Communication from the ASGE Standards of Practice Committee

GUIDELINE

Renewal of and proctoring for endoscopic privileges

This is one of series of statements discussing the use of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) prepared this text. In preparing this guideline, a search of the medical literature was performed by using PubMed supplemented by accessing the "related articles" feature of PubMed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice. The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence (Table 1).[1]

This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.

Endoscopy is an important tool for evaluating, diagnosing, and treating GI symptoms and disease. The procedure requires technical skills combined with a thorough knowledge of GI disease pathophysiology. Technical skills alone do not ensure clinical competence. Rather, a larger volume of knowledge and experience on the part of the endoscopist is necessary. This cognitive component of endoscopy can only be gained through supervised education and training.

With the increasing use of GI endoscopy and evolving technology, there is a definite need to assess endoscopist competence for the delivery of high-quality medical care.[2-5] It is becoming apparent that letters of reference, verification of subspecialty training, and even board certification may not be adequate substitutes for independent evaluation of an endoscopist's skill and expertise. An emerging trend involves the use of proctoring to evaluate applicants for staff appointments and to assess incumbent staff members who request new endoscopic privileges or who must undergo periodic privileging. Until recently, formal evaluation of technical skills (as opposed to cognitive ability) has been uncommon in GI endoscopy. Herein, we recommend updated written guidelines for renewal of endoscopic privileges[6] and for developing an endoscopy proctoring system.[7]

RENEWAL OF ENDOSCOPIC PRIVILEGES

Objectives/purpose of this document

Maintenance of the quality of patient care is the reason for reassessing competence through a renewal of privileges process.[7-12] Maintaining competence is an important aspect of GI endoscopy for several reasons[8,13-15]:

1. Procedural dexterity will optimize patient comfort and safety.
2. Performance of a procedure too infrequently may lead to missed or inappropriate diagnoses and therapies with potentially significant adverse consequences.
3. Changes in instrumentation and technology require continuing familiarity with endoscopic equipment.
4. Endoscopic diagnosis and therapy continually undergoes re-evaluation and evolution.

This document is intended to provide principles by which organizations may create policy and practical guidelines for assessment of competence as a part of a continuing recredentialing process. It is not intended to guide the evaluation of endoscopists applying for new privileges at an institution.[9] The principles and guidelines set out in this document are intended to apply universally to all those who will continue to perform endoscopic procedures as applicable and consistent with federal and state laws.[12]

Definitions of terms

Privileges: Authorization is granted to a practitioner to provide specific patient care services in an institution within well-defined limits, based on the following factors as applicable: license, education, training, experience, competence, health status, and judgment.

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TABLE 1. Grades of recommendation

Grade of recommendation	Clarity of benefit	Methodologic strength/ supporting evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Strong recommendation; likely to apply to most practice settings
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendations; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendations; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendations; alternative approaches may be better under the circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches likely to be better under some circumstances
3	Unclear	Expert opinion study	Weak recommendation; likely to change as data become available

Adapted from Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors: Users' guides to the medical literature. Chicago: AMA Press; 2002. pp. 599-608.

Certification: Certification usually refers to a diploma, awarded as documentation that the endoscopist has completed a residency or fellowship training program successfully and has been exposed to the basic didactic and technical knowledge of that specialty and received a signed statement of general competence from the residency program director. Most institutions require both a general statement certifying competence to practice a specialty and a specific statement certifying competence in each clinical privilege requested before granting that privilege. Over time, new endoscopic procedures may be developed for which additional training and certification of competence may be deemed necessary by the institution before additional privileges are granted.

Credentials: Credentials refers to documented evidence of licensure, education, training, experience, or other qualifications. This may include a medical school diploma, certificate of attendance at a postgraduate course or seminar, or a statement certifying competence by a preceptor. A specialty board certificate can also be considered a type of credential and demonstrates the overlap between certification and credentials. The term ''credentialing'' usually refers to the process of confirming an applicant's credentials.

Competence: For purposes of this document, competence is defined as objective conclusions that are the result of active participation in a continuing peer-review process at an institution. Competence is a minimum acceptable level of skill and can refer to an endoscopist's general ability to care for a patient within a specialty or one's specific ability in the performance of a technical procedure or operation. Although program directors attest to (certify) the cognitive and technical competence of trainees on successful completion of training, either form of competence may change or be compromised, hence the need for periodic re-evaluation of both the general and specific abilities of every endoscopist on the medical staff.

