

## QUALITY INDICATORS

## Quality indicators for capsule endoscopy and deep enteroscopy

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**Background and Aims:** Capsule endoscopy (CE) and deep enteroscopy (DE) can be useful for diagnosing and treating suspected small-bowel disease. Guidelines and detailed recommendations exist for the use of CE/DE, but comprehensive quality indicators are lacking. The goal of this task force was to develop quality indicators for appropriate use of CE/DE by using a modified RAND/UCLA Appropriateness Method.

**Methods:** An expert panel of 7 gastroenterologists with diverse practice experience was assembled to identify quality indicators. A literature review was conducted to develop a list of proposed quality indicators applicable to preprocedure, intraprocedure, and postprocedure periods. The panelists reviewed the literature; identified and modified proposed quality indicators; rated them on the basis of scientific evidence, validity, and necessity; and determined proposed performance targets. Agreement and consensus with the proposed indicators were verified using the RAND/UCLA Appropriateness Method.

**Results:** The voting procedure to prioritize metrics emphasized selecting measures to improve quality and overall patient care. Panelists rated indicators on the perceived appropriateness and necessity for clinical practice. After voting and discussion, 2 quality indicators ranked as inappropriate or uncertain were excluded. Each quality indicator was categorized by measure type, performance target, and summary of evidence. The task force identified 13 quality indicators for CE and DE.

**Conclusions:** Comprehensive quality indicators have not existed for CE or DE. The task force identified quality indicators that can be incorporated into clinical practice. The panel also addressed existing knowledge gaps and posed research questions to better inform future research and quality guidelines for these procedures. (Gastrointest Endosc 2022;■:1-19.)

*Abbreviations:* ACG, American College of Gastroenterology; ASGE, American Society for Gastrointestinal Endoscopy; CE, capsule endoscopy; CO<sub>2</sub>, carbon dioxide; DBE, double-balloon enteroscopy; DE, deep enteroscopy; ESGE, European Society of Gastrointestinal Endoscopy; IPR, interpercentile range; IPRAS, IPR adjusted for symmetry; MR, magnetic resonance; MRI, magnetic resonance imaging; NSAID, nonsteroidal anti-inflammatory drug; RAM, RAND/University of California Los Angeles appropriateness method; SBE, single-balloon enteroscopy; SBTT, small-bowel transit time.

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Small-bowel capsule endoscopy (CE) and deep enteroscopy (DE) are both relatively new procedures that enable evaluation of the entire small bowel. CE has revolutionized small-bowel assessment, particularly for suspected small-bowel bleeding. Currently, CE is a purely diagnostic test. DE is more invasive and complements CE with important therapeutic capabilities. Endoscopists need substantial focused training to gain the expertise necessary to perform each of these procedures with maximal success and best outcomes. Specific criteria for training, required skills, and granting of clinical privileges to perform CE and DE have been published by the American Society for Gastrointestinal Endoscopy (ASGE).<sup>1,2</sup>

Quality of health care can be classically assessed using quality indicators, which were defined by Chassin and Galvin<sup>3</sup> to compare how an individual or group performs against an ideal or benchmark. Quality indicators can be reported as the “ratio between the incidence of correct performance and the opportunity for correct performance or as the proportion of interventions that achieve a predefined goal.”<sup>4</sup> In an update to the 2006 ASGE/American College of Gastroenterology (ACG) guidelines, quality indicators were divided into 3 categories: (i) structural measures, which assess characteristics of the health care environment; (ii) process measures, which assess care at the time of delivery (eg, adequate documentation of anatomic landmarks during CE); and (iii) outcome measures, which assess results of care (eg, resolution of bleeding or rates of adverse events such as perforation).<sup>5</sup> We used a methodologically rigorous process to develop valid quality indicators for both CE and DE.

## METHODS

This report describes new data pertaining to quality indicators for CE and DE. Indicators with wide-ranging clinical applications are prioritized as are those associated with practice variations and outcomes. Whenever possible, we focus on quality indicators validated in clinical studies. The RAND/University of California Los Angeles Appropriateness Method (RAM) was used to develop quality indicators for CE and DE to be used for patients with suspected small-bowel disease.<sup>6</sup> Based on RAM, an appropriate indicator is one in which the benefits outweigh any potential risks, regardless of cost. This method is particularly useful when randomized controlled trials are not available.

### Study design and methods

The ASGE and ACG chose the 2 lead panelists (J.A.L. and G.M.E.) who then chose content experts in CE and balloon enteroscopy. Seven experts composed the study group to assure adequate diversity and allow all experts to participate sufficiently, as per RAM.<sup>6</sup>

An initial conference call established the project purpose, methodology, and assignments. Search terms were identified, and a conference call convened with a Grading of Recommendations, Assessment, Development, and Evaluation expert. A literature search was performed, after which patient problem, intervention, comparison, and outcome questions were finalized for CE and DE. If studies were not available for a specific indicator, we used expert consensus to identify indicators. Some indicators were included that may be challenging to measure, but, as in other quality reviews, we believed their inclusion might prompt eventual adoption. We proposed a comprehensive list of quality indicators, realizing that a small number of these will be widely used. The task force considered indicators related solely to CE and DE. We did not include those structural indicators related to facilities where CE and DE are performed, although quality may be affected by varying institutional practices. Initial quality metrics were developed and discussed during a conference call.

The voting procedure to prioritize the metrics emphasized selection of measures to improve quality, with the intent that they would be calculated and reported at the practice level and would pertain to overall patient care. A measure was considered valid if compliance would be critical to providing quality care, exclusive of cost or feasibility. The panelists were instructed to rate the indicators on the perceived appropriateness and necessity for clinical practice. They were to consider these measures for a typical patient seeking care from a typical physician at a typical hospital. They were also asked to suggest a threshold percentage for benchmarking. After voting and discussion, 2 quality indicators were ranked as inappropriate or uncertain and were not included: bowel prep for CE and formulating an anesthesia plan for DE and discussing it with the patient.

Each quality indicator was categorized by measure type, performance target, and summary of evidence for CE (Table 1) and DE (Table 2). We classified each quality indicator as an *outcome* or *process* measure. Although quality indicators for outcome are preferred, the large amount of data needed, including long-term follow-up and confounding factors, make outcome quality difficult to measure in routine clinical practice.<sup>7,8</sup> In these cases, we used process indicators as surrogate measures of high-quality endoscopy.<sup>7</sup> We included performance targets for each quality indicator, similar to other quality-indicator documents,<sup>5,7,8</sup> and stress that performance targets are goals designed to inform quality improvement but are not necessarily reflective of standard of care.

Quality indicators were defined as applicable to the preprocedure, intraprocedure, and postprocedure intervals of care. For each period, we identified key relevant research questions. However, the classic preprocedure, intraprocedure, and postprocedure periods may not apply to CE, given that the traditional borders between these times are clouded for performance and subsequent interpretation of

**TABLE 1. Appropriate quality indicators for CE with median score, number of experts in each category range, and a suggested threshold benchmark**

Capsule endoscopy	Quality indicator	Median score	No. of experts:			IPR	IPRAS	Proposed threshold (%)
			1-3 range	4-6 range	7-9 range			
Preprocedure	Frequency of demonstrating competency in CE	7	0	1	6	2.0	6.85	100
	Frequency of performing CE for an indication that is documented and included in a published, standard list of appropriate indications	9	0	0	7	1.0	7.6	90
	Frequency of obtaining informed consent, including specific discussions of risks associated with CE	9	0	2	5	1.4	7.3	98
	Frequency of using a test for luminal patency before CE in patients with risk factors for capsule retention in the small bowel	8	0	0	7	1.2	6.25	90
	Frequency of performing CE in a timely manner after an episode of overt, suspected small-bowel bleeding	8	0	0	7	1.2	6.25	90
Intraprocedure	Frequency of performing endoscopic capsule placement for patients with contraindications to swallowing the capsule or for patients at risk of gastric retention	9	0	2	5	1.4	7.3	80
Postprocedure	Frequency of performing photo documentation and documenting small-bowel transit time	9	0	0	7	.2	8.2	98
	Frequency of recommending an appropriate management plan based on CE findings	9	0	1	6	1.2	7.45	80
	Frequency of using a standardized CE reading method for video interpretation	8	0	2	5	1.2	5.95	80
	Frequency of documenting completeness and adequacy of mucosal visualization	8	0	0	7	1.2	7.45	95
	Frequency of tracking CE adverse events and documenting appropriate management	8	0	1	6	1.0	7.6	95
	Frequency of performing abdominal radiography at 2 wk or more after CE when the examination is not completed to the cecum and/or the capsule has not been observed to pass	7	1	0	6	1.2	6.25	90
	Frequency of generating a complete report in the electronic health record for all patients undergoing CE	9	0	0	7	0	8.35	98
Inappropriate or uncertain	Frequency of performing bowel preparation before CE	5	1	4	2	1.6	3.25	N/A

CE, Capsule endoscopy; IPR, interpercentile range; IPRAS, interpercentile range adjusted for symmetry; N/A, not applicable.

