

CREDENTIALING FOR GASTROINTESTINAL ENDOSCOPY

**A reference document for
credentialing committees and physicians
seeking hospital privileges to perform
gastrointestinal endoscopy**

**Produced in collaboration by:
the American College of Gastroenterology (ACG)
and the American Society for Gastrointestinal
Endoscopy (ASGE)**

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JOINT SOCIETY GUIDELINES FOR CREDENTIALING FOR GASTROINTESTINAL ENDOSCOPY

This document pertains to the credentialing of individuals who perform procedures used in gastroenterology and gastrointestinal surgery including, but not limited to upper gastrointestinal endoscopy (esophagogastroduodenoscopy – EGD), colonoscopy, and associated procedures such as endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasonography (EUS). It does not pertain to the performance of flexible sigmoidoscopy. Credentialing for gastrointestinal endoscopy must be predicated on prior training and experience in the performance of these procedures. This experience must be substantiated by documentation provided by the applicant from prior instructors, mentors, and/or supervisors. Eligible mentors and/or supervisors include residency or fellowship program directors, Chiefs of Service, and other members of a residency or fellowship teaching faculty. Individuals applying for privileges for gastrointestinal endoscopy should have demonstrated satisfactory completion of an Accreditation Council for Graduate Medical Education-accredited training program in gastroenterology, general surgery, or in the case of colonoscopy, colorectal surgery. Alternative pathways for training should meet the same standards as accredited programs. Attestation to competency in the performance of these techniques should therefore be provided by the Training Program Director, and if deemed necessary by the Privileging or Qualifications Committee at the institution at which these privileges are being sought. In the case of applicants who already have privileges to perform these procedures and are applying for similar privileges at another facility or for renewal of privileges at the same facility, attestation of competency should be provided by the applicant's respective Chief of Service.

Maintenance of continued competency is the responsibility of the respective institutional performance by their respective Chief of Service. These guidelines should apply to any site at which gastrointestinal endoscopy is performed. These guidelines are intended to supplement previously published guidelines from the American College of Gastroenterology and the American Society for Gastrointestinal Endoscopy. To assist those in a position to evaluate credentials and grant privileges for gastrointestinal endoscopy, the American Society for Gastrointestinal Endoscopy has developed a number of guidelines. These and other standards may be found on the ASGE web site at www.asge.org

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Abstract from

ENDOSCOPY PRIVILEGE GRANTING GUIDELINES

“A guideline addressing methods of granting hospital privileges to perform gastrointestinal (GI) endoscopy has been published by the ASGE (Gastrointest Endosc 1992;38:765-767). Local hospital committees wishing to apply the foregoing criteria may find the following credentialing guidelines helpful”:

1. The hospital staff should have minimal standards which uniformly apply to all endoscopists.
2. Privileges should be granted to applicants based upon completion of a training program that certifies that the applicant has successfully completed a GI endoscopy training program (as detailed in the ASGE Publication: “Principles of Training in Gastrointestinal Endoscopy”).
 - (A) must be able to integrate GI endoscopy into the overall clinical evaluation of the patient;
 - (B) should have sound general medical or surgical training;
 - (C) must have a thorough understanding of the indications, contraindications, individual risk factors and benefit-risk considerations for the individual patient;
 - (D) must be able to clearly describe an endoscopic procedure and obtain informed consent;
 - (E) must have knowledge of endoscopic anatomy, technical features of endoscopic equipment, accessory endoscopic techniques, including biopsy, cytology, photography, thermal and non-thermal endoscopic therapy;
 - (F) must be able to accurately identify and interpret endoscopic findings;

