

Multisociety Sedation Curriculum for Gastrointestinal Endoscopy

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The Multisociety Sedation Curriculum for Gastrointestinal Endoscopy (MSCGE) grew out of the need for a complete and programmatic approach to the training of procedure sedation. As a natural outgrowth of the Gastroenterology Core Curriculum, the sponsoring societies thought that a comprehensive document covering the aspects of procedure sedation from pharmacology, periprocedure assessment, airway management, and the use of anesthesia services was necessary for a variety of reasons. Chief among these was to ensure a standardized basis for instruction through the use of competency-based training.

This constitutes a living document that represents the sponsoring societies' vision of best practices in procedure sedation training based on published data and expert consensus. It provides a framework for developing an individual plan of study and growth that should be tailored to meet the needs of each individual trainee based on the strengths and special qualities of each individual training program. Additionally, the curriculum can serve the practicing gastroenterologist in the updating of both knowledge and skills. The curriculum will continue to evolve with time as new knowledge, methods of learning, novel techniques and technologies, and challenges arise. This edition has been divided into an overview of training and 11 sections encompassing the

breadth of knowledge and skills required for the practice of procedural sedation for GI endoscopy.

This MSCGE represents a joint collaborative effort among the national gastroenterology societies—the American Association for the Study of Liver Diseases, the American College of Gastroenterology, the American Gastroenterological Association Institute, and the American Society for Gastrointestinal Endoscopy. In addition, the Society for Gastroenterology Nurses and Associates played a crucial role in the development of the MSCGE. Other professional non-GI societies and regulatory organizations were invited to take part in the development of the MSCGE. This included the American Association of Nurse Anesthetists, the American Society of Anesthesiologists (ASA), and the Centers for Medicare and Medicaid Services (CMS). The American Association of Nurse Anesthetists did not respond to inquiries, CMS decided not to participate, and the ASA appointed a nonvoting observer who participated in the developmental process.

The executive committees of each of the sponsoring societies, as well as several subject matter experts, made specific recommendations for revising the core curriculum. Each society then named representatives who were charged with overall responsibility for developing, communicating, and distributing the curriculum. Throughout this document, the paramount importance of practice and research based on the highest principles of ethics, humanism, and professionalism is reinforced.

Sedation Pharmacology

Importance

Endoscopic sedation strives to seek a balance between patient comfort and drug-related side effects. Optimal sedation allows the patient the greatest degree of comfort while preserving the greatest degree of safety. To achieve this, the endoscopist must fully understand the sedation that he or she is using. This also requires careful consideration of the patient, the endoscopy facil-

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Abbreviations: ACLS, Advanced Cardiac Life Support; ASA, American Society of Anesthesiologists; BIS, bispectral index; CMS, Centers for Medicare and Medicaid Services; MSCGE, Multisociety Sedation Curriculum for Gastrointestinal Endoscopy.

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ity, and the variables of the procedure itself. Patient factors include age, weight, medical history, concurrent medications, intubation assessment, preprocedure anxiety, and pain tolerance. Procedure variables include the amount of anticipated discomfort, the duration of examination, and how invasive the procedure will be. The drugs most widely used for endoscopic sedation were the benzodiazepines and opioids. Recently, there has been growing interest in the use of other agents with unique pharmacologic properties designed to enhance sedation and analgesia. The endoscopist should be familiar with the sedation agents used including the drug's pharmacokinetic parameters (time of onset, peak response, and duration of effect), pharmacodynamic profile (individual variations in clinical response to a drug), elimination profile, potential adverse effects, and drug-drug interactions.

Goals of Training

Trainees should gain an understanding of the following:

1. The pharmacokinetics and pharmacodynamics of different sedation agents, their synergy and potential interactions with other medications and potential adverse reactions.
2. Mastery of the titration of these agents for the desired level of sedation. For the vast majority of endoscopic cases, this should be moderate sedation.

Training Process

1. Trainees should develop a thorough knowledge of the pharmacokinetics and pharmacodynamics of sedation agents before embarking on endoscopic training.
2. Trainees should develop expertise in the administration of sedation medications under direct supervision in the endoscopy suite. If a high-fidelity sedation simulator is available, this should be used before training in the endoscopy suite. A brief primer in sedation pharmacology is provided in Appendix A.

Assessment of Competence

Knowledge of sedation pharmacology should be assessed as part of the overall evaluation of trainees in gastroenterology during the fellowship. Questions relating to sedation pharmacology should be included on the board examination and should reflect a general knowledge of this content.

Informed Consent for Endoscopic Sedation

Importance

The ethical and legal requirement to obtain informed consent before performing endoscopy derives from the concept of personal (patient) autonomy. The competent patient, after receiving appropriate disclosure of the material risks of the procedure and understanding those risks and the benefits and alternative approaches, makes a voluntary and uncoerced informed decision to proceed.

The process of obtaining informed consent is both a basic ethical obligation and also a legal requirement for physicians. It allows the patient to gain an understanding of the proposed treatment and the risks involved, as well as learn about alternatives or voice any concerns or questions. The physician has the opportunity to ask about the patient's treatment goals and discover any patient-specific information that will enable the most optimal choice of treatment. When an informed patient agrees to proceed with a course of treatment, this allows substantial transfer of the risk of adverse outcome to the patient who understands and accepts the imperfect nature of the procedure and therapy.

Most state laws specify that obtaining informed consent is a nondelegatable duty, ie, it must be performed by the physician and cannot be relegated to one's staff or endoscopy nurse. However, consent is a process, and if sufficient and thorough information is provided, the final portion, in which the physician finalizes consent before the procedure and asks the patient whether there are any other questions remaining, may be very brief. This is most important for the success of an open-access process, so that open-access patients have already received information and have been given the opportunity to ask questions to satisfaction before preparation for the procedure. Language issues need to be addressed by using an interpreter. If the patient is unable to give consent, an appropriate legal representative should be sought.

A risk management recommendation particularly relevant for informed consent for open access is to have an intake/preparation process for open access in which the patient is sent or verbally given information about the procedure, including the purpose, description of the procedure, and risks, benefits, and alternatives. It would be useful to instruct the patient to call in if any concerns or questions occur after having read the information and document this instruction. Further, one could instruct the office staff to be alert to patients who appear uncertain, seem to have many questions, or very worried about proceeding; these patients may be best served with a preprocedure consultation. At the time of the open access, the physician can meet state law obligation by briefly summarizing the information.

The nature of moderate sedation is such that a patient may perceive, but may not be aware of the context and surroundings to sufficiently understand the implications of a demand to stop the procedure. The discomfort is likely to be short-lived and the procedure safe and successful, and often the patient has no recall of difficulty or any request to stop the procedure. Additional medication or additional techniques may allow more comfortable completion of the procedure. Indeed, the patient may wish the discomfort to stop, not the procedure! However, the endoscopist and staff must be aware that consent can be withdrawn. The author surmises, based on conversations with experienced endoscopists, that most requests to stop are not truly withdrawal of consent, but an artifact of sedation causing misperception of the context of procedure activity. However, the prudent endoscopist will

carefully evaluate a request to stop, assessing, for example, whether the patient is speaking in full coherent sentences or mumbling incomprehensibly, to be as certain as possible that it is not a true withdrawal of consent.

Goals of Training

During training, the trainee should gain an understanding of the following:

- I. The principles of informed consent
 - A. Capacity to give consent
 - B. Material risks of endoscopic sedation
 - C. Shared decision making
 1. Discussion of sedation alternatives, from no sedation to anesthesiologist-provided general deep sedation.
 - D. Exemptions for the consent requirement
 1. Emergency exception/waiver
 - E. Withdrawal of consent
 - F. Regulatory and institutional requirements to obtain and document consent
- II. Understand that informed consent includes endoscopic sedation as well as endoscopic procedures, ie, it applies to the sedation portion of the global procedure experience
- III. Understand the special situations and considerations, such as the applications of informed consent in an open-access setting
- IV. Understand shared decision-making concepts
- V. Understand the concept of withdrawal of consent
 - A. An ineffectively sedated patient has the right to demand that the procedure be stopped, even though partially sedated.
 - B. Be aware of risk factors for ineffective sedation, which may prompt withdrawal of consent in a patient expecting significant sedation. These include chronic narcotic and/or anxiolytic use with patients in whom anxiolytic/narcotic sedation is planned and medical conditions that may preclude effective sedation, such as chronic obstructive pulmonary disease, cor pulmonale, advanced cardiomyopathy, and severe obstructive sleep apnea.
- VI. Give the patient the opportunity to ask questions.

Training Process

A short training process will likely be sufficient because most trainees will already have a basic understanding of informed consent. Targeted review and training for endoscopic sedation may include reading materials and/or lecture(s) and/or direct observation of faculty with discussion by faculty.

Assessment of Competence

Adequacy of learning may be assessed by written examination and/or oral discussion with faculty and/or observation by faculty.

Periprocedure Assessment for Endoscopic Procedures

Importance

Periprocedure assessment is a crucial component of the practice of endoscopic sedation. Preprocedure assessment should encompass a thorough review of the patient's sedation history, the identification of medical conditions that may increase the risk of procedure sedation, and balance these findings with the type of procedure scheduled and the targeted level of sedation. Intraprocedure assessment encompasses the maintenance of stable and safe cardiovascular parameters and level of sedation. The postprocedure assessment focuses on ensuring the recovery of baseline physiologic parameters and the identification of any complications. The trainees should be competent in the periprocedure assessment of the patients undergoing sedation for all GI endoscopic procedures.