Clinical privileges: Those functions and procedures that an endoscopist is allowed (''privileged'') to perform in the course of caring for patient in a given institution is called clinical privileges. Every endoscopist requests clinical privileges, usually from among a list of activities and procedures common to his or her specialty.

Privileging process: The process of assessing and validating the qualifications of a licensed practitioner to provide patient care in an institution is called privileging. Defining the mechanism for the granting of clinical privileges is the responsibility of each individual institution.

A facility, institution, or organization may develop its own criteria for the granting of privileges that ensure competence or may use standards developed by specialty boards or national specialty societies. The institution's credentialing committee is asked to evaluate the individual's request for clinical privileges. The determination is based on an evaluation of the individual's current license, training or experience, current competence, and ability to perform procedures for which privileges are requested. On the basis of this evaluation, each endoscopist's privileges are recommended to and may be granted by the institution. Periodically, the quality assurance data, clinical activity, and continuing medical education (CME) record of the individual endoscopist are reviewed and evaluated as part of the reappointment and reprivileging process.

Quality of care: For endoscopy, quality of care is defined by appropriate procedural indications, level of skill of the endoscopist, and recognition and management of complications. Reprivileging processes should include an evaluation of demonstrated integration of endoscopic procedures in the overall care and outcome of patients with GI diseases. With the recent focus on quality of care for specific procedures in GI endoscopy, proposed objective end points can be used in assessing quality.[16-20]

Institution: An institution is defined as an organization involved in the delivery of patient care; this may be a hospital, outpatient surgical center, insurance plan, or other unit where privileges are required.

Continuous quality improvement (CQI): A peer-review evaluation is needed of continuing patient care activities, at a minimum, inclusive of careful evaluation, conclusion, and action plans as needed.

Proctoring: Proctoring is an assessment of skills based on observation by a credentialed endoscopist with institutional privileges that may be used in lieu of data from a peer-review process.[7] It is assumed, for the purposes of this document, that an institution has previously established criteria regarding minimal volumes of procedures. It is expected that the institutional CQI program has previously instituted criteria and guidelines for the acceptance of a proctoring process. Proctoring, if requested by the privileging organization, must be done without bias.

Proctor: A proctor is an independent and unbiased endoscopist in a position to evaluate and monitor the skills and ability of another endoscopist. Experienced endoscopists are commonly assigned proctoring duties in regard to other endoscopists seeking initial or renewal of endoscopic privileges.

Proctorship: A proctorship is a period of time during which completion of the proctoring is accomplished.

Preceptor: A preceptor is an instructor or teacher. When teaching endoscopy to a trainee, the endoscopist is responsible for the actions of the trainee.

Must or shall: This terminology indicates a mandatory or indispensable recommendation.

Should: This terminology indicates a highly desirable recommendation.

May or could: This terminology indicates an optional recommendation; alternatives may be appropriate.

General statement on competence

The principles for the maintenance of endoscopic competence are consistent with the ASGE position on endoscopic training and credentialing.[9,21] The endoscopist should be able to:

1. Recommend endoscopic procedures on the basis of pertinent clinical information[22] and with consideration of the specific indications, contraindications, and possible alternatives.
2. Perform specific endoscopic procedures safely, including appropriate endoscopic intervention and therapeutic maneuvers.
3. Correctly interpret endoscopic findings and integrate endoscopic findings and therapy into patient management plans. At a minimum, the applicant should demonstrate adequate CME activity consistent with licensure and, through a continuing peer-review process, demonstrates his or her ability to manage and interpret GI pathology.
4. Adequately recognize and manage complications.
5. Participate in CQI activities. At a minimum, the applicant should participate in CQI activities that include evaluation of data such as indications and complications. It is recognized that volumes of procedures, complications, and CQI activities may vary from institution to institution. It is also recognized that complication rates and risk of complications are influenced by the population of patients and the environment in which procedures are performed. The ASGE encourages individual institutions to establish thresholds or benchmarks for CQI evaluation.[23]