- (G) must have a thorough understanding of the principles, pharmacology and risks of conscious sedation;
- (H) must be able to document endoscopic findings and therapy, and communicate with referring physicians and integrate endoscopic findings in patient care;
- (I) the applicant for privileges to perform an endoscopic technique must perform competently the procedure for which he or she is credentialed.
3. Endoscopic short courses are unacceptable as the principal evidence of competence for granting of privileges.
 4. Credentialing for all procedures, except sigmoidoscopy, should require the ability to perform associated therapeutic modalities.
 5. Privileges should be granted on a procedure specific basis. Credentialing in one area of endoscopy does not necessarily apply to another endoscopic procedure.
 6. Training requirements for non-endoscopists seeking to be privileged in flexible sigmoidoscopy, while less rigorous than other endoscopic procedures, still require supervised hands-on experience.
 7. The renewal of privileges should be based on demonstration of continued endoscopic skills, participation in continuous quality improvement and evidence of ongoing educational activities.
 8. New endoscopic procedures, or significant advances in existing procedures, may occur. Endoscopists who have not received conventional formal training may wish to acquire privileges to perform these procedures. The degree of training, direct supervision and proctoring will vary with the experience of the endoscopist and the nature of the procedure. When possible, objective criteria of competence should be developed and met.
 9. Subspecialty Board certification or membership in regional/national

societies does not, per se, indicate competence to perform GI endoscopic procedures and should not be the sole or primary criterion for granting procedural privileges.

Methods of Granting Hospital Privileges to Perform Gastrointestinal Endoscopy

This is one of a series of statements discussing aspects of the utilization of gastrointestinal endoscopy in clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy prepared the text. The statement was reviewed and approved by the Patient Care Committee of the American Gastroenterological Association and by other physicians and surgeons with expertise in gastroenterology. Additionally, it has been approved by the Governing Boards of the American Gastroenterological Association and the American College of Gastroenterology.

Guidelines for the appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus. Revision may be necessary as new data appear. Clinical considerations may justify a course of action at variance from these recommendations.

STATEMENT ON CREDENTIALING AND GRANTING PRIVILEGES FOR GASTROINTESTINAL ENDOSCOPY

Scope: This document is intended to provide the principles by which credentialing organizations may create policy and practical guidelines for granting gastrointestinal endoscopic privileges. Additionally, guidelines for defining continued competence, quality improvement and the granting of privileges for newly developed or evolving endoscopic procedures are provided. The principles set out in this document are intended to apply universally to all those who perform endoscopic procedures.

Definition of Terms

Clinical Privileges: Authorization by a local institution to perform a particular procedure or clinical service.

Competence: The minimum level of skill, knowledge and/or expertise, derived through training and experience, required to safely and proficiently perform a task or procedure.

Credentialing Process: The process of assessing and validating the qualifications of a licensed independent practitioner to provide patient care. The determination is based on an evaluation of the individual's current license, knowledge base, training or experience, current competence, and ability to perform the procedure or patient care requested.

Credentials: Documents provided following successful completion of a period of education or training as an indication of clinical competence.

May or could: Indicates an optional recommendation, alternatives may be appropriate.

Must or shall: Indicates a mandatory or indispensable recommendation.

Should: Indicates a highly desirable recommendation.

GENERAL PRINCIPLES OF CREDENTIALING AND GRANTING PRIVILEGES

This statement outlines principles of credentialing that are intended to promote high quality patient care and safety in the area of gastrointestinal endoscopy. These guidelines are intended to complement those of other organizations, including the JCAHO, in the area of granting hospital privileges for the performance of endoscopic procedures. As such, they are intended to apply to all endoscopists, and all areas where gastrointestinal endoscopy is performed.

The practical implementation of a credentialing guideline and the granting of privileges are the responsibility of the individual organizations. (1-5) The credentialing process should focus on the assurance of high quality patient care and be free from political or economic pressures. (2)

