)
I feel comfortable with placement of pancreatic stents	46.2 (6)	46.2 (6)	7.7 (1)	0 (0)	0 (0)
I feel comfortable with independently performing EUS	38.5 (5)	46.2 (6)	7.7 (1)	7.7 (1)	0 (0)
I feel comfortable performing EUS-FNA	61.5 (8)	30.8 (4)	7.7 (1)	0 (0)	0 (0)
I feel comfortable performing celiac plexus block/neurolysis	46.2 (6)	38.5 (5)	7.7 (1)	0 (0)	7.7 (1)
I feel comfortable placing fiducials	16.7 (2)	25 (3)	8.3 (1)	25 (3)	25 (3)
I feel comfortable performing pseudocyst drainage	38.5 (5)	46.2 (6)	7.7 (1)	7.7 (1)	0 (0)
I feel comfortable performing biliary/pancreatic EUS-guided rendezvous procedures	0	23.1 (3)	23.1 (3)	30.8 (4)	23.1 (3)

### Supplementary Table 4. Results of Post-Study Questionnaire Assessing Plans for Independent Practice

What type of environment will you be practicing in? (n, %)	Academic (6, 46.2) Private (5, 38.5) Combination of academic and private practice (2, 15.4)							
Will you be joining a practice with a senior partner who performs high-volume ERCP and/or EUS? (n, %)	Yes (11, 84.6) No (2, 15.4)							
What % of your job will be	0 (0, 0)	Supplementary Table 5. Comparison of AET Programs						
"advanced endoscopy?" (n, %)	1–25 (2, 15.4) 26–50 (5, 38.5) 51–75 (2, 15.4) >75 (4, 30.8)		Programs included in RATES study	Programs not included RATES study	P			
How many EUS procedures do you	Mean, 187.5		(n = 20)	(n = 42)	value			
estimate you will perform in the first year of independent practice? (n, %)	Median, 155 (range, 25-500)	No. of AETs (median) No. of ERCP procedures	1 (1–2) 480 (300–800)	1 (1–2) 450 (225–1015)	<.21 <.36			
How many ERCP procedures do	Mean, 155	(median)						
you estimate you will perform in the first year of independent practice? (n, %)	Median, 175 (range, 25–300)	No. of EUS procedures (median)	450 (300–1200)	400 (300–950)	<.35			

RATES, Rapid Assessment of Trainee Endoscopy Skills.

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