Goals of Training

During fellowship, trainees should obtain a comprehensive understanding of the following during the preprocedure evaluation of patients undergoing endoscopic procedures with sedation:

1. Confirm the patient's suitability to undergo the planned procedure at the targeted sedation level (Table 1).
2. The trainee will obtain a directed history that addresses the potential influence on the procedure and the anticipated level of sedation with particular attention to the following:
 - a. Cardiopulmonary disease (ischemic heart disease, congestive heart failure, asthma, chronic obstructive pulmonary disease). Assessment for obstructive sleep apnea, stridor, neurologic, or seizure disorders. Previous experience with procedural sedation should also be queried.
 - b. A complete list of medications, including over-the-counter agents, and allergies should be recorded.
 - c. The patient should be assessed according to the ASA physical status classification scale (Table 1).
3. Trainees will gain knowledge about the role of moderate sedation in ASA classes 1 through 3.
4. Trainees must ascertain the duration of fasting before a procedure, ie, 2 hours after clear liquid intake and 6 hours after a light meal before sedation to allow administration of moderate sedation or anesthesiologist-directed sedation. These intervals should be lengthened in the setting of gastric-emptying abnormalities.
5. The trainee will perform a targeted physical examination, including vital signs with heart rate, blood pressure, and baseline oxygen saturation. The patient should have a cardiopulmonary assessment to screen for stridor, wheezing, heart murmurs or arrhythmias, as well as an abdominal examination for surgical scars and masses. A limited neurologic examination should assess pre-sedation mental status orientation to assess

Table 1. ASA Physical Status Classification

PS 1	Normal healthy patient	No organic, physiologic, or psychiatric disturbance; excludes the very young and very old; healthy with good exercise tolerance
PS 2	Patients with mild systemic disease	No functional limitations; has a well-controlled disease of 1 body system; controlled hypertension or diabetes without systemic effects, cigarette smoking without COPD; mild obesity, pregnancy
PS 3	Patients with severe systemic disease	Some functional limitation; has a controlled disease of >1 body system or 1 major system; no immediate danger of death; controlled CHF, stable angina, previous heart attack, poorly controlled hypertension, morbid obesity, chronic renal failure; bronchospastic disease with intermittent symptoms
PS 4	Patients with severe systemic disease that is a constant threat to life	Has at least 1 severe disease that is poorly controlled or at end stage; possible risk of death; unstable angina, symptomatic COPD, symptomatic CHF, hepatorenal failure
PS 5	Moribund patients who are not expected to survive without the operation	Not expected to survive >24 h without surgery; imminent risk of death; multiorgan failure, sepsis syndrome with hemodynamic instability, hypothermia, poorly controlled coagulopathy
PS 6	A declared brain-dead patient who organs are being removed for donor purposes	

ASA, American Society of Anesthesiologists; PS, physical status; COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure.

for obvious focal deficits. Finally, a detailed evaluation of the airway, including body habitus, neck structure, cervical spine, hyoid mental distance, and oropharynx, should be performed.

- Trainees should gain knowledge about periprocedure endoscopic sedation in special circumstances, such as pregnancy. Trainees should clearly document the patient's preanesthesia assessment history, physical examination, and informed consent. Before administration of anesthesia, a time out should be performed according to the Joint Commission's Universal Protocol and should include, at a minimum, the procedure team's agreement as to the patient's identity and the type of procedure to be performed.

Assessment of Competency

Procedure assessment for endoscopic procedures should be assessed as part of the overall evaluation of trainees in gastroenterology during fellowship. Questions relating to procedure assessment should be included on the board examination and should reflect a general knowledge of this content.

Levels of Sedation

Importance

In recent years, the Joint Commission has identified the following 4 levels of sedation, which stretch along a continuum without clear boundaries: minimal sedation or anxiolysis, moderate sedation, deep sedation, and general anesthesia. To date, these levels of sedation have been defined by a patient's response to verbal, light tactile, or painful stimuli, although they are generally also associated with physiologic changes in patient vital signs. Viewed from the perspective of a continuum of sedation, targeting minimal levels of sedation by definition creates the potential for patients to become deeply sedated. Accordingly, it has been recommended that all providers be

prepared to rescue patients from deeper levels of sedation than targeted. It should be noted that there are no physiologic data to support these definitions.

Most cardiopulmonary events during GI endoscopy stem from hypoventilation cascading into hypoxia and cardiac decompensation. As a basic component of monitoring, pulse oximetry has become a standard of care in endoscopy units around the world. Yet, pulse oximetry may not adequately reflect hypoventilation, apnea, impending hemodynamic instability, or vasoconstrictive shock. In particular, patients may be well saturated with oxygen and still experience significant carbon dioxide retention. Technological advances in the past decade have enabled the practical measurement of real-time end-tidal carbon dioxide and ventilatory waveforms in nonintubated patients. In this way, capnography has emerged as a noninvasive way of measuring patient ventilation that may be especially useful in patients undergoing deeper levels of sedation.

Consensus also dictates that levels of sedation are directly related to patient risks. Minimal sedation implies the retention of a patient's ability to respond voluntarily to vocal commands (eg, "take a deep breath" or "turn on your back") and to maintain a patent airway with protective reflexes. Moderate sedation describes a depth of sedation at which patients are able to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function, protective airway reflexes, and the ability to react to verbal or tactile stimulation. Deep sedation implies a medically controlled state of depressed consciousness from which the patient is not easily aroused, but can respond purposefully to painful stimulation. General anesthesia describes the deepest level of sedation wherein the patient is unarousable with painful stimuli. Generally speaking, depth of sedation is directly related to cardiovascular and airway instability; the deeper the level of sedation, the more a patient is considered to be at risk of

Table 2. Ramsay Sedation Scale

Response to verbal stimulation	Numerical score
Agitated	6
Responds readily to name spoken in normal tone	5
Lethargic response to name spoken in normal tone	4
Responds only after name called loudly and/or repeatedly	3
Responds only after mild prodding or shaking	2
Does not respond after mild prodding or shaking	1
Does not respond to test stimulus	0

cardiopulmonary events (Table 2). Monitored anesthesia care may include varying levels of sedation, analgesia, and anxiolysis as necessary.

Goals of Training

Trainees in endoscopic sedation should gain an understanding of the following:

1. The concept of sedation depth as a continuum
2. Definitions (stimulus and effect) of the 4 codified levels of sedation and expected physiologic changes in vital signs for each
3. Clinical training in targeting appropriate levels of sedation for patients and/or procedures
4. Patient and/or procedure factors that may affect the depth of sedation targeted and/or achieved
5. Clinical training in assessing levels of sedation continuously throughout a procedure
6. The difference between oxygenation and ventilation, as well how these physiologic processes are reflected by various patient monitors
7. Indications for advanced clinical monitoring during endoscopic procedures, including capnography

Training Process

Training should take place within the framework of clinical care and problem solving. Successful programs require skilled and experienced endoscopic instructors who continually maintain and improve the instructional talents required to teach endoscopy and the periprocedure assessment that is crucial to the performance of such procedures. A structured training experience coupled with ongoing evaluation of trainees' progress should be used.

Assessment of Competence

Knowledge of periprocedure assessment should be assessed as part of the overall evaluation of trainees in gastroenterology during the Fellowship program. Questions relating to periprocedure assessment should be included in the board examination and should reflect a general knowledge of this content.

Training in the Administration of Specific Agents for Moderate Sedation

Importance

The safe and effective administration of pharmacologic agents to induce and maintain a state of moderate sedation is a core skill essential to the performance of GI endoscopic procedures. All trainees should receive comprehensive instruction in the selection and administration of agents used for moderate sedation. Although moderate sedation for endoscopic procedures is most often achieved through the intravenous bolus delivery of opioids and benzodiazepines, trainees should understand that moderate sedation may also be induced and maintained with combination regimens using propofol. Although propofol used in combination with other agents is a valuable option for moderate sedation, deep sedation generally results when it is administered as a single agent for endoscopic sedation. Trainees should recognize that deep sedation may also result from conventional sedation techniques using only opioids and benzodiazepines even when moderate sedation is targeted.

As the use of propofol has rapidly expanded across the spectrum of endoscopic sedation and anesthesia, the specific manner in which it is used, including bolus or continuous-infusion dosing schemes, whether it is used in combination with adjunctive sedating and analgesic agents, and the type of health care provider (registered nurse, nurse anesthetist, physician endoscopist, anesthesiologist, nonanesthesiologist physician) who administers or supervises its use has varied widely in the United States and around the world. This variation is attributable to differing institutional history and professional culture, legal and regulatory requirements, issues of training and credentialing, and economic factors. Endoscopists who do not personally administer propofol or direct its use must still be prepared to make decisions when propofol-mediated sedation by an anesthesia provider is appropriate. They must be skilled in the recognition of delayed propofol-related adverse events that may arise after recovery from sedation, such as fever, chills, or myalgia that may arise within 48 hours of administration. In many states, a certified registered nurse anesthetist must be supervised by the physician endoscopist if the certified registered nurse anesthetist is not otherwise supervised by an anesthesiologist. Endoscopists may also assume responsibility at a managerial or ownership level for the development, approval, and monitoring of policies and procedures defining how propofol is procured, stored, administered, and accounted for in their units. The technique of titrating propofol to a level of moderate sedation after low premedication doses of an opioid, benzodiazepine, or both is known as balanced propofol sedation, which is a form of nonanesthesiologist-administered propofol sedation. Moderate sedation using propofol may also be achieved using a computer-assisted personalized sedation system known as SEDASYS, which at this time is experimental

though has been granted “approvable” status by the U.S. Food and Drug Administration.