Principles of Initial Credentialing

1. Credentials and privileges should be determined independently for each type of endoscopic procedure (sigmoidoscopy [flexible and rigid], colonoscopy, esophagogastroduodenoscopy [EGD], endoscopic retrograde cholangiopancreatography [ERCP], endoscopic ultrasonography) and any other endoscopic procedures. (6,7)
2. Credentialing for all procedures, except sigmoidoscopy, should require the ability to perform common associated therapeutic modalities.
3. Competence in each endoscopic procedure requires both cognitive and technical components. (8,9)
4. Appropriate documentation should be required in the determination of competence in each procedure. This may include the completion of a formal training program (residency or fellowship), or documentation of equivalent training in other settings. Documentation of continued competence should be required for the renewal of endoscopic privileges. (8,11)
5. Following the successful completion of a gastrointestinal endoscopy training program (as detailed in "Principles of Training in Gastrointestinal Endoscopy" *Gastrointest Endosc* 1992; 38: 743-746) the trainee:
 - A. Must be able to integrate gastrointestinal endoscopy into the overall clinical evaluation of the patient.
 - B. Should have sound general medical or surgical training.
 - C. Must have a thorough understanding of the indications, contraindications, individual risk factors and benefit-risk considerations for the individual patient.
 - D. Must be able to clearly describe an endoscopic procedure and obtain informed consent.

- E. Must have a knowledge of endoscopic anatomy, technical features of endoscopic equipment, accessory endoscopic techniques, including biopsy, cytology, photography, thermal and non-thermal endoscopic therapy.
- F. Must be able to accurately identify and interpret endoscopic findings.
- G. Must have a thorough understanding of the principles, pharmacology and risks of sedation/analgesia.
- H. Must be able to document endoscopic findings and therapy, and communicate with referring physicians.
- I. Must competently perform those procedures that were taught.

The training in endoscopic techniques must be adequate for each major category of endoscopy for which privileges are requested. Performance of an arbitrary number of procedures does not guarantee competency. (7,11-14) Whenever possible, competence should be determined by objective criteria and direct observation. The number of supervised procedures necessary to obtain competency will vary tremendously between trainees 15. Previously published required numbers of procedures were an estimate of the "...threshold number of procedures that must be performed before competency can be assessed. The number represents a minimum, and it is understood that most trainees will require more (never less) than the stated number."(Training the Gastroenterologist of the Future: The Gastroenterology Core Curriculum. Gastroenterology 1996; 110:1266-1300.)

Recent prospective studies using objective measures of endoscopic competence in ERCP and colonoscopy have demonstrated that the previously published threshold numbers (Appendix A) are not adequate for most trainees to achieve competence. (6,7,9,12) This emphasizes the need to use objective criteria of skill, rather than an arbitrary number of procedures performed when granting privileges to physicians for endoscopic procedures. For example, in ERCP, the ability to cannulate the duct of interest in 80% of cases is used as the minimum measure of competency. (15) A prospective evaluation of trainees has demonstrated that at least 180 supervised procedures are required for trainees to reach that threshold, a number much higher than the previously published minimum of 75 procedures. (9) Evaluation of colonoscopic skills has also demonstrated that the number of supervised procedures necessary to achieve competency is greater than the previously suggested minimum. (7,12) Specific measures of competency have not yet been developed for all endoscopic procedures. These measures should be rapidly adopted in credentialing processes as they are developed. Even with objective measures of procedural success, the evaluation of endoscopic skills, the ability to interpret endoscopic findings and incorporate these findings into patient care requires repeated direct observation of the candidate by an experienced endoscopist.

Competence in all procedures, exclusive of sigmoidoscopy, requires the ability to perform appropriate therapeutic maneuvers at the same setting. The performance of

diagnostic procedures without the ability to treat all lesions reasonably expected to be encountered during endoscopy cannot be supported.

- J. A clinician can obtain training in formal settings, such as fellowship or residency program, or through less formal training ("Alternative Pathways To Training in Gastrointestinal Endoscopy" *Gastrointest Endosc* 1996; 43: 658-660).
- K. New endoscopic procedures, or significant advances in existing procedures, may occur. Endoscopists who have not received conventional formal training may wish to acquire privileges to perform these procedures. The degree of training, direct supervision and proctoring will vary with the experience of the endoscopist and the nature of the procedure. (16) When possible, objective criteria of competence should be developed and met.