CE. Therefore, for CE, quality measures were divided in a logical manner on the basis of clinical practice.

Quality indicators common to all GI endoscopic procedures<sup>5</sup> are not discussed in this document except as they specifically relate to CE and DE.

Previous quality articles introduced the concept of priority indicators that an individual endoscopist could use to measure their performance.<sup>5</sup> A high-priority subset of the indicators for CE and DE was considered. However, the panel did not feel that enough robust data existed to support ranking of priority indicators at this time. As more performance data become available, the development of outcome indicators and a better understanding of practice variation will identify key priority indicators. The panel agreed that future iterations of the document should identify priority indicators.

## Search strategy and systematic review of literature

A literature search was performed in Ovid MEDLINE (1946 to present and Epub ahead of print, in-process and other nonindexed citations, and Ovid MEDLINE). A combination of keywords and Medical Subject Headings terms were used to create the search strategy. The Boolean operators “AND” and “OR” were used to combine terms, keywords, and concepts (Table 3). We reviewed references within documents to identify additional studies.

## Statistical analysis

The 7-member panel was instructed to rank each proposed quality measure based on reporting the measure at the practice level and not to rank a measure specific to an individual patient. For suggested quality measures

**TABLE 2. Appropriate quality indicators for DE with median score, number of experts in each category range, and a suggested threshold benchmark**

Deep enteroscopy	Quality indicator	Median score	No. of experts:			IPR	IPRAS	Proposed threshold (%)
			1-3 range	4-6 range	7-9 range			
Preprocedure	Frequency of demonstrating competency in DE	9	1	0	6	2.0	6.85	100
	Frequency of performing DE for an indication that is documented and included in a published, standard list of appropriate indications	9	0	0	7	1.0	7.6	90
	Frequency of reviewing a CE or cross-sectional imaging study before DE	7	0	2	5	.4	5.35	80
	Frequency of discussing the management of anticoagulation with the patient and documenting the periprocedural anticoagulation plan	9	0	1	6	1.2	7.45	90
	Frequency of documenting choice of insertion route based on CE transit time or cross-sectional imaging	7	0	1	6	1.2	6.25	95
Intraprocedure	Frequency of performing DE in a timely manner after a bleeding episode	8	0	0	7	2.0	6.85	90
	Frequency of using carbon dioxide insufflation for DE	7	0	2	5	1.4	6.1	90
	Frequency of estimating depth of advancement	7	0	3	4	2.2	4	90
	Frequency of marking the most distal point of advancement when indicated	9	0	1	6	1.2	7.45	90
	Frequency of characterizing and treating clinically significant lesions	9	0	0	7	.2	8.2	98
	Frequency of treating a vascular lesion that is believed to be a potential source of bleeding	9	0	1	6	.2	8.2	98
Postprocedure	Frequency of generating a complete report that includes findings, specific techniques performed, accessories used, and adverse events	9	0	0	7	0	8.35	98
	Frequency of tracking DE adverse events and documenting appropriate management	9	1	0	6	.2	8.2	95
Inappropriate or uncertain	Frequency of formulating an anesthesia plan, discussing the plan with the patient, and documenting rationale	6	1	5	1	.2	3.7	N/A

CE, Capsule endoscopy; DE, deep enteroscopy; IPR, interpercentile range; IPRAS, interpercentile range adjusted for symmetry; N/A, not applicable.

that were appropriate, a threshold percentage used as a benchmark was determined. Each proposed indicator was ranked on a 9-point scale for which a score of 1 to 3 was considered as *inappropriate*; 4 to 6, *of uncertain appropriateness*; and 7 to 9, *appropriate*.

The median scores of the appropriateness ratings were calculated, and the frequency of scores in the 1 to 3, 4 to 6, and 7 to 9 ranges was shown for each measure. Interpercentile range (IPR) (30th to the 70th percentile of scores) was calculated, and the IPR was adjusted for symmetry (IPRAS) based on methods from RAM, which have been shown to be robust for smaller panels.<sup>6</sup> The RAM methods were used to determine agreement and consensus with the proposed indicator. With this method, median scores in the 7 to 9 range are deemed to demonstrate agreement among the panel. If the IPR is less than the IPRAS value, extreme dispersion of scores does not exist, and thus, consensus exists among the panel. If both agreement and consensus are met, then the indicator should be considered for use.

### Preprocedure quality indicators

The preprocedure period for CE and DE includes the time of all contact between members of the endoscopy team and the patient before the procedure begins and up to the time of sedation for DE. Issues common to all endoscopic procedures during the preprocedure period are appropriate indication, informed consent, risk assessment, formulation of a sedation plan, clinical decision-making regarding prophylactic antibiotic therapy and management of antithrombotic drugs, and timeliness of the procedure.<sup>5</sup>

### Intraprocedure quality indicators

The intraprocedure period for CE extends from oral ingestion or sedation for endoscopic deployment until the monitoring equipment is returned. For DE, the intraprocedure period extends from the start of sedation to endoscope removal. Patient sedation and monitoring are part of this period.

TABLE 3. Search strategy\*

MeSH terms	Keywords
Intestine, small	Small intestine; small bowel
Single-balloon enteroscopy	Enteroscopy; device-assisted enteroscopy
Double-balloon enteroscopy	Deep enteroscopy; spiral enteroscopy
Balloon enteroscopy	Push enteroscopy; sonde enteroscopy
Capsule endoscopy	Video capsule
Gastrointestinal hemorrhage	Obscure GI bleed; † small-bowel bleed; † mid-GI bleed; † and gastrointestinal bleed†
Crohn's disease	Small-bowel Crohn†
Intestinal obstruction	Small-bowel stricture; small-bowel ulcer
Intestinal neoplasms	Small-bowel tumor†
Intestinal polyps	Small-bowel polyp†
Peutz-Jeghers syndrome	PJP; Peutz-Jeghers polyp†
Meckel diverticulum	Jejunal diverticulum
Cholangiopancreatography and endoscopic retrograde	ERCP
Quality indicators, health care	Quality indicator†

\*The literature search for this project was performed in Ovid MEDLINE (1946 to present and Epub ahead of print, in-process and other nonindexed citations and Ovid MEDLINE). A combination of keywords and Medical Subject Headings (MeSH) terms were used to create the search strategy. The Boolean operators "AND" and "OR" were used to combine terms, keywords, and concepts. The following table lists the keywords and MeSH terms used.

†Indicates truncation of word.

### Postprocedure quality indicators

In CE, the postprocedure period extends from procedure completion, including video interpretation, to subsequent follow-up. In DE, this period extends from enteroscope removal to subsequent follow-up. Postprocedure activities include procedure documentation, recognition and documentation of adverse events, and communication of an appropriate management plan to referring physicians.