Although moderate sedation, during which the patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, is an appropriate target level of sedation for most endoscopic procedures, deep sedation, during which the patient is not easily arousable but is purposely responsive after repeated or painful stimulation, should be anticipated when patient-related or procedure-related factors suggest that moderate sedation may be inadequate. The trainee must be familiar with these factors and must recognize that transient deep sedation at some time during endoscopic procedures is a frequent outcome of conventional sedation using benzodiazepines and opioids, even when these agents are specifically titrated with the intent of maintaining moderate sedation.

Although unintended periods of deep sedation may occur when moderate sedation is targeted, the planned targeting of deep sedation raises specific regulatory concerns in addition to requiring a higher level of competency in rescue techniques. The CMS has defined moderate sedation, as described previously, to be outside the scope of anesthesia services and thus exempt from the facility requirements to which hospitals are subject when anesthesia is provided. In contrast, targeted deep sedation or general anesthesia requires elements of the preanesthesia and postanesthesia evaluations that must be documented in the medical record and require that these evaluations and the anesthesia care itself be provided only by individuals who are qualified under statute §482.52(a) to administer anesthesia. Deep sedation, in contrast to moderate sedation, is currently viewed by the CMS to be a form of anesthesia (monitored anesthesia care), and thus deep sedation is subject to the statutory requirements that are applicable to anesthesia services in general.

The selection and dosing of sedation agents must reflect an understanding of key principles of endoscopic sedation.

1. An individual patient’s response to each sedation agent is unique. Response may be related to age, weight, and pharmacologic profile as well as unpredictable and unidentified factors. This patient-specific unique response necessitates careful titration to effect and to the procedure needs rather than strict adherence to standard dosing regimens.
2. Accumulation of drug effect occurs with repeated dosing, necessitating an understanding and consideration of time to onset of action, time to peak action, and the half-life of action for each agent used.
3. Synergism of drug effect occurs among sedating agents, necessitating appropriate dose reductions.
4. Levels of stimulation during the course of endoscopic procedures may vary markedly, potentially necessitating related adjustments to the depth of sedation during the procedure. Anticipation of periods of increased noxious stimulation allows anticipatory strategic dos-

ing schemes, particularly if propofol is used in the balanced moderate sedation model.

Goals of Training

During a fellowship, trainees should gain an understanding of the following:

1. Appropriate selection of patients for moderate sedation based on findings from personal consultation and consideration of
 - a. The nature of the intended procedure
 - b. Comorbidities
 - c. Airway factors and other physical factors potentially affecting the sedation process
 - d. Pharmacologic profile
 - e. History of illicit drug or alcohol use
 - f. Psychiatric profile
 - g. Sedation/anesthesia history (including intolerance or potential allergy to any of the planned drugs)
 - h. Patient expectations and consent issues relating specifically to the sedation process
2. Pharmacologic profiles of drugs used for endoscopic sedation (see Sedation pharmacology section and Table 3)
3. Dosing regimens for induction and maintenance of moderate sedation that reflect consideration of age, weight, and pharmacologic synergy that include appropriate time intervals between doses and maximum recommended doses for commonly used moderate sedation agents and antagonists
 - a. Meperidine
 - b. Fentanyl
 - c. Naloxone
 - d. Diazepam
 - e. Midazolam
 - f. Flumazenil
 - g. Propofol
 - h. Ketamine
 - i. Nitrous oxide
 - j. Dexmedetomidine
 - k. Diphenhydramine
 - l. Promethazine
 - m. Droperidol
 - n. Fospropofol
4. Regulatory issues (including issues related to U.S. Food and Drug Administration labeling; CMS definitions of sedation and anesthesia; pertinent state laws; institutional regulations, policies, and procedures; and issues related to diversion control)
5. Safe injection practices
6. Documentation of drug administration
7. Supervision/direction of delivering sedation agents and monitoring the patient’s status. This should include effective and constant communication among members of the endoscopy sedation team, including the manner in which drug orders are provided to nursing staff and information regarding the patient’s status is shared with the responsible physician endoscopist.

Table 3. Pharmacologic Profile of Drugs Used for Endoscopic Sedation*

Drug	Onset of action, min	Peak effect, min	Duration of effect, min	Initial dose	Pharmacologic antagonist	Side effects
Dexmedetomidine, μg	<5	15	Unknown	1/kg	None	Hypotension, bradycardia
Diazepam, mg	2-3	3-5	360	5-10	Flumazenil	Respiratory depression, chemical phlebitis
Diphenhydramine, mg	2-3	60-90	>240	25-50	None	Dizziness, prolonged sedation
Droperidol, mg	3-10	30	120-240	1.25-2.5	None	QT interval prolongation, ventricular arrhythmia, extrapyramidal effects
Fentanyl, μg	1-2	3-5	30-60	50-100	Naloxone	Respiratory depression, vomiting
Flumazenil, mg	1-2	3	60	0.1-0.3	None	Agitation, withdrawal symptoms
Ketamine, mg	<1	1	10-15	0.5/kg	None	Emergence reaction, apnea, laryngospasm
Meperidine, mg	3-6	5-7	60-180	25-50	Naloxone	Respiratory depression, pruritus, vomiting, interaction with MAOI
Midazolam, mg	1-2	3-3	15-80	1-2	Flumazenil	Respiratory depression, disinhibition
Naloxone, mg	1-2	5	30-45	0.2-0.4	None	Narcotic withdrawal
Nitrous oxide	2-3	Dose dependent	15-30	Titrate to effect	None	Respiratory depression, headache
Promethazine, mg	2-5	Unknown	>120	12.5-25	None	Respiratory depression, hypotension, extrapyramidal effects
Propofol, mg	<1	1-2	4-8	10-40	None	Respiratory depression, cardiovascular instability

MAOI, Monoamine oxidase inhibitor.

*For healthy individual <60 years of age.

- Dynamic decision making related to depth of sedation and procedure tolerance (see Anesthesiologist Assistance for Endoscopic Procedures section)
- Determining failure of moderate sedation and institution of alternative management strategies (see Anesthesiologist Assistance for Endoscopic Procedures)

Training Process

Training in the administration of sedation agents should take place within the framework of general training in endoscopy, although it should be structured and evaluated as a distinct component of endoscopic competency.

Cognitive training. Didactic training should incorporate lectures and independent study of a core of essential literature.

Procedure training. Level 1: Use of a high-fidelity sedation simulator, if available. Observation of faculty physician managing sedation

Level 2: Independent ordering of sedation drug administration under faculty supervision

Case Review

Trainees should participate in the discussion of cases of sedation-related adverse events.

Assessment of Competence

- Written test
- Subjective assessment of faculty supervisor specific to sedation-related competency pertaining to use of sedation agents
- Sedation outcomes assessment, including cardiopulmonary events and related interventions, unplanned procedure termination, and unplanned hospital admission or anesthesiology or critical care management
- Knowledge of the use of sedation agents targeted to moderate sedation should be assessed as part of the overall evaluation of trainees in a gastroenterology fellowship program. This will require knowledge of the pharmacology of the sedation agents and mastery of the continuum of sedation with the ability to provide rescue when deeper than intended levels of sedation are reached. See (Table 3, Appendix A).

Training in Airway/Rescue Techniques and Management of Complications

Importance

Sedation accounts for a substantial proportion of endoscopic complications. The most common serious and life-threatening complications related to sedation are respiratory in etiology. Of these, the most serious is aspira-

tion because its consequences may be impossible to correct or prevent once substantial aspiration has occurred. Even minor episodes of aspiration may result in prolonged coughing, bronchospasm, or pulmonary infections. Thus, avoidance of pulmonary aspiration is critical for safe endoscopic practice.

The most common respiratory events during endoscopy are related to hypoventilation induced by sedation agents. These events are related to the depth of sedation and may result from suppression of respiratory drive in the central nervous system or from airway collapse that occurs with sedation. Although avoidance of these events can be largely achieved by preprocedure airway assessment followed by titration of sedation doses to the minimal depth of sedation needed to complete the procedure and ensure adequate patient satisfaction, the variable pharmacologic response to all available sedatives means that the occurrence of impaired respiration is arguably more of an expected part of an endoscopic sedation than a complication. The term complication is probably better applied to any consequences of hypoventilation that are not promptly corrected by the managing team and lead to sustained adverse consequences including death, neurologic or other permanent sequelae, and pulmonary infection. As such, the ability to recognize an increased risk of apnea and airway obstruction and to apply corrective measures promptly and effectively is fundamental to the performance of endoscopy.

Cardiovascular complications are less commonly life threatening during endoscopy, and, when life threatening, they most often follow a period of inadequate ventilation and hypoxemia. Nevertheless, the physiologic response to sedation and the physical stress of endoscopy is quite variable. Individual patients have a susceptibility to vagally mediated bradycardia and hypotension that can be precipitated by simple placement of an intravenous catheter or stretching the sigmoid mesentery during passage of a colonoscope. In other patients, marked tachycardia may develop if the procedure is started when they are inadequately sedated, particularly during upper endoscopic procedures. Hypertension is seen commonly during endoscopic procedures and is often aggravated by patients not taking their medications for hypertension on the day of the procedure. Although hypotension and hypertension during endoscopy very rarely result in permanent complications, they occasionally reach levels for which corrective action is appropriate. Finally, atrial or ventricular arrhythmias are rarely precipitated by sedation or stress of the procedure. The endoscopist must be able to accurately diagnose arrhythmia, recognize when arrhythmias are life threatening or resulting in cardiovascular compromise, and institute corrective measures when appropriate.