Principles of Recredentialing and Renewal of Privileges

The goal of recredentialing is to assure continued clinical competence, promote continuous quality improvement and maintain patient safety 17-19. The principles of maintenance of competence are detailed in ASGE publication "Maintaining Competency in Endoscopic Skills". (*Gastrointest Endosc* 1995; 42: 620-621). These guidelines should be applied in conjunction with those of national accrediting organizations, such as the JCAHO.

Assuring continued competence in the performance of endoscopic procedures includes ongoing:

1. Documentation of adequate procedure volume to maintain clinical skills. This can include procedure log books or a review of patient records. Such a review should include documentation of objective measures of the number of procedures, procedure success, therapeutic interventions and complications.
2. Review of above statistics in a continuous quality improvement setting.
3. Documentation of continued cognitive training through participation in educational activities.

The purpose of this review and documentation should be restricted to use in continuous quality improvement and endoscopic credentialing.

Documentation of Guidelines

Appendices B & C include criteria for assessing competence for credentialing and recredentialing. Appendix B may be used by the program director or endoscopic trainer as means of attesting to the satisfactory attainment of each of the skills for each procedure. Appendix C include criteria for recredentialing by a department chair based on supporting records of each activity and skill. Satisfactory accomplishment should be documented in each cognitive and technical area.

APPENDIX A

MINIMUM NUMBER OF PROCEDURES BEFORE COMPETENCY CAN BE ASSESSED

STANDARD PROCEDURE	NUMBER OF CASES REQUIRED
Diagnostic EGD	100
Total Colonoscopy	100
Snare polypectomy	20*
Nonvariceal hemostasis (upper and lower; includes 10 active bleeders)	20*
Variceal hemostasis (Includes 5 active bleeders)	15
Esophageal dilation with guide wire	15
PEG	10
Advanced Procedures	
ERCP (Diagnostic)	75
ERCP (Therapeutic)	25 #
Tumor ablation	20
Pneumatic dilation for achalasia	5
Laparoscopy	25
Esophageal stent placement	10

* Included in total number

Includes 20 sphincterotomies and 5 stent placements and is in addition to the 75 diagnostic ERCP procedures

From: Training the Gastroenterologist of the Future: The Gastroenterology Core Curriculum. Gastroenterology 1996; 110:1266-1300.

**APPENDIX B
INITIAL CREDENTIALING GUIDELINES**

Preliminary Training

Cognitive Skills

Indications /Contraindications.

Consent

Endoscopic Anatomy

Technical Aspects

Sedation/Analgesia

Reporting/ Documentation

Integration of Care

Endoscopic Skills

Technical Skill

Number of Procedures

Success Rate

Complication Rate

Interpretation

Therapeutic Intervention

Patient Care

**APPENDIX C
RE-CREDENTIALING GUIDELINES**

Endoscopic Skills

Number of Procedures

Success Rate

Complication Rate

Educational Activity

Participation in Continuous Quality Improvement

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Proctoring and Hospital Endoscopy Privileges

This is one of a series of statements discussing the use of gastrointestinal procedures commonly performed by endoscopists. The text has been prepared by the Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy. This statement has been reviewed and approved by the Patient Care Committees of the American Gastroenterological Association and American College of Gastroenterology, by other physicians and surgeons with expertise in gastroenterology, and by the governing boards of the American Society for Gastrointestinal Endoscopy, the American Gastroenterological Association, the American College of Gastroenterology, and the Society of American Gastrointestinal Endoscopic Surgeons.

Guidelines for the appropriate use of endoscopy are based on critical review of the available data and expert consensus. Controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical considerations may justify a course of action at variance from these recommendations.