General principles of renewing privileges

Endoscopists who have previously established privileges to perform endoscopic procedures may change the breadth of their clinical activities. An endoscopist may reduce the frequency or cease to perform one or more endoscopic procedures. It has been suggested that technical skills involving advanced procedures require continuing experience and that decreasing the frequency of performing a procedure may result in a diminution of technical skills.[13,14,24] Low annual colonoscopy volume (fewer than 200 procedures) is associated with lower cecal intubation rates for endoscopists early in their careers (ie, less than 5 years in practice) but not for those with more experience.[25] In a study of 207 members of the Society of American Gastrointestinal Endoscopic Surgeons, annual colonoscopic volume was significantly associated with procedure completion rates.[26] Endoscopists performing fewer than 100 procedures annually completed fewer than 90% of examinations. Although there are limited

data, the issue of endoscopic volume may be particularly important for higher-risk procedures such as ERCP. Endoscopists averaging more than 2 ERCPs per week had significantly greater bile duct cannulation rates than did those endoscopists performing fewer (95.5% vs 91.5%, $P = .0001$).[27] In another study, endoscopists with higher case volume, defined as at least 1 sphincterotomy per week, had significantly fewer total complications (8.4% vs 11.1%) and less frequent severe complications (0.9% vs 2.9%) than did endoscopists with lower procedural volumes.[28] Thus, it is likely that the quality of care provided may suffer if endoscopists do not have continuing endoscopic experience.

Data from specialties outside endoscopy may have implications for endoscopists. There is evidence that surgeons older than 60 years of age, particularly those with lower surgical volumes, have higher operative mortality rates than do their younger counterparts for selected complex procedures.[29] Similarly, studies focusing on primary care have suggested an inverse relationship between physician age and clinical performance.[30-32] Older physicians have been shown to have lower performance on recertification examinations and are less likely to have a current knowledge base.[33,34] Although prior studies have documented declines in manual dexterity, strength, and visuospatial ability with age,[35-38] it has not been shown that these changes are associated with worse outcomes for patients. In fact, some studies have demonstrated that physician youth and inexperience may be more important predictors of adverse surgical outcomes.[39,40]

It should be stressed that data to support minimal threshold numbers for documenting continuing endoscopic experience and data on the association between advanced endoscopist age and patient outcomes are lacking. Data from the medical literature suggest that the continued performance of any procedure is required to maintain technical and cognitive competence.[24,41,42] Each institution should consider a threshold number of procedures performed over a defined period of time as part of a reprivileging process. This threshold number of procedures should be commensurate with the technical skill required and the risk for an adverse outcome in the performance of that procedure. One survey of endoscopy centers suggests that most are not using threshold numbers to guide reprivileging.[43]

Endoscopists should consider not performing selected complex endoscopic procedures unless they are undertaken on a regular basis. The process of renewal of privileges should entail continued demonstration of endoscopists' abilities and should enable institutions to document the continuing endoscopic competence of their staff. Endoscopists should consider maintaining a ''report card'' summarizing their performance to facilitate the process.[44] The ASGE and the American College of Gastroenterology established a joint task force on quality in endoscopy that recently published proposed quality indicators for GI endoscopy.[16-20] These quality indicators may serve as one means by which to assess the endoscopist's abilities and determine the appropriateness of renewing privileges and could be included in a report card.

Credentials and privileges should be determined and granted independently for each type of endoscopic procedure. Competence in each endoscopic procedure requires both cognitive and technical components as well as CME in GI endoscopy.[15] It is the responsibility of each institution to develop and maintain guidelines for granting and renewing privileges. This includes the frequency of the renewal process. It has been mandated by The Joint Commission that renewal of clinical endoscopic privileges be made for a period of no more than 2 years for hospital-based endoscopy centers.[10] Ambulatory surgical and endoscopy centers require that renewal of clinical endoscopic privileges be made at least every 3 years unless state law provides otherwise.[45] Individual institutions should have a mechanism in place for addressing instances when minimal competence cannot be assured. These mechanisms may include proctoring, CME, retraining, or limitation of privileges.

Role of proctor

1. Acts as an independent and unbiased monitor to evaluate, not teach, the technical and cognitive skills of another endoscopist.
2. Does not participate directly in patient care and has no physician/patient relationship with the patient being treated.
3. Is responsible to the institution in connection with credentialing of those seeking endoscopic privileges.
4. Does not receive a fee related directly to patient care while proctoring. A proctor may or may not receive a fee from the institution as compensation for time spent in proctoring services.