Goals of Training

During training, trainees should gain an understanding of the following:

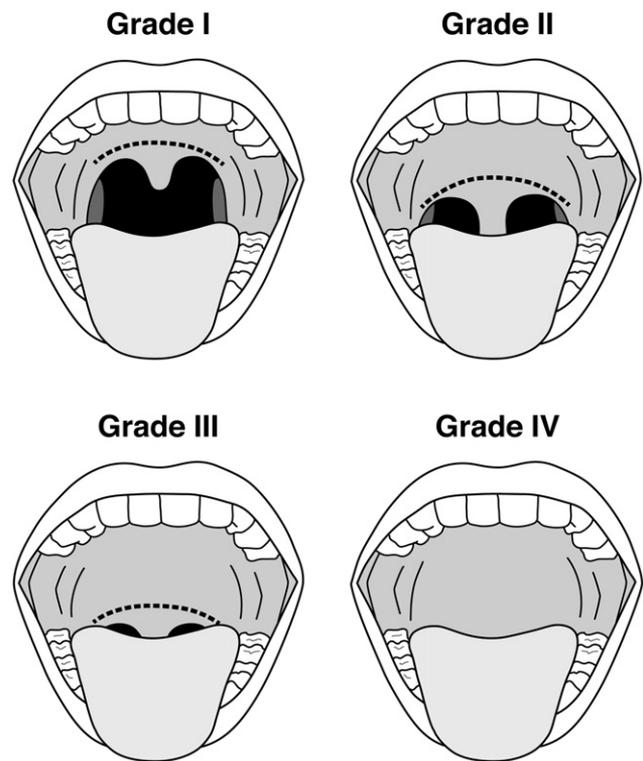


Figure 1. Modified Mallampati Classification. Class 1, full visibility of tonsils, uvula, and soft palate; class 2, visibility of hard and soft palate, upper portion of tonsils, and uvula; class 3, soft and hard palate and base of the uvula are visible; class 4, only hard palate is visible.

1. Anatomy of the mouth, pharynx, hypopharynx, and nasopharynx. This should include use of the modified Mallampati classification, which may predict the ease of endotracheal intubation (Fig. 1).
2. Conditions associated with an increased risk of pulmonary aspiration including active upper GI hemorrhage, achalasia, bowel obstruction with gastric distention, and delayed gastric emptying
3. Patient positioning to reduce the risk of aspiration such as elevation of the head of the bed
4. Signs that gastroesophageal reflux or emesis is or may be occurring during endoscopy and necessitate protective measures including frank emesis, drooling during colonoscopy, excessive retained fluid in the esophagus or stomach, hiccoughing, and protracted coughing
5. Clinical signs of apnea including the absence of chest wall and diaphragmatic movement (abdominal wall movement), absence of air movement at the mouth, and interpretation of capnography readings
6. Clinical signs of airway obstruction including snoring, laryngospasm, paradoxical chest movement, absence of air movement at the mouth, and interpretation of capnography readings
7. The relationship of hypoxemia to impaired ventilation in patients using and not using supplemental oxygen
8. The use of supplemental oxygen to treat and prevent hypoxemia

9. Indications for and performance of the head-tilt maneuver
10. Indications for and performance of the chin-lift or jaw-thrust maneuver
11. Indications for and placement of a nasopharyngeal airway
12. Indications for and placement of an oropharyngeal airway
13. Indications for and performance of bag-mask ventilation
14. Indications for, contraindications to, and placement of a laryngeal mask airway
15. Indications for, contraindications to, and dosing of naloxone
16. Indications for, contraindications to, and dosing of flumazenil
17. Completion of Advanced Cardiac Life Support (ACLS) certification, including recognition of common atrial and ventricular arrhythmias, interpretation of the significance of arrhythmias, management of arrhythmias, and performance of cardiopulmonary resuscitation
18. Indications for and dosing and administration of atropine or glycopyrrolate or vagolytic agents for treatment of bradycardia
19. Indications for and use of position change and fluid bolus for the management of hypotension
20. Indications for, contraindications to, and dosing of intravenous agents for the treatment of severe hypotension, including ephedrine
21. Indications for, contraindications to, and dosing of intravenous agents for the treatment of severe hypertension, including β -blockers

Training Process

Trainees should complete the ACLS training or the equivalent, such as the Advanced Trauma Life Support course that includes hands-on airway training, and hold a valid ACLS certificate. Trainees should learn the anatomy of the airway through study of anatomic drawings and models. Trainees should learn airway assessment (see Periprocedure assessment section) and learn recognition of apnea and airway obstruction through experience assessing ventilation in the endoscopy unit. An understanding of capnography can be gained from instruction available in the literature, and training should include real-time interpretations of capnographic waveforms in the endoscopy unit if capnography is used in the unit. Didactic training is necessary for pharmacologic agents that are not covered in ACLS or are used in endoscopy outside their roles in emergencies. These include naloxone, flumazenil, agents for hypotension and hypertension, and the use of atropine (glycopyrrolate or vagolytic agents) for vasovagal reactions.

Specific maneuvers for opening the airway should be practiced initially on models, including the head-tilt, chin lift, or jaw-thrust maneuvers; placement of naso-

pharyngeal and oropharyngeal airways; and bag mask ventilation.

Specific elements of training should include the following:

1. Didactic session on risk factors for aspiration during endoscopy and prevention of aspiration
2. Didactic sessions and study of written materials on airway anatomy, airway assessment, and identification of impaired and absent ventilation
3. ACLS certification including hands-on airway training
4. Didactic training in the significance of hypoxemia with reference to ventilation in patients using and not using supplemental oxygen
5. Didactic training in the use of supplemental oxygen to prevent and treat hypoxemia
6. The head-tilt and jaw-thrust maneuvers, placement of a nasopharyngeal airway, oropharyngeal airway, bag-mask ventilation, and laryngeal mask airway should be practiced on models.
7. Didactic training in the use of reversal agents for opioids and benzodiazepines
8. Didactic training in the use of intravenous agents for bradycardia, hypotension, and hypertension

Assessment of Competence

Competence should be assessed by completion of the ACLS examination, by a written examination covering issues not addressed by ACLS (including aspiration risk, recognition of compromised ventilation, hypoxemia-ventilation relationship, use of reversal agents, use of intravenous medications for hypotension and hypertension), by demonstration of techniques to open the airway on models, and by assessment of trainee's ability to prevent aspiration, assess airway risk, and manage airway compromise and other sedation complications promptly and appropriately.

Anesthesiologist Assistance for Endoscopic Procedures

Importance

Many factors may contribute to the decision to have anesthesiologist-directed sedation for endoscopic procedures. Procedure-related factors include prolonged procedures requiring deep sedation and/or general anesthesia. Patient-related factors are also important. Chief among these are increasing levels of adverse physiology and uncooperative patients. An ASA Physical Status of 4 or greater has been associated with an increased risk of cardiopulmonary complications. The use of sedatives, analgesics, and alcohol can also increase sedation-related risk (Table 4).

Goals of Training

During training, trainees should gain an understanding of the following:

1. Didactic training in the recognition of clinical conditions, history, and physical findings that may predis-

Table 4. Guidelines for Anesthesiology Assistance During GI Endoscopy

Prolonged or therapeutic endoscopic procedures requiring deep sedation or general anesthesia
Anticipated intolerance, paradoxical reaction or allergy to standard sedation regimens
Increased risk of complications because of severe comorbidity (ASA class 4 and higher)
Increased risk of airway obstruction
History of stridor
History of severe sleep apnea
Dysmorphic facial features
Trisomy 21
Pierre-Robin syndrome
Oral abnormalities
<3 cm oral opening in adults
Protruding incisors
Macroglossia
High arched palette
Tonsillar hypertrophy
Mallampati score of 4
Neck abnormalities
Decreased hyoid-mental distance (<3 cm in adults)
Short thick neck
Limited neck extension
Cervical spine disease (eg, advanced rheumatoid arthritis) or trauma
Severe tracheal deviation
Jaw abnormalities
Retrognathia
Micrognathia
Trismus
Severe malocclusion

ASA, American Society of Anesthesiologists.

pose to increased risk of cardiopulmonary complications with standard sedation (Table 4).

2. Didactic and clinical training in the use of Mallampati classification.
3. Didactic and clinical training in ASA physical status assessment

Training Process

The training process will involve didactic lectures as well as clinical instruction and demonstration.

Assessment of Competence

Competence should be assessed during clinical training as well as by a part of a comprehensive written examination.

Intraprocedural Monitoring

It is the responsibility of the nurse to monitor the patient’s vital signs, comfort, and clinical status. In addition, an individual other than the physician performing the endoscopy, such as a nurse, needs to possess the skills necessary to recognize and intervene in the event that adverse events occur during the endoscopic procedure. It is imperative that the physician-nurse team maintain ongoing communication throughout the procedure to opti-

mize the early recognition and treatment of cardiopulmonary events.

Minimal monitoring requirements recommended for the patient receiving moderate sedation and analgesia are periodic assessment of blood pressure and continuous assessment of cardiac rhythm and rate, ventilation, oxygenation, level of consciousness, and pain. The combination of observation and electronic monitoring provides a thorough method of patient assessment. Electronic devices that are useful are pulse oximetry, electronic blood pressure devices, continuous electrocardiogram monitoring, and capnography. In a recent publication regarding Standards for Basic Anesthetic monitoring, the ASA House of Delegates states “During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.”

It should be noted that the only evidence suggesting that capnography may be of benefit are in adults undergoing prolonged procedures such as ERCP and EUS and in the pediatric population undergoing upper endoscopy and colonoscopy. Currently, there are no data showing a benefit of capnography in adults undergoing upper endoscopy or colonoscopy. It is to be determined whether this will become a standard requirement for future endoscopic practice.