Hospital policies with respect to medical staff appointment and delineation of clinical privileges are changing to meet requirements for quality assurance. This is especially true in areas of medicine such as gastrointestinal endoscopy, where a variety of invasive procedures are performed.(1-3) Professionals involved in quality assurance are becoming aware that letters of reference, verification of subspecialty training, and even board certification may not be adequate substitutes for independent evaluation of a physician's skills. An emerging trend involves the use of proctoring to evaluate initial applicants for staff appointment as well as to assess incumbent staff members who request new endoscopic privileges or as part of their periodic recredentialing. Formal evaluation of technical skills (as opposed to cognitive ability) has heretofore been common in gastrointestinal endoscopy. Herein we propose tentative guidelines for hospital medical staff desiring to develop a hospital endoscopy proctoring system.

A proctor acts as a monitor to evaluate the technical and cognitive skills of another physician. His position differs from that of a consultant or supervising instructor in that he does not directly participate in patient care, has no physician/patient relationship with the patient being treated and does not receive a fee from the patient. A proctor represents the medical staff and is responsible to the medical staff in connection with the credentialing of physicians seeking endoscopic privileges.

DEVELOPMENT OF A PROCTORING POLICY

A. Written Guidelines

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

Appropriate candidates for proctoring include initial applicants for appointment to the medical staff and for delineation of new clinical privileges. These categories would include new graduates, physicians newly located to the area and incumbent staff members newly trained in endoscopic procedures.

Proctoring may also be appropriate for incumbent medical staff members 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 prior training may no longer be adequate. In addition, proctoring may be one of several appropriate follow-up actions when a potential practice problem is identified by the hospital's quality assurance or risk management programs.

Applicants must first meet all objective standards for hospital appointment and initial delineation of privileges. Proctoring is not a substitute for training, and the proctor's function is to evaluate, not teach, the applicant. Comprehensive training in endoscopy must be acquired in an accredited program.(4)

The American Board of Internal Medicine has only recently extended its evaluation of essential clinical skills in gastroenterology to include endoscopic procedures.(5-6) Many otherwise well trained graduates will have had little direct experience in certain endoscopic techniques such as ERCP with sphincterotomy and biliary stent insertion. An additional year of fellowship may be required of applicants seeking privileges for such high risk invasive maneuvers.(7) Competency to perform each procedure must be evaluated by training program directors. Graduates should have specific data from log books regarding the number of each procedure performed. Graduates of accredited training programs who have completed a predetermined minimum number of procedures may undergo a more expedited review process.

B. Qualifications of the Proctor

The proctor should be a physician who holds clinical privileges in the procedure being observed, and should possess sufficient expertise to judge the quality of care being rendered.

The proctor should always be identified as a member or representative of a committee of the medical staff established by the bylaws as having responsibility for proctoring as one of its peer review functions. Legal counsel should be consulted in order to take greatest advantage of peer review immunity available under state law, which varies from state to state.

The proctor should not receive a fee directly related to patient care. A proctor may or may not receive a fee from the medical staff as compensation for time for proctoring services.

If no suitable proctor is available on the medical staff, outside experts should be recruited. State or local endoscopic or other specialty societies may be helpful in such a search. A medical staff may accept evidence of proctoring from a nearby institution to supplement its own proctoring, provided that the proctor in the nearby hospital would have been eligible to serve as a proctor in the subject hospital.

Ideally, each applicant for endoscopic privileges should be evaluated by more than one proctor. Insofar as practical, the proctor should be free of actual or perceived conflicts of interest which might create a bias against, or in favor of, the applicant.

C. The Proctoring Process

The proctor must engage in direct observation of the performance of endoscopic procedure over a specified period of time or for a specified number of cases. Although this may be coupled with retrospective review of cases, retrospective review cannot replace concurrent observation. Videoendoscopy may be a valuable adjunct. The proctor should evaluate all aspects of the management of care in each case. Individual circumstances will dictate which procedures require a formal proctoring process. Upper GI endoscopy(8), colonoscopy(9), polypectomy, esophageal dilation, ERCP(10), percutaneous endoscopic gastrostomy, flexible sigmoidoscopy(11) and therapeutic use of heater probe or laser are examples of techniques appropriate for proctoring. Diagnostic and therapeutic applications must be addressed separately.