DEVELOPMENT OF A PROCTORING POLICY

Policy guidelines

When proctoring is implemented, guidelines must be written carefully and included in the institutional bylaws as an integral part of the credentialing and privileging process. In departmentalized institutions, the bylaws may provide for each department to establish proctoring protocols.

Appropriate candidates for proctoring include:

- Applicants for new staff appointment seeking delineation of clinical privileges as a routine policy or when adequate evidence supporting competence is lacking
- Incumbent staff members newly trained in additional or novel endoscopic procedures
- Sanctioned endoscopists needing recredentialing because of a loss or reduction of privileges or as part of the routine recredentialing process required of all staff members

Proctoring may also be appropriate for incumbent medical staff who hold privileges for an endoscopic procedure

but who have performed few procedures over an extended period of time or when a procedural technique changes in such a way that their previous training may no longer be adequate. Last, proctoring may be one of several appropriate actions when a potential practice problem is identified by the institution's quality improvement or risk management programs. Applicants must first meet all objective standards for appointment and initial delineation of privileges for the institution. Proctoring is not a substitute for training, and the proctor's function is to evaluate, not teach, the applicant. As outlined elsewhere, comprehensive training in endoscopy must be acquired in a training program that is equivalent to that of a GI fellowship or surgical residency.[46,47]

A written proctoring process and assessment of competence guidelines should be written in the institution's bylaws. Provisions for failure of the minimum competence during proctorship should be in place, including recommendations for additional training (if necessary) or restrictions of certain privileges.

Qualifications of the proctor

The proctor should be an endoscopist who holds clinical privileges in the procedure being observed and should possess sufficient expertise to judge technical and cognitive skills and the quality of care being delivered. He or she should be free of actual or perceived conflicts of interest, which may create a bias against or in favor of the applicant. The proctor should always be identified as a member or representative of a committee of the institution established by the bylaws as having responsibility for proctoring as one of its peer-review functions. If no suitable proctor is available on the medical staff, outside experts should be recruited by the institution's credentialing committee. State or local endoscopic experts or other specialty societies may be helpful in such a search. An institution may accept evidence of proctoring from a nearby institution in lieu of its own proctoring, provided the proctor in the nearby institution would have been eligible to serve as a proctor in the subject's hospital.

The proctoring process

The proctor must engage in the direct observation of the performance of endoscopic procedures over a specified period of time or for a specified number of cases on the basis of predetermined criteria. Although this process may be coupled with retrospective review of cases, it cannot replace direct observation. The proctor should evaluate all aspects of the management of care provided in each case, as outlined in Table 2.

It is currently recommended that proctoring be conducted for all endoscopic procedures.[48-52] Certain low complexity procedures (eg, flexible sigmoidoscopy) may require a shorter proctoring period compared with more technically demanding procedures (eg, ERCP and EUS). All procedures require competence in all standard therapeutic maneuvers. The applicant must therefore demonstrate competence in both diagnostic and therapeutic procedures. Because of time constraints for most proctorships and limited availability of appropriate patients, it may be impractical to proctor an individual in all therapeutic techniques.

TABLE 2. Components to be evaluated during evaluation of endoscopy competence

- Reviews patient records/x-ray films
- Identifies potential risk factors
- Understands indications/contraindications
- Believes findings will influence management
- Obtains proper informed consent
- Uses appropriate sedation
- Intubates GI tract with good technique
- Correctly identifies landmarks
- Conducts thorough examination
- Detects and identifies all pathologic conditions
- Completes the examination within a reasonable period
- Obtains tissue properly
- Performs therapeutic maneuvers successfully/effectively
- Recognizes and manages procedure-related complications
- Prepares an accurate report
- Plans correct management and disposition
- Discusses findings with patient/family and other health care providers
- Arranges proper follow-up, review of pathologic findings, case outcome

Proctoring forms for all endoscopic procedures should be available in the endoscopy department. These forms should be filled out by the proctor immediately after each observed procedure. As the proctoring process is completed, these forms, along with a confidential written report, should be forwarded to the institution for review. The report should describe the type and numbers of cases observed and evaluate the applicant's performance. The credentialing committee may then grant privileges to endoscopists with demonstrated clinical competence. Applicants subject to proctoring should retain all rights of appeal under the credentialing process as set forth by the institution.