The nurse should be familiar with all of the monitoring equipment. Pre-sedation equipment evaluation is necessary to validate its functionality.

It is important to monitor the level of consciousness of the patient. Many clinical scoring systems have been developed to assist in determining the level of sedation and patient responsiveness, such as the Modified Observers Assessment of Alertness and Sedation score and the Ramsay score (Tables 2 and 5). These are useful tools for the titration of medications throughout the procedure.

Bispectral index (BIS) monitoring may be another tool used in the care of patients undergoing sedated procedures. This enables the clinician to monitor a

Table 5. Modified Observer’s Assessment of Alertness/Sedation Scale

Responsiveness	Numerical score
Responds readily to name spoken in normal tone	5
Lethargic response to name spoken in normal tone	4
Responds only after name is called loudly and/or repeatedly	3
Responds only after mild prodding or shaking	2
Responds only after painful trapezius squeeze*	1
No response after painful trapezius squeeze	0

*Purposeful response, not withdrawal.

patient's level of consciousness. The BIS monitor uses electroencephalographic waveforms to measure consciousness. Currently, there are no data supporting the role of BIS monitoring during procedure sedation for GI endoscopy.

The nurse must be knowledgeable about the significance of the patient's hemodynamic physiologic changes, ventilation and oxygenation status, and level of sedation. Pain assessments are needed throughout the procedure. This often poses a challenge in the sedated patient. Visual cues of discomfort and the knowledge and use of various pain scales are helpful to evaluate a patient's comfort status.

Communication between the nurse and endoscopist is expected if any of the patient needs or physiologic parameters change. Complete documentation of the assessments and monitoring data is imperative during the sedation process. It is required that documentation occurs at regular intervals throughout the procedure.

Goals of Training

The trainee should learn the necessary components of intraprocedure monitoring. This would generally include the following competencies:

1. State the necessary monitoring requirements for a patient undergoing procedure sedation
2. Demonstrate the proper use of monitoring tools during sedation: noninvasive blood pressure devices, pulse oximetry, electrocardiographic monitoring, and capnography
3. Document required vital signs and monitoring.
4. Identify and document the sedation scale used during the procedure

Training Process

Training in physiologic monitoring should include familiarity with equipment and troubleshooting should there be dysfunction of the physiologic monitoring equipment. Once this baseline core competency is completed, training with equipment during GI endoscopic procedures should ensue. Trainees should gain experience and interpretation of physiologic monitoring values and demonstrate the appropriate intervention should alarm values be noted. Additionally, the trainee should demonstrate the ability to periodically assess the level of consciousness of patients during procedure sedation.

Assessment of Competence

The assessment of competence with intraprocedure monitoring should be assessed as part of the overall evaluation of trainees in their GI endoscopy training during the fellowship. Questions related to intraprocedure monitoring should be included on the board examination and should reflect a general knowledge of this competency.

Postprocedure Assessment Training

Importance

As with intraprocedure monitoring, the continuum of physiologic monitoring and its importance in determining physiologic recovery as well as early identification of oversedation should be emphasized.

In the postprocedure area, the recovery of physiologic and basic functional parameters as outlined by basic postsurgical and anesthesia grading schemes should be emphasized.

The trainee should learn the appropriate standards of postprocedure monitoring and predischarge assessment and understand the risk of postprocedure sedation-related complications of procedure sedation. This should include the following:

1. The importance of periodic assessment of vital signs. This should include blood pressure, pulse, oximetry, and, in selected situations, electrocardiography.
2. The indications, contraindications, dosing, and side effects of reversal agents such as flumazenil and naloxone. The risk of re sedation must also be addressed.
3. Pain assessment according to established institutional protocols
4. Familiarity with the assessment of the level of consciousness according to an established grading system (ie, Ramsay or Modified Observers Assessment of Alertness and Sedation score; see Tables 2, 5).
5. Familiarity with a standardized discharge assessment scoring system such as the Post-Anesthetic Discharge Scoring System or the Aldrete score (Tables 6,7).
6. Familiarity with verbal and written instructions outlining diet, activity, medication, and follow-up instructions. Patients who have received any sedation must have an adult escort and may not drive themselves home.

Table 6. Aldrete Score

Respiration	2 = Able to take deep breath and cough
	1 = Dyspnea/shallow breathing
	0 = Apnea
Oxygen saturation	2 = Maintains >92% on room air
	1 = Needs O ₂ inhalation to maintain O ₂ saturation >90%
	0 = Saturation <90% even with supplemental oxygen
Consciousness	2 = Fully awake
	1 = Arousable on calling
	0 = Not responding
Circulation	2 = BP ±20 mm Hg preprocedurally
	1 = BP ±20-50 mm Hg preprocedurally
	0 = BP ±50 mm Hg preprocedurally
Activity	2 = Able to move 4 extremities
	1 = Able to move 2 extremities
	0 = Able to move 0 extremities

Total score is 10. Patients scoring ≥8 (and/or are returned to similar preoperative status) are considered fit for transition to phase II recovery.

BP, Blood pressure.

Goals of Training

During training, trainees should gain an understanding of and demonstrate operational competency in the following:

1. Didactic training in the recognition of clinical conditions, history, and physical findings that may predispose to increased risk of cardiopulmonary complications with standard sedation. (Table 1).
2. Didactic and clinical training in the use of Mallampati classification. In patients receiving anesthesia-assisted sedation, an increased Mallampati score has been shown to be a risk factor for the need for anesthesia-directed airway manipulation. There are no similar data for endoscopic sedation targeting moderate sedation (Fig. 1).
3. Didactic and clinical training in the ASA physical status classification assessment.

Training Process

The training process will involve didactic lectures as well as clinical instruction and demonstration. Trainees must demonstrate proficiency in the interpretation of physiologic monitoring data as well as recovery assessment. This experience should include the cognitive and technical aspects of physiologic monitoring. In addition, the use of extended monitoring devices such as capnography should be considered in those instances in which deep sedation is targeted or direct observation of the patient's respiratory activity cannot be obtained.

Assessment of Competence

Knowledge of procedure monitoring and recovery assessment should be assessed as part of the overall evaluation trainees in gastroenterology. Questions relating to physiologic monitoring should be included on the board examination and should reflect general knowledge of this content.

Table 7. Postanesthetic Discharge Scoring System

Vital signs
2 = Within 20% of preoperative value
1 = 20%-40% of preoperative value
0 = >40% of preoperative value
Activity and mental status
2 = Oriented \times 3 and steady gait
1 = Oriented \times 3 or steady gait
0 = Neither threshold is reached
Pain, nausea, and/or vomiting
2 = Minimal
1 = Moderate, having required treatment
0 = Severe, requiring treatment
Bleeding
2 = Minimal
1 = Moderate
0 = Severe
Intake and output
2 = Has had oral fluids and voided
1 = Has had oral fluids or voided
0 = Neither

Total score is 10; ≥ 9 considered for discharge.

Table 8. Indications for Endoscopy During Pregnancy

- | |
|---|
| 1. Significant or continued GI bleeding |
| 2. Severe or refractory nausea and vomiting or abdominal pain |
| 3. Dysphagia or odynophagia |
| 4. Strong suspicion of a colonic mass |
| 5. Severe diarrhea with a negative evaluation |
| 6. Biliary pancreatitis, choledocholithiasis, or cholangitis |
| 7. Biliary or pancreatic ductal injury |

Endoscopy in Pregnant and Lactating Women

Importance

The safety and efficacy of GI endoscopy during pregnancy is not well studied. The fetus is particularly sensitive to maternal hypoxemia and hypotension that can potentially lead to fetal compromise. It is therefore imperative to know the potential risks to the fetus and to balance these risks with clear indications when endoscopic intervention is necessary. Additionally, caution needs to be exercised with the use of certain medications because they may be transferred to the infant from the breast milk.

Goals of Training

1. Knowledge of the indications for and contraindications to endoscopy during pregnancy. This should include a trimester-specific approach to the procedure whenever possible, patient positioning, minimal radiation exposure, and the use of obstetric support (Tables 8,9).
2. Knowledge of the safety of commonly used medications for endoscopy during pregnancy. This should include sedation and reversal agents, topical anesthetics, antispasmodics, antibiotics, and colon-cleansing agents (Tables 10, 11).
3. Knowledge of which medications can be transferred to a breastfeeding infant (Table 12).

Training Process

A combination of cognitive/clinical skills and knowledge in the setting of endoscopic training is necessary for training in the care of women who are pregnant or lactating.

Table 9. General Principles Guiding Endoscopy During Pregnancy

- | |
|--|
| 1. Always have a strong indication, particularly in high-risk pregnancies |
| 2. Delay endoscopy until the second trimester whenever possible |
| 3. Use the lowest effective dose of sedative medications |
| 4. Wherever possible, use category A or B drugs |
| 5. Minimize procedure time |
| 6. Position patients in left pelvic tilts or left lateral position to avoid vena caval or aortic compression |
| 7. Presence of fetal heart sounds should be confirmed before procedure is begun and after the endoscopic procedure |
| 8. Obstetric support should be available in the event of a pregnancy-related complication |
| 9. Endoscopy is contraindicated in obstetric complications such as placental abruption, imminent delivery, rupture of membranes, and eclampsia |

Table 10. U.S. FDA Categories for Drugs Used in Pregnancy

Category	Description
A	Adequate, well-controlled studies in pregnant women have not shown an increased risk of fetal abnormalities
B	Animal studies have revealed no evidence of harm to the fetus; however, there are no adequate or well-controlled studies in pregnant women <i>or</i> Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus
C	Animal studies have shown an adverse effect and there are no adequate or well-controlled studies in pregnant women <i>or</i> No animal studies have been conducted, and there are no adequate and well-controlled studies in pregnant women
D	Adequate well-controlled or observational studies in pregnant women have demonstrated a risk to the fetus; however, the benefits of therapy may outweigh the potential risk
X	Adequate well-controlled or observational studies in animals or pregnant women have demonstrated positive evidence of fetal abnormalities; use of the product is contraindicated in women who are or may become pregnant

FDA, Food and Drug Administration.