## CAPSULE ENDOSCOPY

### Quality indicators

#### Preprocedure.

1. Frequency of demonstrating competency in CE

Type of measure: process

Performance target: 100%

Evidence summary: Formal training in CE can be obtained during fellowship or postgraduate and subspecialty-society-sponsored courses. As for any endoscopic procedure, a minimum standard of performance is required for an endoscopist to be deemed competent, understanding that learners may achieve competency after different numbers of CE studies performed. Multiple society guidelines recommend a minimum number of CE procedures. The 2017 ASGE guideline recommended 20 CE studies, whereas the 2019 European Society of Gastrointestinal Endoscopy (ESGE) guideline suggested that 30 to 50 CE studies should be required.<sup>2,9</sup> The ESGE recently published a curriculum framework for CE training that includes a minimum number of CE procedures and a

combined hands-on and didactic format for courses, with recommendations for both course content and faculty experience.<sup>10</sup> The ESGE curriculum statement offered multiple options for competency assessment, including a structured CE course with direct observation; proctored, supervised CE study interpretation; test videos; and/or written assessment. A small prospective study showed that 20 CE studies were the number at which diagnostic yield was no longer significantly different between gastroenterology trainees and attending physicians.<sup>11</sup> A multicenter study using a CE competency test to compare trainees to CE experts showed that trainees who underwent a structured CE training program should complete at least 25 supervised CE study interpretations before assessment of competency because that number was where the learning curve flattened.<sup>12</sup> Whether interpretation of a minimum number of studies is regularly required to maintain competency remains unclear.<sup>9</sup>

2. Frequency of performing CE for an indication that is documented and included in a published, standard list of appropriate indications

Type of measure: process

Performance target: 90%

Evidence summary: Although applications of CE continue to evolve, standard indications for the procedure are well established and have been outlined by societies.<sup>13-15</sup> An appropriate indication should be documented for each CE procedure. If CE is performed for a nonstandard indication, justification should be documented. Substantial evidence and expert consensus exist to justify use for the following: Overt and occult suspected small-bowel bleeding

**TABLE 4. Indications for capsule endoscopy**

Appropriate indications (ASGE/ESGE)	Low-yield indications
Obscure GI bleeding/suspected small-bowel bleeding	Abdominal pain
Iron-deficiency anemia	Diarrhea
Crohn's disease (known or suspected)	Malabsorption
Inherited polyposis syndromes (familial adenomatous polyposis and Peutz-Jeghers syndrome)	Iron-deficiency anemia without evidence of GI bleeding
Abnormal small-bowel imaging	
Complicated/refractory celiac disease	

ASGE, American Society for Gastrointestinal Endoscopy; ESGE, European Society of Gastrointestinal Endoscopy.

including iron-deficiency anemia, diagnosis and surveillance of Crohn's disease, evaluation of refractory celiac disease, surveillance of polyposis syndromes, evaluation of suspected small-bowel tumors, and further evaluation of abnormal small-bowel imaging when DE is contraindicated<sup>9,13,15-18</sup> (Table 4). Low-yield indications include evaluation of abdominal pain, iron-deficiency anemia in the absence of suspected GI bleeding, diarrhea, and malabsorption in the absence of a diagnosis, or suspicion of one of the aforementioned conditions. An appropriate indication for CE markedly increases diagnostic yield. Nonstandard indications are associated with low diagnostic yield.<sup>19</sup>

3. Frequency of obtaining informed consent, including specific discussions of risks associated with CE

Type of measure: process

Performance target: 98%

Evidence summary: Written informed consent should be obtained before CE and should include a list of relevant adverse events, including capsule retention. If the capsule is to be placed endoscopically, consent should include risks of esophagogastroduodenoscopy. Consent for a self-dissolving patency capsule should include the risk of retention, although patency capsule retention is exceptionally rare. Other risks requiring explanation include missed lesions and battery expiration before the capsule reaches the cecum (incomplete examination). The U.S. Food and Drug Administration has approved CE for children older than 2 years, although in young children, the capsule may need to be placed endoscopically because children may be unable to swallow it. Patients should be instructed to avoid undergoing MRI until the capsule has been confirmed to pass per rectum, given the theoretical and, to date, unreported risk of capsule migration leading to bowel injury and because the capsule can interfere with imaging during an MRI.<sup>20</sup> Given the former potential for harm and the latter practical concern, MRI should be avoided until the capsule has been expelled. Patients should be assessed for contraindications to capsule placement and risk of capsule retention, which will be discussed in upcoming sections.

**Contraindications.** Absolute contraindications to CE are known stenosis unless surgery is planned, known perforation, and known or suspected intestinal obstruction

in patients who refuse or are not candidates for surgery. Limited data suggest patients with small-bowel motility disorders, such as chronic intestinal dysmotility, are not at increased risk of capsule retention.<sup>21</sup>

Relative contraindications to CE are pregnancy, given limited safety data and potential fetal risk if CE retrieval is required endoscopically or surgically; high risk of stenosis if imaging or a patency capsule test is not performed first; age less than 2 years; and presence of implanted cardiac devices.<sup>20,22</sup> Pregnancy is contraindicated only because of theoretical harm to the fetus, although this has not been established in vivo. Given the lack of data, however, CE should be delayed when possible until after delivery.<sup>20</sup> Implantable cardiac devices (pacemakers, defibrillators, and left ventricular assist devices) are cited as contraindications to CE by device manufacturers. Despite initial theoretical concerns that these devices would interfere with CE, this has not been shown in multiple studies or clinical practice, apart from cases of impaired CE image acquisition for patients with left ventricular assist devices.<sup>14,17</sup> The ESGE no longer deems these devices a contraindication to CE. The American Gastroenterological Association also generally endorses the use of CE in patients with pacemakers.<sup>14,17</sup>

Concerns have been raised regarding incomplete capsule studies because of proximal retention or slow transit in patients with surgically altered anatomy. However, a small study of patients with surgically altered anatomy showed no increased risk of swallowed versus endoscopically placed capsules.<sup>23</sup> Thus, capsule ingestion seems to be safe and effective unless there are concerns for capsule retention in a patient with a known stricture or gastroparesis.

4. Frequency of using a test for luminal patency before CE for patients with risk factors for capsule retention in the small bowel

Type of measure: process

Performance target: 90%

Evidence summary: All patients undergoing CE should be evaluated for risk factors for capsule retention, including Crohn's disease, history of small-bowel obstruction or previous resection (risk of adhesive disease), previous abdominal or pelvic radiotherapy, chronic use of a high-dose

nonsteroidal anti-inflammatory drug (NSAID), and known stricture or mass.<sup>16,17,24</sup> If any of these conditions are present or the patient has symptoms concerning for obstruction, results from a patency capsule test, a CT or magnetic resonance (MR) enterography procedure, or a combination of these procedures should be obtained before standard capsule administration.

Capsule retention is defined as the presence of the capsule in the intestine for 2 weeks or more.<sup>16,25</sup> Capsule retention occurs in 2.1% of patients undergoing CE for suspected small-bowel bleeding, 2.2% of those with abdominal pain or diarrhea, 2.4% of those with suspected Crohn's disease, and 4.6% or more of those with known Crohn's disease, with an overall pooled prevalence for all indications of approximately 1.4% to 2.5%.<sup>16,24,26</sup> Recent meta-analyses of retention rates for patients with suspected or known Crohn's disease report lower rates than earlier studies possibly because of the increased use of a patency capsule test for these patients.<sup>26</sup>

The patency capsule is the same size as the actual capsule endoscope, but it has an outer shell consisting of a parylene coating that dissolves after 30 hours. Use of a patency capsule has been shown to predict safe passage of a standard capsule endoscope (pooled overall sensitivity, 97%; specificity, 83%)<sup>27</sup> and to decrease risk of capsule retention in patients with known Crohn's disease.<sup>24</sup> Although the risk of capsule retention is much smaller with the use of a patency capsule than with the standard device, a multicenter study reported occurrences of retention.<sup>28</sup> Therefore, use of a patency capsule should be followed by abdominal radiography, a "spot" CT scan, or scanning the device up to 30 hours after ingestion to ensure that it is no longer in the small intestine and has passed into the colon.