The issue of whether and to what extent the proctor should intervene in a procedure is complex and unsettled. It is generally believed that a proctor, while proctoring, has no duty to the patient. Absent a duty, no liability can accrue to the proctor. Generally proctors are not found liable for the negligence of the observed endoscopist through a theory of vicarious liability.

To minimize an individual's liability while proctoring, a few suggestions are worthwhile: (1) the proctor should not interfere with the proctored endoscopist, (2) the proctor should not offer advice or interact with the patient other than for the purpose of introduction and to state the proctoring role, (3) in the absence of substandard medical care that is harmful to the patient, the proctor should only report to the institution or regulatory body that the proctor represents, and (4) in the event the proctor witnesses substandard medical care that is harmful to the patient, the proctor has a duty to take remedial action. The proctor should consider contacting an appropriate superior, asking the proctored endoscopist to stop his or her substandard actions (if possible) or, as a last resort, actually intervene. It is imperative that the proctor document his or her actions.[53] When an individual being proctored has an associate who also holds privileges in the procedure being proctored, some institutions have encouraged the associate to be present to assist (if necessary) in the procedure, to avoid the necessity for the proctor to become involved.

A proctor's involvement should be disclosed in the patient's chart and in the proctor's confidential report to the credentials committee. The proctor may or may not be included in the patient's informed consent; such inclusion may expose the proctor to risk beyond that of mere proctoring. In a reported court decision addressing this issue, the court held that a proctor had no duty to intervene in a surgical procedure because the proctor had done nothing to place the patient at risk.[54] Potential legal problems can be ameliorated by having a formal, written protocol for proctoring and by maintaining detailed records. Legal counsel should be consulted to take greatest advantage of peer-review immunity available under state law, which varies from state to state. A suitably performed and documented program of proctoring for a GI endoscopic procedure is an important credentialing tool in the quality improvement system. Ultimately, the goal of institutional credentialing committees in granting endoscopy privileges to endoscopists should be to ensure the delivery of the highest quality care possible, without compromise, to all patients who seek health care.

RECOMMENDATIONS

1. Documentation of continuing satisfactory performance and frequency of an endoscopic procedure (as determined by institutional criteria) should allow an institution to renew the privileges of the endoscopist for that procedure (Level 3).
2. Failure to demonstrate continuing competence for specific endoscopic procedures may be addressed by (1) renewal of privileges after critical review of the endoscopists' procedure-specific records, (2) renewal of privileges after direct observation of the endoscopist performing the procedure (proctoring), (3) granting of conditional privileges with specific requirements for CME, retraining, or proctoring, (4) removal or nonrenewal of privileges (Level 3).
3. The process for renewal of privileges requires review of accurate and verifiable records of endoscopic procedures and outcomes. The institution is ultimately responsible for developing a continuing mechanism to maintain records and summaries. The institution may delegate some or all of these responsibilities to the CQI committee and peer-review process. It is up to each institution to set guidelines or requirements for accepting documentation from other institutions (Level 3).
4. The person requesting renewal of privileges must provide evidence of CME in the field of gastroenterology, gastrointestinal endoscopy, or surgical endoscopy (Level 3).
5. Appropriate candidates for proctoring include new staff appointments when there is inadequate supportive evidence of competence within their applications, incumbent staff seeking privileges for new procedures, or those with recredentialing issues that have been raised during the review process. In addition, some institutions may choose to proctor all applicants for privileges (Level 3).
6. Proctoring should be performed by an unbiased individual who possesses adequate expertise in a given procedure to allow judgment of technical and cognitive skills for the procedure (Level 3).
7. The proctor should be involved in direct observation but not teaching or active patient care (Level 3).

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Prepared by:
STANDARDS OF PRACTICE COMMITTEE
Jason A. Dominitz, MD, MHS
Steven O. Ikenberry, MD
Michelle A. Anderson, MD
Subhas Banerjee, MD
Todd H. Baron, MD, Chair
Brooks D. Cash, MD
Robert D. Fanelli, MD, SAGES Representative
Seng-Ian Gan, MD
M. Edwyn Harrison III, MD
David Lichtenstein, MD
Bo Shen, MD
Trina Van Guilder, RN, BSN, SGNA Representative
Kenneth K. Lee, MD, NAPSGHAN Representative
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