The proctor should prepare a confidential written report for use by the credentials committee which describes the type and number of cases observed and evaluates the applicant's performance. Ultimate responsibility for the format of the proctor's written evaluation should reside with the department or division chairman. The proctor's report should be maintained in the applicant's credentials file and should be evaluated by the credentials committee at the time the applicant is considered for promotion from provisional status. Applicants subject to proctoring should retain all rights of appeal under the credentialing process set forth in the hospital's bylaws.

The issue of whether and to what extent a proctor should intervene in a procedure is complex and unsettled. Certain clinical situations, or simple humanitarian concern, may dictate that the proctor become a consultant to the applicant or actually intervene to assist in a procedure gone awry. The proctor must realize that if he goes beyond merely observing the procedure, he has undertaken a duty to the patient which can result in liability arising from sequelae of the procedure. A proctor's involvement should be disclosed on the patient's chart and in the proctor's confidential report to the credentials committee. In situations where an applicant has an associate who holds privileges in the procedure being proctored, some hospitals have encouraged the associate to be present to assist (if necessary) in the procedure and to avoid the necessity for the proctor to become involved. The proctor may or may not be included in the patient's informed consent, recognizing that such inclusion may expose the proctor to risk beyond that of mere proctoring. In the only reported court decision addressing the issue, the court held that a proctor had no duty to intervene in a surgical procedure, reasoning that no duty arose because the proctor had done nothing to place the patient at risk.(12) Potential legal problems can be ameliorated by having a formal, written protocol for proctoring and by maintaining detailed records.

A suitably performed and documented program of proctoring for gastrointestinal endoscopic procedures is one important credentialing tool in the modern hospital's quality assurance system.

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ASGE Publication No. 1024

Maintaining Competency in Endoscopic Skills

Position Statement

This statement addresses the maintenance of endoscopic competence by physicians who have attained initial competence by endoscopic training in a formal fellowship or residency in gastroenterology or surgery, as defined in the ASGE "Statement on Endoscopic Training."

Objectives

Consistent with the ASGE position on endoscopic training, the principles for maintenance of endoscopic competence include objectives that trained endoscopists will be able to:

- A. Recommend endoscopic procedures based on findings of a personal consultation and in consideration of specific indications, contraindications, and diagnostic/therapeutic alternatives.
- B. Perform specific procedures safely, completely, and expeditiously.
- C. Correctly interpret most endoscopic findings and undertake endoscopic intervention when indicated.
- D. Integrate endoscopic findings or therapy into patient management plans.
- E. Understand risk factors, recognize and manage complications.
- F. Recognize personal and procedural limits and know when to request help.

In contrast to the extensive processes and procedural experience involved in initial endoscopic training, maintenance of learned endoscopic skills is expected to require less intensive activities and fewer procedural numbers. Nevertheless, maintenance of skills requires demonstration of some minimal and sustained level of activity. Maintenance of competency is an important aspect of GI endoscopy for several reasons:

- A. Procedural dexterity can optimize patient comfort and safety.
- B. Performance of a procedure too infrequently may lead to missed or inappropriate diagnoses with potentially significant clinical consequences.
- C. Changes in instrumentation and technology requires ongoing familiarity by the endoscopist (e.g. video vs. fiberoptic equipment).
- D. The understanding and recognition of endoscopic lesions may change over time (e.g. portal hypertension gastropathy, the importance of *Helicobacter pylori*, recognition of visible vessels, etc.).
- E. Endoscopic therapy continually undergoes reevaluation and evolution (e.g. utility of prophylactic sclerotherapy or of monopolar coagulation for visible vessels).

The ASGE has endorsed the principle that undertaking an endoscopic procedure requires the skill and ability to treat detected pathology (e.g. polypectomy at colonoscopy or biliary drainage at ERCP). Just as skill in endoscopic therapy requires greater initial training than skills in diagnostic endoscopy, it is expected that greater attention may be required to maintain therapeutic skills.