If imaging is performed to screen a patient at risk of capsule retention, CT or MR enterography are the preferred methods because small-bowel follow-through and traditional abdominal or pelvic CT without the dedicated enterography protocol are unreliable for identification of possible strictures.<sup>29</sup> Although some studies have shown CT enterography to be equally predictive for capsule passage as a patency capsule,<sup>30,31</sup> others suggest that CT enterography does not always predict capsule retention in patients with Crohn's disease.<sup>32</sup> Thus, caution should be exercised in patients at high risk of capsule retention, and a patency capsule test should be performed if concerns remain, even if CT or MR enterography shows no obstructive areas. A patency capsule test is also preferred if NSAID-associated diaphragmatic strictures are suspected because they may be missed by cross-sectional imaging. If a patency capsule does not pass or CT or MR enterography reveals a stricture, CE should not be performed, unless it would aid in surgical removal of a lesion and the surgeon is available to operate in the event of an obstruction.

An incomplete examination refers to lack of passage of the capsule endoscope into the cecum before the battery expires. This occurs in 16% to 20% of patients and is usually caused by slow intestinal transit times.<sup>16,25</sup> These rates can be decreased by using capsules with a longer battery life or by endoscopic placement of the capsule into the small bowel (thus bypassing the stomach).

5. Frequency of performing CE in a timely manner after an episode of overt, suspected small-bowel bleeding

Type of measure: process

Performance target: 90%

Evidence summary: CE should ideally be performed within 48 hours for hospitalized patients with overt, suspected small-bowel bleeding to optimize diagnostic yield whenever possible. The diagnostic yield of CE is more than 90% when CE is administered within 48 hours of bleeding onset, and timely performance has been shown to decrease morbidity, mortality, and readmission rates, as well as to shorten and decrease hospitalizations.<sup>33-36</sup> For outpatients, performance of CE within 14 days of a bleeding episode also improves diagnostic yield.<sup>15</sup>

## Preprocedure research questions

1. Is the use of a purgative bowel preparation necessary and, if so, what is the optimal purgative and overall preparation regimen?
2. Does improved small-bowel mucosal visualization with a purgative regimen improve diagnostic yield in high-risk patients?
3. Can an effective scoring system for quality of bowel preparation in the small intestine be developed and validated?
4. Are other technologies available to predict capsule retention in high-risk patients?

## Intraprocedure

1. Frequency of performing endoscopic capsule placement for patients with contraindications to swallowing the capsule or for patients at risk of gastric retention

Type of measure: process

Performance target: 80%

Evidence summary: Oral capsule ingestion is a relative contraindication for patients with swallowing difficulty or gastric motility disorders. Specific risks include capsule aspiration for patients with oropharyngeal dysphagia, retention with esophageal dysphagia or known Zenker's diverticulum, and gastric retention with impaired gastric emptying. Endoscopic placement of the capsule endoscope into the small intestine can overcome the risks associated with these conditions.<sup>20,22</sup>

The patient's health history should be reviewed, and patients should be asked about symptoms suggestive of the following conditions: pharyngeal or esophagogastric neuromuscular injury or dysfunction, aspiration, Zenker's diverticulum, esophageal stricture, eosinophilic esophagitis,

and aperistalsis associated with achalasia or scleroderma. Endoscopic placement can help maximize small-bowel visualization in patients with delayed gastric emptying from narcotic use or gastroparesis.<sup>37</sup> Patients with altered mental status should undergo endoscopic deployment, and patients at risk of, or with a history of, an incomplete capsule study, such as bedbound patients, should be considered for endoscopic capsule deployment.<sup>38</sup> As discussed earlier, for postbariatric surgery patients and those with altered upper gut anatomy, studies suggest that oral ingestion of the capsule endoscope yields satisfactory completion rates with no risk of retention.<sup>23,39</sup>

Endoscopic placement should also be considered for children older than 2 years.<sup>40</sup> To assess whether a pediatric patient could ingest a capsule endoscope, the so-called jelly bean test can be used, whereby the child attempts to swallow a whole jelly bean approximating the size of the capsule endoscope. The success of jelly bean ingestion correlates directly with success of capsule endoscope ingestion.<sup>41</sup>

### Intraprocedure research questions

1. What is the diagnostic miss rate of CE when clinically significant lesions are found on DE only?
2. Does real-time CE monitoring in the emergency department improve triaging and diagnostic yield in acute GI bleeding?
3. Is delayed gastric emptying of the capsule endoscope an indication of a motility disorder, and is further evaluation indicated?
4. What are optimal methods to improve CE completion rates in outpatient and inpatient settings?
5. What is needed to improve localization of lesions on CE?
6. Will controllable capsule endoscopes improve the diagnostic yield and management of small-bowel lesions?

### Postprocedure

1. Frequency of performing photo documentation and documenting small-bowel transit time (SBTT)

Type of measure: process

Performance target: 98%

Evidence summary: Photo documentation of lesions of interest and certain anatomic landmarks are the standard protocol when CE videos are interpreted. A systematic approach is important for interpreting CE videos to facilitate the identification of important anatomic landmarks and comprehensive evaluation of the small-bowel lumen.<sup>42</sup> Specifically, the first duodenal and first cecal (or stomal) images enable calculation of the SBTT, which in turn facilitates estimation of the anatomic location of relevant findings and proper choice of the DE route (antegrade vs retrograde) to reach small-bowel lesions of interest most efficiently. Lesions identified in the first 60% of SBTT are usually accessed from the antegrade approach, whereas lesions greater than 60% of SBTT are usually accessed from a retrograde approach.<sup>43</sup> Abnormalities should be

documented with photographs, and lesions should be described using standardized terms.

2. Frequency of recommending an appropriate management plan based on CE findings

Type of measure: process

Performance target: 80%

Evidence summary: CE is considered a diagnostic test only because it allows for lesion visualization but not therapeutic intervention. Accurate documentation of CE findings and clinical recommendations are paramount for optimal patient care. If DE is recommended, the endoscopist should consider either reviewing the CE video or at least communicating with the clinician who interpreted the CE.<sup>44</sup> In addition to relevant diagnostic findings, CE procedure reports should include a plan of care, such as performance of DE, cross-sectional imaging, surgery, or a combination of procedures.<sup>45</sup> This is important even if conservative measures alone, such as observation or iron replacement, are recommended because implicit to interpreting CE findings is expertise in treatment of small-bowel diseases. The plan should be conveyed to the referring physicians, so that no lapses occur in patient care. In addition, if a patient is to undergo DE, good communication is imperative between the gastroenterologist reading the capsule study and the endoscopist to determine an appropriate insertion route.<sup>46</sup> Ideally, CE findings should be reviewed beforehand to allow endoscopists the best understanding of lesions of interest and the chances of reaching them.<sup>46</sup>

3. Frequency of using a standardized CE reading method for video interpretation

Type of measure: process

Performance target: 80%

Evidence summary: As in any endoscopic procedure, a systematic approach is important to improving performance and quality. In the case of CE, this approach begins with video interpretation and continues through documenting key components in a CE report. Besides reporting of anatomic landmarks, a global assessment is suggested for study adequacy, including completeness of the capsule reaching the cecum or operative stoma and quality of the bowel preparation. Regarding CE video interpretation, a systematic approach is necessary to maximize efficiency for the reader and the quality of reporting for the patient. Mindfulness of the possibility of reader fatigue is important if readers are interpreting CE studies late in the day or if multiple CE studies are read in series.<sup>22</sup> CE video playback may be viewed as a single-frame, dual-frame, or multiple-frame image. The maximum recommended view speed for single-frame viewing is 15 images per second, whereas the maximum recommended speed is 20 images per second for dual-frame or multiple-frame viewing. A speed greater than 20 frames per second is associated with an increased rate of missed lesions.<sup>47</sup> There is no compromise in yield between single-frame and multiple-frame viewing when reading speeds remain within the aforementioned limits.<sup>47-50</sup>



Adaptive frame-rate technology is built into most CE devices (ie, more images are captured if the CE device is moving more rapidly); however, single-frame lesions may be missed, especially in the proximal small bowel. Therefore, it may be wise to consider slowing reading speed for the proximal small bowel to overcome the potential for missed lesions.<sup>9,17</sup> Commercially available CE platforms contain automated software algorithms aimed at removing potentially duplicate images, with the goal of reducing reading time. Although these algorithms, which continue to be refined, can reduce overall reading time and improve performance characteristics, single-frame lesions may still be missed at an estimated rate of 6.5% to 12.0%.<sup>51-57</sup> Therefore, the use of automated software algorithms for CE interpretation cannot currently be recommended as an acceptable substitute for conventional CE reading modalities.