Assessment of Competence

Knowledge of endoscopy in pregnant and lactating women should be assessed as a part of an overall evaluation of trainees in gastroenterology during and after the fellowship. Questions relating to this topic should be included in the board examination and should reflect a general knowledge of this content.

Assessment of Competency in Endoscopic Sedation

Importance

The assessment of competency is of critical importance during training in procedure sedation and monitor-

Table 11. U.S. FDA Categories for Drugs Used During Endoscopy

Medication	FDA Category
Meperidine	B
Fentanyl	C
Naloxone	B
Benzodiazepines	D
Flumazenil	C
Propofol	B
Simethicone	C
Glucagon	B
Topical anesthetics	B
Colonoscopy preparations	
PEG solutions	C
Sodium phosphate/biphosphate	C
Sodium phosphate/bisphosphate enemas	C

FDA, Food and Drug Administration; PEG, polyethylene glycol.

Table 12. Breastfeeding Recommendations for Medications Used During Endoscopy

Medication	Secreted into breast milk	Recommendations
Midazolam	Yes	Refrain from nursing for at least 4 h after administration
Fentanyl	Yes	Secreted in very low concentrations; considered safe for breastfeeding
Meperidine	Yes	Detectable up to 24 h after administration; although considered compatible with breastfeeding, fentanyl should be used when possible
Propofol	Yes	Excreted into breast milk for 4-5 h after administration; continued breastfeeding after exposure is not recommended; length of prohibition not determined
Penicillin/cephalosporins	Yes	Trace amounts excreted; considered compatible with breastfeeding
Quinolones	Yes	Potential for arthropathy in the infant; should be avoided
Sulfonamides	Yes	Contraindicated in nursing infants <2 months of age; avoid if infant is premature, ill, or has glucose-6-phosphate dehydrogenase deficiency

ing during GI endoscopy. Whenever possible, basic knowledge such as pharmacology and the use of physiologic monitoring should be established before the trainee is placed in the environment of the procedure room. The use of simulators and Web-based programs that are designed to assess technical and cognitive abilities should be used whenever possible. After demonstration of this knowledge, the trainee then continues with training in the procedure room environment.

Goals of Training

As listed in Table 13, there are many types of competencies that need to be addressed including medical knowledge, practical competencies, interpersonal and communication skills, patient care, professionalism, practice-based learning improvement, and systems-based learning. This is based on the competency evaluation process as outlined by the American Board of internal Medicine and currently used in gastroenterology fellowship programs.

It should be noted that the attainment of competency is not a static process. It is not infrequent that a trainee

Table 13. Competencies and Assessment Tools

Competencies to be evaluated	Assessment tools
Medical knowledge Indications and contraindications Principles of airway management Available agents (pharmacology, dosing, administration intervals, antagonists)	Web-based objective examination Current certificate including hands-on training and skills demonstration of airway management and automated external defibrillator use; demonstrated competency in bag-valve-mask ventilation, use of oral and nasal airways, supraglottic airways
Practical competencies ACLS protocols (PALS if pediatric patients treated) Proficiency in airway management Interpersonal and communication skills Informed consent process	Direct observation. Performance sampling by patient feedback tool and/or medical record audit. Web-based patient simulations.
Patient care Application of techniques to clinical scenarios, complications Professionalism	Multisource feedback from nurses, technicians, patients; portfolio (reflective narratives)
Practice-based learning and improvement Systems-based practice	Medical record audits; patient satisfaction surveys Medical record audits; Patient satisfaction surveys; QA/PI projects including adverse events monitoring

ACLS, Advanced Cardiac Life Support; PALS, Pediatric Advanced Life Support; QA, Quality Assessment; PI, Performance Improvement.

who is taken out of a learning environment for some time may exhibit decrement in a previously achieved competency. It is recommended therefore that exposure to procedure sedation and GI endoscopy is continued on a regular basis so that competencies can be conserved.

Principles of Assessment

1. Assessment should be linked to learning goals and completion of learning modules.
2. Learning environment and evaluation should be of high quality.
3. Evaluation should be timely, reliable, transparent, engaging, and efficient.

Proposed Mechanisms for Assessment

1. Web-based interactive instructional modules or workbook with the opportunity to present information in a structured fashion that will engage the learner and build on existing knowledge.
2. Web-based objective examination for medical knowledge.
3. Web-based patient simulations/clinical scenarios to test application of knowledge to simple and complex situations.
4. Development of feedback tools, audit blueprints, and portfolio guides for other competencies for use by local medical staffs.
5. Mechanism for certification of successful completion of training process for presentation to privileging committees (for staff) or program directors (for trainees).

Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of

Gastroenterology at www.gastrojournal.org, and at <http://dx.doi.org/10.1053/j.gastro.2012.05.001>.

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Appendix: A Pharmacology Primer

Opioids

Opioids exert their pharmacologic effects by binding to opioid receptors that are present throughout the central nervous system and peripheral tissues. Chemical structure differences between these medications account for their differences in pharmacokinetic parameters and receptor specificity and affinity.

Meperidine. The induction dose of meperidine for conscious sedation is 25 to 50 mg administered slowly over 1 to 2 minutes. Additional doses of 25 mg may be administered every 2 to 5 minutes until adequate sedation is achieved. Its onset of action is 3 to 6 minutes, and its duration of effect ranges from 1 to 3 hours. The half-life of meperidine may be significantly prolonged in patients with renal insufficiency, increasing the potential for neurotoxicity. For this reason, it is generally recommended that fentanyl be used for sedation in patients with significant renal insufficiency. The major adverse effects associated with meperidine are respiratory depression and, to a lesser extent, cardiovascular instability. The use of a barbiturate or benzodiazepine with an opioid has a synergistic effect on the risk of respiratory depression. At low doses, opioid-induced nausea and vomiting are not dose dependent. A neurotoxic reaction with myoclonus and convulsions caused by the accumulation of normeperidine has been reported in patients with renal failure.

Fentanyl. Fentanyl is a synthetic opioid narcotic and is structurally related to meperidine. The onset of action is 1 to 2 minutes and duration of effect is 30 to 60 minutes. The initial dose of fentanyl is usually 50 to 100 μg . Supplemental doses of 25 μg each may be administered every 2 to 5 minutes until adequate sedation is achieved. A dose reduction of 50% or more is indicated in the elderly. With repeated dosing or continuous infusion, fentanyl accumulates in skeletal muscle and fat, and its duration of effect can be prolonged.

The major adverse effect associated with fentanyl administration is respiratory depression. Respiratory depression may last longer than the analgesic effect of fentanyl. In large doses, fentanyl may induce chest wall rigidity and generalized hypertonicity of skeletal muscle.

Naloxone (opioid antagonist). Naloxone hydrochloride is an opioid antagonist that antagonizes all of the central nervous system effects of the opioids, including ventilatory depression, excessive sedation, and analgesia. It is ineffective for reversing the effects of nonopioid drugs such as benzodiazepines and barbiturates.

Naloxone is commercially available at concentrations of 0.2 mg/mL, 0.4 mg/mL, and 1 mg/mL. It is recommended that patients receive an initial dose of 0.2 to 0.4 mg (0.5-1.0 $\mu\text{g}/\text{kg}$) intravenously every 2 to 3 minutes until the desired response is attained. Supplemental doses may be required after 20 to 30 minutes. The onset of action after intravenous naloxone is 1 to 2 minutes, and its half-life is 30 to 45 minutes. The administration of additional doses of naloxone may be required in patients

receiving narcotics with a longer half-life. Patients receiving naloxone should be monitored for an extended period of time.

Clinical use of naloxone for rescue during GI endoscopy is based on experience with naloxone in opiate overdose. There are no large prospective trials evaluating the use of naloxone for rescue in the endoscopy suite. The use of naloxone is very safe. Jasinski administered doses of naloxone as high as 24 mg in 70-kg adults without any major side effect. However, nausea, vomiting, sweating, restlessness, and seizures have been reported. There should be a minimum of 2 hours of observation after administration of naloxone to ensure that re sedation does not occur.

Benzodiazepines. The pharmacologic effects of benzodiazepines include anxiolysis, sedation, amnesia, anticonvulsant activity, muscle relaxation, and anesthesia. The amnestic effect may persist after sedation has worn off. Benzodiazepines enhance activity of the inhibitory neurotransmitter GABA by binding to the GABA_A receptor. The most common benzodiazepines used for endoscopic sedation are diazepam and midazolam.

Diazepam. Diazepam is used in combination with an opioid for endoscopic sedation, although with less frequency than is the benzodiazepine midazolam. The initial induction dose for endoscopic procedures is 5 to 10 mg over 1 minute. If required, additional doses may be administered at 5-minute intervals. Dose reduction is required in debilitated or elderly patients. In general, 10 mg intravenously is sufficient for most endoscopic procedures, although as much as 20 mg may be necessary if a narcotic is not being coadministered. The major side effects of diazepam are coughing, respiratory depression, and dyspnea. The respiratory depressant effect of diazepam and other benzodiazepines is dose dependent and results from depression of the central ventilatory response to hypoxia and hypercapnea. Respiratory depression is more likely to occur in patients with underlying respiratory disease or those receiving combinations of a benzodiazepine and an opioid.