The Process of Maintaining Endoscopic Skills

No published studies exist which address issues of the processes or procedure numbers which might assure maintenance of endoscopic skills. It can nonetheless be recommended that both cognitive and technical aspects are involved.

- A. Ongoing familiarity with the current literature of GI endoscopy, to assure appropriate endoscopic recommendations as well as optimal performance.
- B. Continuing Medical Education credits specifically in the field of gastroenterology and GI endoscopy.
- C. Ongoing familiarity with changes in endoscopic instrumentation, particularly with respect to those instruments and devices which are available to the specific practitioner.
- D. Actual 'hands on' endoscopic performance, as the primary endoscopists, utilizing those skills for which the practitioner is credentialed. The actual number of performed procedures which might be required to maintain skills is uncertain, and probably varies according to prior experience of the individual endoscopist. However it is likely that intrinsic complexity of the individual procedure relates to the frequency with which it must be performed. Thus, it would be expected that colonoscopic expertise requires numerically greater ongoing experience than does upper GI endoscopy, and ERCP (with its frequent need for therapeutic intervention) requires substantially greater experience, as does therapeutic upper GI endoscopy in the treatment of GI bleeding.
- E. The advantage of intermittent procedure "proctoring" or supervision by unbiased, similarly credentialed endoscopist colleagues, in order to share skills and advice, may have a beneficial role in maintenance of endoscopic skills, and is encouraged.

Endoscopy by Non-Physicians

Guidelines for the practice of endoscopy are developed by the American Society for Gastrointestinal Endoscopy using an evidence based methodology. A literature search is performed to identify relevant studies on the topic. Each study is then reviewed for both methodology and results. Controlled clinical trials are emphasized, but information is also obtained from other study designs and clinical reports. In the absence of data expert opinion is considered. When appropriate, the guidelines are submitted to other professional organizations for review and endorsement. As new information becomes available revision of these guidelines may be necessary.

These guidelines are intended to apply equally to all who perform gastrointestinal endoscopic procedures, regardless of specialty or location of the service. Practice guidelines are meant to address general issues of endoscopic practice. By their nature they cannot encompass all clinical situations. They must be applied in the appropriate context for an individual patient. Clinical considerations may justify a course of action at variance to these recommendations.

Purpose

Gastrointestinal endoscopy is defined as the visualization of the digestive tract with flexible or rigid diagnostic tools. Endoscopic technology has advanced rapidly over the past thirty years, becoming an integral part of clinical gastroenterology. The ASGE has continually promoted safe and responsible endoscopic practice. Guidelines have been developed and disseminated regarding appropriate use of and training in endoscopy. Given the increasing demands for endoscopy, as well as the growing range of its diagnostic and therapeutic options, non-physician endoscopists have been trained to provide screening sigmoidoscopy, and in some cases, upper endoscopy and colonoscopy (17). The purpose of this guideline is to address the issues surrounding endoscopic practice by non-physicians.

Definitions

Competent endoscopic practice requires thorough training in both the cognitive and technical aspects of endoscopy. Cognitive skills include knowledge of procedural indications/contraindications, risks, benefits and alternatives as well as accurate identification and interpretation of gross pathology (1). It also includes the ability to assess the implications of information regarding the patient's condition and the capability to integrate endoscopic findings into clinical practice.

Technical skills refer to the ability to perform the physical aspects of endoscopy, such as insertion, advancement, maneuvering through the gastrointestinal tract, biopsy, therapeutic interventions and withdrawal of the instrument. Trained physician endoscopists include, but are not limited to, physicians with fellowship training in gastrointestinal disease and formal training in endoscopy as defined in prior ASGE publications (2). Non-physician endoscopists are defined as any non-physician medical personnel performing endoscopy, including but not limited to, nurses, nurse practitioners, physician assistants, and medical assistants.