#### 4. Frequency of documenting completeness and adequacy of mucosal visualization

Type of measure: process

Performance target: 95%

Evidence summary: The clinical usefulness of CE depends on various factors, including study adequacy. Adequacy has multiple components, but at a minimum, it consists of study completeness (the capsule reaches the cecum or operative stoma during recording), an SBTT of 2 hours or more, and assessment of the quality of bowel preparation. An SBTT less than 2 hours increases the risk of a missed lesion, thereby deeming a study inadequate.<sup>58</sup> Quality of visualization needs to be assessed because suboptimal visualization may affect the diagnostic yield and clinical usefulness of the CE study. Multiple scoring systems have been proposed, which are based on a combination of quantitative and qualitative or subjective and objective indices, some of which have been well-validated in small studies.<sup>59-61</sup> The widespread adoption of any of these scoring systems has been limited because they are often cumbersome. No recommendation can be made at this time to use a specific scoring system, but rather, at a minimum, a global assessment of bowel preparation should be made with quality considered as adequate or inadequate.

#### 5. Frequency of tracking CE adverse events and documenting appropriate management

Type of measure: process

Performance target: 95%

Evidence summary: The CE procedure is infrequently associated with adverse events, but when adverse events occur, they should be recorded and categorized as preprocedure, intraprocedure, or postprocedure. Adverse events include bowel preparation-associated preprocedural adverse events, aspiration, perforation, and capsule retention. Capsule retention, as discussed previously, is the most common adverse events, which underlies the rationale for appropriate preprocedure screening to minimize potential harm for patients at increased risk. In the case of capsule aspiration, a pulmonologist should be consulted

urgently for potential capsule removal by bronchoscopy.<sup>62</sup> Rarely, capsule retention can lead to small-bowel obstruction and more rarely to perforation.<sup>63</sup> Adverse events related to the performance of CE and image capture should be recorded at the time of report generation as well as after the procedure if they occur subsequent to capsule reading.

#### 6. Frequency of performing abdominal radiography at 2 weeks or more after CE when the examination is not completed to the cecum and/or the capsule has not been observed to pass

Type of measure: process

Performance target: 90%

Evidence summary: Retention has been defined as a capsule remaining in the GI tract for at least 2 weeks, as discussed above. Although the proportion of incomplete CE studies is approximately 16% to 20%, the risk of CE retention remains less than 2%.<sup>9</sup> Retention should be suspected when the capsule is not visualized in the colon or operative stoma in an asymptomatic patient at the time of capsule read and the patient has not reported seeing the capsule excreted or when a patient has symptoms consistent with possible small-bowel obstruction or perforation.<sup>64</sup>

International expert consensus has recommended that abdominal radiography be performed at 2 weeks after a capsule is deployed when the capsule does not reach the cecum during the recorded video and the patient has not seen the capsule excreted.<sup>65</sup> However, the 2-week cutoff to perform plain-film radiography is somewhat arbitrary.<sup>66</sup> Patients with suspected capsule retention should undergo imaging at symptom onset. If retention is identified, asymptomatic patients may be monitored unless a malignant neoplasm is suspected as the cause for retention. Asymptomatic patients may remain so for months or longer without adverse effects.<sup>16</sup> Symptomatic patients should undergo urgent endoscopy or surgery to remove the capsule. For asymptomatic patients with evidence of retention, a management plan should be developed and conveyed to the patient and treating clinicians. Endoscopic removal is a sensible option, especially if an underlying lesion is suspected or a patient prefers capsule removal.

Medical therapy should be instituted as appropriate for patients with Crohn's disease to see if the capsule will pass.<sup>67</sup> In the case of NSAID enteropathy, offending medications should be discontinued. A DE may be attempted for capsule retrieval for symptomatic patients without a neoplasm for whom medical therapy would either not be successful (eg, anastomotic stricture or radiation enteropathy) or be too slow to take effect. If DE retrieval fails, surgery should be considered when appropriate. Management plans for patients with capsule retention should be appropriately documented.

#### 7. Frequency of generating a complete report in the electronic health record for all patients undergoing CE

Type of measure: process

Performance target: 98%

Evidence summary: As for all types of endoscopy procedures, a timely report should be generated for all patients undergoing CE. The report should include a detailed description of key components (Box 1).<sup>22,68</sup> Although consensus is lacking about details to be included in a CE report, many elements are common to all endoscopic procedures, and some are unique. Key components include patient identifiers (date of birth; name), date of procedure, confirmation of informed consent, indication, mention of endoscopic placement versus oral ingestion, and overall adequacy of the CE study, including completeness of the capsule reaching the cecum or operative stoma and quality of small-bowel mucosa visualization. Documentation of first duodenal and first cecal images should be included. Calculation and reporting of gastric (when applicable) and SBTT should be included. Reports should also indicate if adequate SBTT was achieved at more than 2 hours, given the increased risk of missed lesions if rapid SBTT (<2 hours) is present. Clinical findings, images of relevant findings, impression of findings, and management recommendations should be included. Several small-bowel scoring systems and CE-structured terminology have been developed, but these are not yet in widespread use.<sup>69-71</sup>

### Postprocedure research questions

1. How often are lesions identified on CE found on subsequent DE performed for biopsy or therapeutic intervention?
2. What are the diagnostic yields and outcomes of CE in nonacademic gastroenterology practices?
3. How do we improve use of capsule SBTT to predict the correct route for DE?
4. What is the ideal management approach to capsule retention?
5. What are ideal standards for training and competency in the performance and interpretation of CE?
6. What are best ways to assess adequacy of the mucosal examination and use of CE image-processing algorithms?
7. Is it feasible to use artificial intelligence to assist in CE video interpretation to identify all clinically meaningful lesions, increase diagnostic yield, and reduce reading time?

### Conclusion

The proposed quality indicators for CE, summarized in Table 5,<sup>7</sup> were selected because the task force felt that these components were most important to a high-quality CE examination. The task force believes that these quality indicators will lead to improved documentation of the procedure and communication of findings and will provide critical information to enhance clinical management and possibly improve outcomes. Certainly, more high-quality studies are needed to confirm the benefit of the quality in-

### BOX 1. Quality reporting components for capsule endoscopy

Key components
Indication and brief clinical history
Endoscopic vs oral ingestion
Gastric and small-bowel transit times
Quality of bowel preparation with mention of adequacy
Diagnostic findings
Image landmarks
Completeness of study
Comment on retention, if indicated

dicators. As CE technology evolves, these quality indicators will be adjusted, and new ones will be included.

## DEEP ENTEROSCOPY

### Quality indicators for DE

#### Preprocedure.

1. Frequency of demonstrating competency in DE

Type of measure: process

Performance target: 100%

Evidence summary: Limited data exist regarding training requirements for DE, which is labor-intensive with a steep learning curve. The procedure requires a unique set-up and instruments and a trained, skilled nurse/technologist or team. Two studies using balloon enteroscopy reported that procedural time and small-bowel extent visualized improves after 10 to 15 procedures.<sup>72,73</sup> In a single-center study of double-balloon enteroscopy (DBE), clinical impact increased from 58% for an endoscopist's first 50 procedures to 86% at 200 procedures.<sup>74</sup> The clinical impact of total enteroscopy increased from 8% for the first 50 procedures to 63% for the last 50 of 200 procedures.<sup>74</sup> For single-balloon enteroscopy (SBE), a reasonable recommended learning curve is about 30 procedures for experienced endoscopists.<sup>75</sup> Spiral enteroscopy may require less training, and competency seems to improve after 5 procedures.<sup>76</sup> A recent ESGE position statement suggested that DE training should be structured, so that trainees perform a minimum of 75 procedures and acquire skills to independently manage small-bowel pathology, after which they would undergo formal evaluation.<sup>10</sup> In the United States, however, DE training is not yet standardized.