Midazolam. Midazolam is distinguished from diazepam by its more rapid onset of action and shorter duration of effect. After intravenous administration, the onset of effect for midazolam is 1 to 2 minutes, and peak effect is achieved within 3 to 4 minutes. Its duration of effect is 15 to 80 minutes. Midazolam clearance is reduced in the elderly, obese, and those with hepatic or renal impairment.

Endoscopists prefer the use of midazolam to diazepam because of its favorable pharmacologic profile. The initial intravenous dose in healthy adults younger than 60 years of age is 1 to 2 mg (or no more than 0.03 mg/kg) injected over 1 to 2 minutes. Additional doses of 1 mg (or 0.2-0.3 mg) may be administered at 2-minute intervals until adequate sedation is achieved. When midazolam is used with an opioid, a synergistic interaction occurs, and a reduction in the dose of midazolam may be indicated. Patients older than 60 and those with ASA physical status 3 or above require a dose reduction of 20% or more. A total intravenous dose greater than 6 mg is usually not required

for routine endoscopic procedures. Patients who are undergoing a prolonged endoscopic procedure and those with a benzodiazepine tolerance may require larger doses.

Cole performed a double-blind, randomized study that compared diazepam with midazolam for endoscopic sedation. Midazolam was found to be more potent and faster acting, reducing the time required for the induction of sedation an average of 2.5 minutes per procedure. Fewer adverse events, including respiratory depression, were reported in the patients receiving midazolam. Midazolam demonstrated superior amnestic properties, and recovery was comparable in the 2 groups. Lee et al evaluated midazolam versus diazepam for sedation in 149 patients undergoing EGD. Midazolam was associated with better patient tolerance, less thrombophlebitis, and more amnesia compared with diazepam. Recovery time was similar with midazolam and diazepam.

The major side effect of midazolam is respiratory depression. Deaths from respiratory depression have been reported in patients receiving midazolam and an opioid. In some cases, apnea may occur as long as 30 minutes after administration of the last dose of midazolam. In general, midazolam-induced respiratory depression is short-lived and often responds to verbal stimulation and supplemental oxygen. Disinhibition reactions, manifested by hostility, rage, and aggression may occur with the use of benzodiazepines.

Flumazenil (benzodiazepine antagonist). Flumazenil competitively antagonizes the central effects of benzodiazepines, reversing sedation, psychomotor impairment, memory loss, and respiratory depression. It is more effective in reversing the benzodiazepine-induced sedation and amnesia than the respiratory depression. The half-life of flumazenil after intravenous administration is 0.7 to 1.3 hours, and the average duration of antagonism is 1 hour. Because the effects of midazolam may persist 80 minutes or longer, sedation may recur.

Andrews randomized 50 patients undergoing EGD under midazolam sedation to receive either flumazenil or placebo post-procedure and 30 minutes later. Patients receiving flumazenil (0.5 mg) experienced greater improvement in memory, psychomotor performance, and coordination at 5 minutes post-procedure ($P < .001$). Re-evaluation 3.5 hours post-procedure noted no difference in these same measured parameters between the flumazenil-treated group and the placebo-treated group. Bartelsman et al evaluated the use of flumazenil versus placebo in 69 patients sedated with midazolam for EGD. Flumazenil or placebo was administered 15 seconds after completion of the endoscopic procedure. Mean sedation scores returned to baseline within 5 minutes after the administration of flumazenil, and this effect persisted for 60 minutes. This response was significantly different compared with placebo. No evidence of re-sedation was noted during a 6-hour observation period in patients receiving flumazenil.

Caution should be exercised when administering flumazenil to patients using chloral hydrate, carbamazepine, high-dose tricyclic antidepressants, or chronic ben-

zodiazepines because it may induce seizures or withdrawal reactions.

The elective use of flumazenil after completion of endoscopy has been demonstrated to reduce recovery time, although the practical benefits to the patient or the endoscopy unit have not been proven.

Propofol. Propofol (2,6-diisopropofol) is a hypnotic with minimal analgesic effect. At subhypnotic doses, propofol produces sedation and amnesia. Propofol is highly lipid soluble and has an onset of action of 30 to 45 seconds. Its duration of effect is 4 to 8 minutes. The pharmacokinetic parameters of propofol are altered by a variety of factors including weight, sex, age and concomitant disease. However, the presence of cirrhosis or renal failure does not significantly affect its pharmacokinetic profile. The coadministration of other central nervous system medications such as opioids and barbiturates potentiate the sedative effect of propofol.

The current formulation of propofol contains 1% propofol, 10% soybean oil, 2.25% glycerol, and 1.2% purified egg phosphatide. Propofol should therefore be avoided in persons with allergies to egg, soy, or sulfite.

The cardiovascular effects of propofol include decreases in cardiac output, systemic vascular resistance, and arterial pressure. Pain on injection is reported in as many as 30% of patients receiving an intravenous bolus of propofol. This occurs when small veins are chosen for the IV site. The use of lidocaine can minimize the discomfort.

There are only a few published studies that directly compare combination propofol with standard sedation agents. Papsatis studied propofol plus midazolam (mean doses 80 and 3 mg) versus midazolam and pethidine (mean doses 5 and 75 mg) in 120 patients undergoing colonoscopy. Patients receiving propofol were more likely to report no discomfort during their procedure (84.3% vs 66%, $P < .05$) and recovered faster. No difference in the rate of cardiopulmonary complications was observed. Reiman randomized 79 patients undergoing colonoscopy to receive sedation either with propofol plus midazolam (median doses 100 and 2 mg) or midazolam (median dose 9 mg) either alone or combined with nalbuphine (median dose 20 mg). Patients in the propofol group were more likely to rate their procedure as comfortable (81 vs 47%, $P = .02$), and recovery time was shorter (12 vs 93 minutes, $P < .001$). There was no difference in cardiorespiratory parameters between the 2 groups.

Other agents. Ketamine. Ketamine, unlike many other drugs used for sedation, possesses both analgesic and sedative properties. It is further distinguished by its lack of depressant effect on the cardiovascular and respiratory systems. Ketamine produces a trance-like cataleptic state that impairs sensory recognition of painful stimuli and memory. It also blocks opiate receptors in the brain and spinal cord, accounting for some of its analgesic effect.

Ketamine is highly lipid soluble with a rapid onset of action (<1 minute) and short duration of action (15-30 minutes). Ketamine is easy to administer and, in contrast to benzodiazepine/narcotic regimens, does not depress

airway or cardiovascular reflexes even when administered at doses 5 to 100 times greater than intended.

The use of ketamine for endoscopic sedation has been studied predominantly in the pediatric setting. In a retrospective review of children ranging in age from 1 month to 20 years, a combination of ketamine (0.75-2.0 mg/kg) and midazolam (0.05-0.2 mg/kg) (N = 128) was compared with 2 alternative regimens, midazolam and meperidine (1-2 mg/kg) (N = 192) and midazolam, meperidine, and ketamine (N = 82). Inadequate sedation was less frequent with ketamine/midazolam than either of the other sedation groups (3.1 vs 8.9% and 8.6%, $P = .07$). Complications, predominantly hypoxemia, were significantly more common with midazolam/meperidine than in either of the ketamine arms. A single patient in the ketamine group (1/128, <1%) experienced transient hypoxemia; otherwise, there were no serious adverse events. In adults, ketamine has been useful as an adjunct to standard sedation for difficult-to-sedate patients.

Ketamine produces a dose-dependent increase in heart rate, blood pressure, and cardiac output, mediated through stimulation of the sympathetic nervous system. Emergence reaction, manifested by floating sensations, vivid dreams, hallucinations, and delirium, has been reported in 10% to 30% of adults. The use of midazolam in combination with ketamine is reported to minimize this reaction.

Nitrous oxide. Nitrous oxide is an inhalational agent coadministered with oxygen. Nitrous oxide is a relatively strong analgesic and weak hypnotic that may be used alone or in combination with other agents. After inhalation, the gas is quickly cleared and excreted unchanged by the lungs. The benefits of nitrous oxide include rapid onset, rapid recovery, and an excellent safety profile.

Saunders performed a randomized, placebo-controlled trial of patient-controlled nitrous oxide versus intravenous pethidine and midazolam (mean doses 50 and 2.5 mg) in patients undergoing routine colonoscopy. Procedure-related discomfort was comparable between study groups. Patients receiving intravenous sedation experienced more prolonged sedation and slower recovery than the nitrous oxide group (60 vs 32 minutes, $P = .001$). Hypotension and oxygen desaturation were more common with intravenous sedation than with nitrous oxide, whereas many in the nitrous oxide group experienced headache.

Maslekar recently reported the results of a randomized, controlled study that compared nitrous oxide with intravenous fentanyl and midazolam. One hundred twenty patients undergoing colonoscopy were randomized. Patients in the nitrous oxide arm all completed colonoscopy without supplemental medications and scored better with respect to overall satisfaction and the assessment of pain. The time to discharge was significantly shorter in the nitrous oxide arm (26 vs 44 minutes; $P = .0004$).

The major risk of nitrous oxide is hypoxia, which is avoided by coadministration with 30% to 50% oxygen.

Hypertension, arrhythmias, nausea, vomiting, and headache have also been reported with nitrous oxide.

Dexmedetomidine. Unlike other sedative agents, patients sedated with dexmedetomidine return to their baseline level of consciousness when stimulated. Furthermore, dexmedetomidine produces less respiratory depression than other sedative agents. The pharmacologic effects of dexmedetomidine can be reversed by the α_2 -receptor antagonist atipamezole. These beneficial properties make dexmedetomidine an attractive sedation agent for short procedures.

The usual dose of dexmedetomidine for procedure sedation is 1 $\mu\text{g}/\text{kg}$, followed by an infusion of 0.2 $\mu\text{g}/\text{kg}/\text{h}$. Its onset of action is less than 5 minutes, and the peak effect occurs within 15 minutes. Jalowiecki randomized patients undergoing colonoscopy to dexmedetomidine (1 $\mu\text{g}/\text{kg}$ followed by 0.2 $\mu\text{g}/\text{kg}/\text{h}$) or meperidine (1 mg/kg) and midazolam (0.05 mg/kg). Supplemental fentanyl (0.1-0.2 mg) was available on demand. Forty-seven percent of patients receiving dexmedetomidine required supplemental fentanyl to achieve satisfactory analgesia. Hypotension (4/19, 21%), bradycardia (2/19, 10%), and vertigo (5/19, 26%) were reported in the group receiving dexmedetomidine. Recovery time was longest (85 minutes) in patients receiving dexmedetomidine.

Diphenhydramine. The usual dose of intravenous diphenhydramine as an adjunct for endoscopic sedation is 25 to 50 mg. Diphenhydramine is quickly distributed throughout the body, including the central nervous system. Its onset of action is several minutes and duration of effect is up to 4 to 6 hours. Its hypnotic effect is increased when given in combination with alcohol or other central nervous system depressants such as benzodiazepines and opioid narcotics. Diphenhydramine has a modest stimulatory effect on ventilation and has been reported to counteract opioid-induced hypoventilation.

Diphenhydramine was assessed as an adjunct to meperidine and midazolam during colonoscopy in a randomized, double-blind trial. Two hundred seventy patients received intravenously either diphenhydramine 50 mg or placebo 3 minutes before initiating sedation. Patient scores for overall sedation were better in the group receiving diphenhydramine (9.4 vs 9.04, $P = .017$). Further, the diphenhydramine group required less meperidine (89.7 vs 100 mg, $P = .003$) and midazolam (3.4 vs 4.0 mg, $P < .001$). Procedure, recovery, and discharge times were comparable between both groups.

The adverse effects of diphenhydramine include hypotension, dizziness, blurred vision, dry mouth, epigastric discomfort, urinary retention, and wheezing.

Promethazine. Promethazine is a phenothiazine that possesses antihistamine, sedative, antiemetic, and anticholinergic effects. Promethazine has also been investigated as an adjunct for sedation during minor surgical and endoscopic procedures.

The clinical effects of promethazine are evident within 5 minutes of intravenous administration. Its duration of action is 4 to 6 hours, and the plasma half-life is 9 to 16 hours. The usual dose of promethazine is 12.5 to 25 mg

intravenously, infused slowly (≤ 25 mg/min) to minimize the risk of hypotension. A total dose of 25 to 50 mg may be used as an adjuvant to narcotics and benzodiazepines. The use of promethazine may require a reduction in the dose of standard sedation agents.

The adverse effects of promethazine include hypotension, respiratory depression, neuroleptic malignant syndrome, and extrapyramidal effects ranging from restlessness to oculogyric crises. Adverse reactions including burning, pain, thrombophlebitis, tissue necrosis, and gangrene can occur with inadvertent perivascular extravasation, unintentional intra-arterial injection, and intraneuronal or perineuronal infiltration.

Droperidol. Droperidol is a neuroleptic (tranquilizer) agent. It can be given intramuscularly or intravenously. Droperidol is used as an adjunct to standard sedation for complex endoscopic procedures or difficult-to-sedate patients such as alcoholics and long-term drug abusers. Droperidol's onset of action is 3 to 10 minutes, and its duration of effect is 2 to 4 hours. The usual dose of droperidol for endoscopic sedation is 1.25 to 2.5 mg intravenously, although higher doses have been used.

LeBrun reported the first large series using droperidol for endoscopic sedation. Patients achieved adequate sedation for upper endoscopy, although 24% experienced transient hypotension. No major complications were reported. Sixty difficult-to-sedate patients undergoing EGD were sedated with either fentanyl/diazepam or fentanyl/droperidol. Sedation with fentanyl/droperidol was assessed to be better than the diazepam/fentanyl combination. Wilcox used droperidol as an adjunct to standard sedation in 764 patients undergoing 1102 endoscopic procedures. The indications for droperidol included active alcohol withdrawal, patients who were difficult-to-sedate during a previous endoscopic examination, and long-term narcotic and/or intravenous drug users. The total dose of droperidol ranged from 1.25 to 5.0 mg intravenously. Hypotension was the most common complication. No patient experienced respiratory depression requiring ventilatory support.

Hypotension, prolongation of the QT_c interval, and extrapyramidal signs are the major side effects of droperidol. In 2001, the U.S. Food and Drug Administration revised their product labeling that warned of the potential for sudden cardiac death at high doses of droperidol (>25 mg) in psychiatric patients. A "black-box" warning was added to the product label, indicating that even low-dose droperidol should be used only when first-line drugs are unsuccessful. Droperidol use is contraindicated in patients with a prolonged QT_c interval (>440 ms in males, >450 ms in females) and should be avoided in patients at increased risk of the development of QT interval prolongation (history of congestive heart failure, bradycardia, diuretic use, cardiac hypertrophy, hypokalemia, hypomagnesemia, 65 years of age and older, and alcohol abuse).

Fospropofol. Fospropofol disodium, a water-soluble prodrug of propofol, is designed to modify the pharma-

cokinetic properties of propofol emulsion to enhance its effectiveness and safety profile during procedure sedation. It is a sedative/hypnotic. Fospropofol is rapidly hydrolyzed by alkaline phosphatases, releasing propofol as an active metabolite along with formaldehyde and phosphate. After bolus administration of fospropofol, the plasma concentration of liberated propofol has a slower upward slope, lower peak, and prolonged plateau phase compared with an equipotent dose of propofol emulsion.

A phase II, double-blind, multicenter dose-response study randomized patients undergoing elective colonoscopy to 1 of 4 weight-based doses of fospropofol disodium (2, 5, 6.5, or 8 mg/kg) or midazolam (0.02 mg/kg). All patients received a pretreatment dose of fentanyl (50 μ g). Fospropofol 6.5 mg/kg produced moderate sedation throughout most of the examination (84.6%), and only 1 of 26 patients in this dose group experienced transient deep sedation. More than 90% of patients and physicians indicated their satisfaction with this level of sedation. The time from completion of procedure to ready for discharge was 9.1 minutes. The most common adverse events were burning sensation (23.8%), paresthesias (8.9%), and pruritus (7.9%). To date, there are no reported trials comparing fospropofol with propofol for endoscopic sedation.

Pharyngeal anesthetic agents. Topical anesthetic agents such as benzocaine, lidocaine, and tetracaine have been used as an adjunct to moderate sedation to facilitate upper endoscopic procedures. From a meta-analysis of 5 randomized, controlled studies, subjects who rated their discomfort as none/minimal were more likely to have received pharyngeal anesthesia (odds ratio 1.88; 95% CI, 1.13-3.12). Endoscopists were more likely to rate the procedure as "not difficult" if the subjects received pharyngeal anesthesia (odds ratio 2.60; 95% CI, 1.63-4.17). However, topical anesthetic agents have been associated with a potentially life-threatening adverse event known as methemoglobinemia. Diagnosis is by multiple wavelength co-oximetry. The condition cannot be detected by standard pulse oximetry or blood gases. A high level of clinical suspicion manifested by the presence of cyanosis despite adequate supplemental oxygen delivery should alert the endoscopist to the possibility of methemoglobinemia. Treatment is with intravenous methylene blue 1 to 2 mg/kg over 3 to 5 minutes, followed by a 15- to 30-mL fluid flush. If there is no improvement, an additional 1-mg/kg dose of methylene blue can be administered in 30 to 60 minutes. Failure to improve at this point may be because of coexistent glucose-6-phosphate dehydrogenase or reduced nicotinamide adenine dinucleotide phosphate oxidase methemoglobin reductase deficiency.

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Contributors

John J. Vargo, MD, MPH, Committee Chair

*Cleveland Clinic Lerner College of Medicine
Chairman, Department of Gastroenterology and Hepatology
Digestive Disease Institute
Cleveland Clinic
Cleveland, Ohio, USA*

Mark H. DeLegge, MD
*Digestive Disease Center
Medical University of South Carolina
Charleston, South Carolina, USA*

Andrew D. Feld, MD, JD
*Group Health Cooperative
Division of Gastroenterology
University of Washington
Seattle, Washington, USA*

Patrick D. Gerstenberger, MD
*Digestive Health Associates, PC
Durango, Colorado, USA*

Paul Y. Kwo, MD
*Medical Director, Liver Transplantation
Gastroenterology/Hepatology Division
Indiana University School of Medicine
Indianapolis, Indiana, USA*

Jenifer R. Lightdale, MD, MPH
*Children's Hospital Boston
Harvard Medical School
Boston, Massachusetts, USA*

Susan Nuccio, RN, MSN, ACN-BC, CGRN
*Aurora St. Luke's Medical Center
Milwaukee, Wisconsin, USA*

Douglas K. Rex, MD
*Indiana School of Medicine
Director of Endoscopy
Indiana University Hospital
Indianapolis, Indiana, USA*

Lawrence R. Schiller, MD
*Digestive Health Associates of Texas
Baylor University Medical Center
Dallas, Texas, USA*