2. Frequency of performing DE for an indication that is documented and included in a published, standard list of appropriate indications

Type of measure: process

Performance target: 90%

Evidence summary: DE indications have been reported in previous guidelines and are listed in Box 2.<sup>77</sup> The indication for the procedure should be documented and,

**TABLE 5. Quality indicators ranked as appropriate for CE**

Quality indicator	Type of measure	Performance target (%)
<b>Preprocedure</b>		
Frequency of demonstrating competency in CE	Process	100
Frequency of performing CE for an indication that is documented and included in a published, standard list of appropriate indications	Process	90
Frequency of obtaining informed consent, including specific discussions of risks associated with CE	Process	98
Frequency of using a test for luminal patency before CE for patients with risk factors for capsule retention in the small bowel	Process	90
Frequency of performing CE in a timely manner after an episode of overt, suspected small-bowel bleeding	Process	90
<b>Intraprocedure</b>		
Frequency of performing endoscopic capsule placement for patients with contraindications to swallowing the capsule or for patients at risk of gastric retention	Process	80
<b>Postprocedure</b>		
Frequency of performing photo documentation and documenting small-bowel transit time	Process	98
Frequency of recommending an appropriate management plan based on CE findings	Process	80
Frequency of using a standardized CE reading method for video interpretation	Process	80
Frequency of documenting completeness and adequacy of mucosal visualization	Process	95
Frequency of tracking CE adverse events and documenting appropriate management	Process	95
Frequency of performing abdominal radiography at 2 wk or more after CE when the examination is not completed to the cecum and/or the capsule has not been observed to pass	Process	90
Frequency of generating a complete report in the electronic health record for all patients undergoing CE	Process	98
<b>Ranked as inappropriate or uncertain</b>		
Frequency of performing bowel preparation before CE	Process	N/A

CE, Capsule endoscopy; N/A, not applicable.

Modified from Adler et al.<sup>7</sup>

when nonstandard, the reasons should be clearly documented. DE is indicated when a small-bowel lesion is suspected from symptoms or previous testing and requires further investigation or therapy. DE is not typically performed as the initial diagnostic test for small-bowel evaluation. DE differs from CE and cross-sectional imaging in that it allows for biopsy, lesion marking, and other therapeutic procedures. DE complements small-bowel CE and cross-sectional imaging and is usually considered after less-invasive testing suggests a small-bowel lesion. Small-bowel CE, CT, or MR enterography, or a combination of these procedures,<sup>17</sup> can be used to assist with the diagnosis and localization of small-bowel lesions to guide the DE approach (antegrade vs retrograde) and therapy. Studies have shown that using CE or cross-sectional imaging, or both, to guide DE is an ideal practice and may increase the diagnostic yield.<sup>78,79</sup>

The most common indication for DE is small-bowel bleeding. DE may be the initial test of choice to control massive small-bowel bleeding. Other indications include suspected small-bowel masses, polyps, inflammatory bowel disease, foreign-body removal, stricture dilation, a percutaneous endoscopic jejunostomy procedure, and access to altered anatomy for endoscopic retrograde cholangiopan-

#### **BOX 2. Appropriate indications for deep enteroscopy**

Indication
Small-bowel bleeding
Small-bowel tumor or polyp
Inflammatory bowel disease
Foreign-body removal
Stricture dilation
Placement of percutaneous endoscopic jejunostomy
Access for altered anatomy for endoscopic retrograde cholangiopancreatography

creatography<sup>80</sup> (Box 2). Malabsorptive syndromes and refractory celiac disease may also be indications for DE, especially when lesions need to be evaluated or biopsies taken. DE is indicated in the evaluation of suspected Crohn's disease when patients have symptoms, but other tests are negative or nondiagnostic.<sup>81</sup> DE may also be useful in Crohn's disease to assess for disease activity or for response to therapy when other studies are not helpful. DE is indicated for the evaluation and dilation of short strictures, both for Crohn's disease and NSAID

enteropathy.<sup>82,83</sup> In addition, retained capsule endoscopes can be retrieved using DE.<sup>84</sup> There are no specific contraindications to performing DE beyond what applies to any endoscopic procedure.

### 3. Frequency of reviewing a CE or cross-sectional imaging study before DE

Type of measure: process

Performance target: 80%

Evidence summary: A reported small-bowel lesion on CE or cross-sectional imaging should be reviewed by the endoscopist before performing DE, whenever possible. Review of a CE video or imaging study, or both, before DE is helpful to determine the risk/benefit of the procedure and to plan the endoscopic approach to the lesion as well as therapy. When the entire CE video is not available, color pictures of the lesion should be reviewed. Red blood identified on CE warrants more urgent DE for therapy. The pylorus, ampulla, ileocecal valve, fold protrusions, and air bubbles are sometimes mistaken for a mass lesion or polyp on CE. Red spots, mucosal erythema, or prominent veins may be interpreted as vascular lesions. Small-bowel wall thickening on cross-sectional imaging may be due to incomplete lumen distension with contrast, and intussusceptions may be physiologic. Visualization of the suspected small-bowel lesion on CE or imaging studies, or both, allows for correlation with findings at DE to ensure the lesion was reached.

### 4. Frequency of discussing the management of anticoagulation with the patient and documenting the periprocedural anticoagulation plan

Type of measure: process

Performance target: 90%

Evidence summary: In the periprocedural period, anticoagulation should be managed according to current society guidelines. A documented anticoagulation plan is critical for evaluating and managing suspected cases of small-bowel bleeding. When small-bowel bleeding is suspected from a lesion that has been difficult to identify, performing DE without discontinuing anticoagulation should be considered, but preparations should be made for the possibility of increased bleeding in the periprocedural period. No studies have been published that explore DE risks of patients taking antiplatelet agents or anticoagulants.<sup>46</sup> The overall risk of hemorrhage associated with diagnostic DE is low, .2%, but it increases to 3.3% if polypectomy is performed.<sup>85</sup> In a small study describing the results of spiral enteroscopy, no significant risk of bleeding was reported.<sup>76</sup>

No studies have been published to guide the management of anticoagulation in the setting of suspected small-bowel bleeding and DE. Studies that have been published described bleeding with polypectomy and ulcer.<sup>86,87</sup> Current guidelines base management on the overall procedural risk of bleeding.<sup>86,87</sup> Diagnostic balloon-assisted enteroscopy is considered a low-risk procedure.<sup>86</sup> However, a therapeutic DE procedure for polypectomy would be considered high

risk of bleeding. Initially, it is reasonable to continue aspirin and NSAIDs before DE but to discontinue anticoagulants and other antiplatelet agents.<sup>86</sup> Studies have shown that postprocedural hemorrhagic events were not higher for anticoagulated patients if they were treated according to current guidelines.<sup>88</sup> In a small subset of clinically stable patients with recurrent GI bleeding, when no lesion is found, continuing anticoagulation may help identify the actively bleeding lesion. However, the only data to support this approach are provocative mesenteric angiography in lower GI hemorrhage.<sup>89</sup> The overall results were good, with a low adverse events rate.

### 5. Frequency of documenting the choice of insertion route based on CE transit time or cross-sectional imaging

Type of measure: process

Performance target: 95%

Evidence summary: The route chosen for DE should be documented and based on lesion location on CE SBTT or cross-sectional imaging. If the lesion location is unknown, the approach should be based on the clinical history, differential diagnosis, and type of bleeding. The decision to perform DE is usually based on findings from small-bowel CE or CT or MR enterography or a combination of these findings. In adults, the small intestine averages 600-cm long. Other than the ampulla in the duodenum and lymphoid hyperplasia in the terminal ileum, no reliable landmarks exist in the small bowel to predict the location of a lesion identified on CE. Study results have suggested that a time-based index could be used to guide an antegrade or retrograde approach.<sup>90</sup> If a lesion was identified more than 75% of the total time from ingestion to cecal visualization, the decision to start through the retrograde approach had a high positive predictive value (94.7%) and negative predictive value (96.7%). Two subsequent studies evaluated lesion localization based on the SBTT when the capsule passed the pylorus. In these studies, an SBTT of less than 60% best determined an antegrade route.<sup>91,92</sup>

An antegrade approach may have a higher diagnostic and therapeutic yield than a retrograde approach<sup>93,94</sup> because of the common location of vascular lesions in the proximal small bowel and deeper insertion length. The antegrade approach can reach a maximal insertion distance of 240 cm to 360 cm, whereas the retrograde approach has an insertion distance of 102 to 180 cm.<sup>72,74,95</sup> The presence of melena predicts bleeding in the proximal small bowel.<sup>96</sup> With massive overt GI bleeding, an antegrade approach is recommended because of the higher diagnostic and therapeutic yield.<sup>17,97,98</sup> The lower approach is generally reserved for patients with suspected Crohn's disease or neuroendocrine tumors.<sup>93,94</sup> Total enteroscopy may be indicated if a lesion is not identified during the initial examination and may be successful when attempted in 45% to 86% of cases.<sup>95,99</sup>

For the retrograde approach, a bowel purge, as in colonoscopy, is necessary. There are no data to suggest that a

bowel purge before an antegrade enteroscopy is needed or leads to an increased diagnostic yield.

### Preprocedure research questions

1. How much training is required to be competent in the performance of DE and what methods can be developed to assess DE competency?
2. What is optimal anticoagulation management for patients undergoing DE that not only improves safety but also improves diagnostic yield?
3. When should DE be performed directly and bypass CE for suspected small-bowel lesions?
4. What is the optimal timing of DE in the setting of GI bleeding?
5. Should total enteroscopy be routinely performed for patients with suspected small-bowel bleeding when the initial approach is negative?
6. How accurate is noninvasive imaging in determining the best route of DE insertion?
7. What is the ideal sedation method for DE?

### Intraprocedure

1. Frequency of performing DE in a timely manner after a bleeding episode

Type of measure: process

Performance target: 90%

Evidence summary: DE should be performed within 72 hours, when available, for patients with urgent or ongoing overt, suspected small-bowel bleeding to optimize diagnostic and therapeutic yield.<sup>100-105</sup> In patients with urgent and/or persistent bleeding, it may be prudent to proceed with DE without CE when expertise is available. Alternative approaches include interventional radiology or intraoperative enteroscopy when DE is not available. The diagnostic and therapeutic yield of DE is highest when DE is performed soon after a bleeding episode and decreases when there is a delay in performing the procedure. One study reported a decrease in diagnostic yield from 84% to 57% when DBE was performed more than 1 month after an episode of overt GI bleeding.<sup>104</sup> Most studies, however, suggest that performing DE within 72 hours is ideal. For suspected small-bowel bleeding deemed urgent, DBE performed within 72 hours of a major bleeding event was associated with a 70% diagnostic yield compared with a diagnostic yield of 30% for nonurgent examinations.<sup>100</sup> Another study showed that therapeutic yield decreased when DBE was performed at 72 versus 24 hours after a bleeding episode.<sup>101</sup> Most importantly, a more recent study showed that DE within 72 hours not only improved diagnostic yield but also showed improved outcomes as measured by transfusion requirements and rebleeding rates.<sup>103</sup>

2. Frequency of using carbon dioxide insufflation for DE

Type of measure: process

Performance target: 90%

Evidence summary: DE is a lengthy procedure that requires gas insufflation in the small bowel for visualization.

However, air is poorly absorbed, which can cause pain and render bowel pleating less efficient with push-and-pull enteroscopy because of air trapping in bowel loops. The use of carbon dioxide (CO<sub>2</sub>) with DE improves depth of insertion and reduces patient discomfort. Therefore, CO<sub>2</sub> is the preferred method of insufflation for DE when available.

In a randomized, controlled, double-blind trial using DBE,<sup>105</sup> CO<sub>2</sub> insufflation, when compared with air, significantly improved depth of insertion and reduced patient discomfort. A similar finding was reported in a controlled, double-blind trial using SBE and CO<sub>2</sub> insufflation.<sup>106</sup> In a multicenter, randomized, controlled trial using SBE, CO<sub>2</sub> insufflation versus air significantly improved depth of insertion only in those patients who had previous surgery, but all patients reported less pain. Significantly less pain was also reported with CO<sub>2</sub> insufflation and DBE in a prospective, randomized, double-blind trial.<sup>107</sup> The cost-effectiveness of using CO<sub>2</sub>, including as it relates to procedure length, has not been studied.

3. Frequency of estimating depth of advancement

Type of measure: process

Performance target: 90%

Evidence summary: An estimate of advancement into the jejunum or ileum should be documented as in other endoscopic procedures to predict whether the site of a suspected lesion was examined and whether total enteroscopy will be feasible in difficult DE cases. When possible, the depth of insertion in centimeters should be estimated. There are few landmarks available in the small intestine to determine distance advanced or location of a lesion on imaging studies or DE. After several push-or-pull cycles or with the spiraling technique, the depth of insertion becomes progressively more difficult to predict. This situation has clinical implications when a definitive small-bowel lesion found on capsule or enterography is not reached.

The distance of each push-and-pull cycle can be estimated on insertion of the endoscope, which is a validated method for measuring the depth of insertion using DBE.<sup>108-110</sup> This method is accurate within 10% of the actual lesion location, which is based on results of animal and human studies. Other studies that reported using fold count on withdrawal<sup>111</sup> and depth of insertion using spiral enteroscopy<sup>112</sup> have not been validated. The clinical usefulness and outcomes based on estimating depth of insertion using these methods are unknown.

4. Frequency of marking the most distal point of advancement when indicated

Type of measure: process

Performance target: 90%

Evidence summary: When a lesion is not reached, a tattoo should be placed at the deepest site of insertion to mark the extent reached, especially when complete enteroscopy is planned. Complete enteroscopy is rare from a single upper or lower approach and is required when a

suspected small-bowel lesion is not reached from the initial approach. Estimating depth of insertion by counting during DE is an imperfect method for determining the distal point of advancement.<sup>108-111</sup> Placing a tattoo by submucosal injection at the deepest site of insertion allows for complete enteroscopy from the opposite approach when the previously placed tattoo is reached. A higher success rate has been reported for complete enteroscopy when the upper and lower approaches were performed on separate days.<sup>113</sup> If complete enteroscopy is not possible and surgery is needed, previously placed tattoos at the deepest ends of insertion will allow the surgeon to focus on the unexamined small bowel to find the lesion. Because there are overlying loops of small bowel in the abdominal cavity, care must be taken to avoid tattooing adjacent bowel loops. Submucosal saline-injection lift followed by ink injection may limit this risk.

5. Frequency of characterizing and treating clinically significant lesions

Type of measure: process

Performance target: 98%

Evidence summary: DE is usually performed for tissue sampling or therapy of a suspected small-bowel lesion identified on CE or cross-sectional imaging. Localization of lesions can be difficult because of the length of the small bowel and lack of landmarks. It is therefore important to document that the lesion reached at DE correlates with CE or the imaging study. The nomenclature “erythematous patches,” “red spots,” and “phlebotasia” should be used to describe lesions found during DE, which are similar terms to those in the recently proposed nomenclature for small-bowel CE.<sup>114</sup> Ulcers and tumors should be biopsied and marked for possible resection. DE can also be used in treating small-bowel vascular lesions and in polypectomy. Dilation of strictures, which generally result from NSAID use or Crohn’s disease, is safe and effective for patients with a single stricture less than 5-cm long that is relatively straight and nonulcerated, as described in several systematic reviews.<sup>115-122</sup>

6. Frequency of treating a vascular lesion that is believed to be a potential source of bleeding

Type of measure: process

Performance target: 98%

Evidence summary: Vascular lesions identified at DE should be described and interpreted according to proposed nomenclature and treated with endoscopic therapy when small-bowel bleeding is suspected or found.<sup>114,123</sup> Low-wattage settings should be used because the small intestine wall is thin. No safety studies support any thermal therapy device over another. A classification of small-bowel vascular lesions has been proposed based on whether the lesion is flat or punctate (angioectasia), raised or pulsating (Dieulafoy type), or raised with surrounding venous dilation (arteriovenous malformation).<sup>123</sup> This classification allows for a common descriptive language that may guide endoscopic therapy and facilitate future

research. For recurrent small-bowel bleeding, a repeat DE with therapy of vascular lesions may be useful.<sup>104,124</sup> The rate of recurrent GI bleeding after endoscopic therapy is high in those with medical comorbid conditions or left ventricular assist devices. Conservative management using endotherapy combined with a somatostatin analogue<sup>125</sup> or somatostatin with intravenous iron and transfusions with or without endotherapy<sup>126</sup> may be warranted for such patients.

### Intraprocedure research questions

1. What factors may affect the sensitivity of the DE examination for finding clinically significant lesions seen on CE?
2. What factors, such as type of enteroscope, bowel preparation quality, and withdrawal time, affect diagnostic yield?
3. What technology is needed to optimize and improve the depth of insertion?
4. What technology is needed to determine the optimal route of insertion based on noninvasive imaging?
5. What technical improvements in DE are needed to reduce procedure time?
6. What tools can be developed and designed for DE that will improve small-bowel endoscopic therapy?
7. What approach to anesthesia and sedation for DE is ideal?
8. What technology is available to determine depth of insertion more accurately?

### Postprocedure

1. Frequency of generating a complete report that includes findings, specific techniques performed, accessories used, and adverse events

Type of measure: process

Performance target: 98%

Evidence summary: DE is a labor-intensive procedure. Lesions identified in the small bowel should be photographed and described, including with a diagnostic impression, in the endoscopy report. The endoscopy report should also include whether a mucosal lesion correlates with the lesion identified on a previous CE or cross-sectional imaging study. A detailed report should be generated after each DE procedure that includes route of insertion, estimated depth of insertion, whether a suspected lesion was reached, details of therapeutic interventions, representative endoscopic and fluoroscopic images if these procedures were performed, and adverse events. Documentation should include whether the primary goal was achieved, and the findings communicated to the referring physician. The report should document all relevant findings and procedure duration. The endoscopist should specify whether the lesion in question was identified and treated. Equipment and techniques used to perform a procedure should also be documented, eg, whether a tattoo was placed to mark the deepest site of insertion,

**TABLE 6. Quality indicators ranked as appropriate for DE**

Quality indicator	Type of measure	Performance target (%)
<b>Preprocedure</b>		
Frequency of demonstrating competency in DE	Process	100
Frequency of performing DE for an indication that is documented and included in a published, standard list of appropriate indications	Process	90
Frequency of reviewing a CE or cross-sectional imaging study before DE	Process	80
Frequency of discussing the management of anticoagulation with the patient and documenting the periprocedural anticoagulation plan	Process	90
Frequency of documenting choice of insertion route based on CE transit time or cross-sectional imaging	Process	95
<b>Intraprocedure</b>		
Frequency of performing DE in a timely manner after a bleeding episode	Process	90
Frequency of using carbon dioxide insufflation for DE	Process	90
Frequency of estimating depth of advancement	Process	90
Frequency of marking the most distal point of advancement when indicated	Process	90
Frequency of characterizing and treating clinically significant lesions	Process	98
Frequency of treating a vascular lesion that is believed to be a potential source of bleeding	Process	98
<b>Postprocedure</b>		
Frequency of generating a complete report that includes findings, specific techniques performed, accessories used, and adverse events	Process	98
Frequency of tracking DE adverse events and documenting appropriate management	Process	95
<b>Ranked as inappropriate or uncertain</b>		
Frequency of discussing the management of anticoagulation with the patient and documenting the periprocedural anticoagulation plan	Process	N/A

CE, Capsule endoscopy; DE, deep enteroscopy; N/A, not applicable.  
Modified from Adler et al.<sup>7</sup>

limitations that would guide future procedures, and images of lesions found. The DE report should document the standard quality indicators common to all GI procedures<sup>5</sup> and any specimens obtained for pathology or special studies. Follow-up instructions should include information for resuming diet, medications, anticoagulants, and next plans with the endoscopist or referring physician.

## 2. Frequency of tracking DE adverse events and documenting appropriate management

Type of measure: process

Performance target: 95%

Evidence summary: All acute adverse events should be identified and managed appropriately. When identified intraprocedure, an intestinal perforation should be repaired endoscopically when possible. The risk of other adverse events including aspiration, acute pancreatitis, bleeding, and undetected perforation requires postprocedure monitoring. When an adverse event is identified, the endoscopy report should include the adverse events and management plans.

The overall risk of DE adverse events is approximately 1.2%.<sup>127</sup> The risk increases with therapeutic interventions including cautery of vascular lesions, dilation of strictures,

and resection of large polyps, with estimates of adverse events occurring in 4.3% to 8.0% of cases.<sup>85,98,127-132</sup> The most common adverse events are perforation, bleeding, and pancreatitis. SBE and DBE have similar adverse events rates.<sup>133-137</sup> The risk of perforation may be increased in patients undergoing retrograde DBE who have a history of surgically altered anatomy, but this observation is based on limited data.<sup>138</sup> Pancreatitis, a risk that is usually associated with antegrade DE, occurs in less than 1% of patients. Lipase and amylase levels should not be routinely ordered unless a patient is symptomatic. There are no reports of pancreatitis with SBE, but the procedure has a perforation risk.<sup>139,140</sup> Patients who have comorbid conditions, are clinically unstable, or are undergoing a complicated therapeutic intervention may be admitted for observation. Any recognized adverse events should be managed immediately.<sup>17</sup> Resumption of anticoagulation or antiplatelet therapy, or both, should be based on endoscopic guidelines. No guidelines have been published regarding dietary restrictions after DE. Standard practice for recovery and resumption of oral intake used for endoscopic procedures should be followed.

## Postprocedure research questions

1. What are the diagnostic yields and outcomes of DE in nonacademic gastroenterology practices?
2. How often are clinically significant lesions identified on DE missed on CE?
3. How can we improve the reporting frequency of adverse events, including immediate and delayed adverse events?
4. What is the impact of DE on clinical outcomes for vascular lesions, such as reduction of transfusion requirements, rate of recurrent bleeding, and need for recurrent interventions?

## Conclusion

Table 6 summarizes proposed quality indicators for DE,<sup>7</sup> which were selected because the task force believed they were most important to a high-quality DE examination. The task force believes these quality indicators will lead to improved procedure documentation and communication of findings, will provide critical information to enhance treatment, and will possibly improve outcomes. More high-quality studies are needed to confirm the benefit of the quality indicators. As DE technology evolves, these quality indicators will be adjusted, and new ones will be added.

## CONCLUSION

CE and DE have an important positive impact on the diagnosis and management of small-bowel diseases. However, comprehensive quality indicators for CE and DE performance have been lacking, despite previous efforts to create individual quality metrics. The task force hoped to improve the quality performance of these relatively new small-bowel diagnostic techniques by compiling comprehensive recommendations of quality indicators for CE and DE procedures. Incorporating the measures into clinical practice will improve standardization of these procedures, further increasing quality. Finally, we have identified knowledge gaps and posed specific research questions to help guide future studies that may continue improving the quality of CE and DE procedures.

## CONFLICTS OF INTEREST

**Guarantor of the article:** Jonathan A. Leighton, MD.

**Specific author contributions:** All authors meet the 4 ICMJE criteria for authorship, that is, substantial contributions to conception and design of the work; acquisition, analysis, and interpretation of data for the work; drafting the work or revising it critically for important intellectual content; and final approval of the version to be published. All authors agree to be accountable for all aspects of the work.

## Study Highlights

### WHAT IS KNOWN

- ✓ Capsule endoscopy and deep enteroscopy (DE) are available technologies that can be useful for diagnosing and treating suspected small-bowel diseases.
- ✓ Comprehensive quality indicators are lacking for the performance of capsule endoscopy and DE.

### WHAT IS NEW HERE

- ✓ Comprehensive guidelines are presented for quality indicators of capsule endoscopy and DE.
- ✓ The guidelines address existing knowledge gaps and pose questions to better inform future quality guidelines.

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