Discussion

The decision to utilize non-physician endoscopists should be made based upon competence in endoscopy. Additionally, factors to consider include availability of physician resources and volume of procedural demand as dictated by local conditions. Physician endoscopists undergo extensive formal training in gastrointestinal disease as well as endoscopic procedures. It is unreasonable to expect non-physicians to be trained to this extent. Because of this, non-physicians will not attain the cognitive expertise necessary for optimum patient care as is expected of a physician. In this light, non-physicians who have performed endoscopy have been trained and subsequently supervised by physician endoscopists.

At this time, the majority of non-physician endoscopists perform flexible sigmoidoscopy only. Flexible sigmoidoscopy requires fewer supervised examinations to attain objective measures of technical competency (3) than other endoscopic procedures, does not require sedation and has a low rate of endoscopically related complications. Non-physician endoscopists have been performing sigmoidoscopies since 1972 (4) and there have been several studies supporting the safety and efficacy of flexible sigmoidoscopy by non-physicians (5-7). A recent randomized controlled trial demonstrated no significant differences in depth of insertion or polyp detection between gastroenterologists and nurse endoscopists (8).

Screening flexible sigmoidoscopy is becoming a population-based screening tool for colorectal cancer, which is the third most commonly diagnosed cancer and the second leading cause of cancer related mortality in the United States. An estimated 131,000 new cases of colorectal cancer will be diagnosed and over 56,000 will die from it each year (9). Retrospective (case-control) studies have demonstrated a 55-70% reduction in colorectal cancer related mortality with screening sigmoidoscopy (10-12). Currently, less than 10% of the at risk U.S. population undergoes screening sigmoidoscopy, which is in part due to the lack of available skilled endoscopists (13). By the year 2000, over 50 million individuals in the U.S. will be eligible for screening sigmoidoscopy (13). The British Society of Gastroenterology and the Society of Gastroenterology Nurses and Assistants have written policy statements endorsing the practice of flexible sigmoidoscopy by registered nurses (14,15). Currently, 34% of state boards of nursing do not approve this practice, but allow flexible sigmoidoscopy by nurse practitioners (16).

Non-physician endoscopists also perform upper endoscopy and colonoscopy (16). The prevalence of this practice is unknown at this time. However, the non-physician's ability to administer sedation, perform endoscopic therapy and evaluate for and treat complications has not been done. The performance of these procedures demands intensive training as well as supervision during procedures by a physician endoscopist. The thresholds for determination of endoscopic competence should be equal to that expected of a physician trainee. It is unclear at this time whether patient needs and demand for endoscopy merit non-physicians performing procedures other than screening flexible sigmoidoscopy. All endoscopy by both physicians and non-physicians should be subjected to a quality monitoring program as discussed in the ASGE guideline (17).

Recommendations

The delivery of health care in gastroenterology has been expanding at a rapid pace. This phenomenon has begun to modify the traditional roles of non-physician medical personnel. These individuals have increasingly performed the role of non-physician endoscopists.

At this time, the medical literature supports the utilization of non-physician endoscopists for screening flexible sigmoidoscopy only. Performance of flexible sigmoidoscopy for symptom assessment by non-physicians has not been studied. The less demanding requirements for training, the absence of sedative use and the need for large scale screening further support this practice. It is recommended that a trained physician endoscopist be available for immediate assistance and confirmation of findings.

Certification of non-physician endoscopists should remain within the limits of state licensure as well as institutional policy. This guideline is not meant to substitute for local determination of practice and policy.

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ASGE Publication No. 1035

Methods of Privileging for New Technology in Gastrointestinal Endoscopy

Guidelines for the practice of endoscopy are developed by the American Society of Gastrointestinal Endoscopy using evidence-based methodologies. A literature search is performed to identify relevant studies on the topic. Each study is then reviewed for both methodology and results. Controlled clinical trials are emphasized, but information is also obtained from other study designs and clinical reports. In the absence of data, expert opinion is considered. When appropriate, the guidelines are submitted to other professional organizations for review and endorsement. As new information becomes available revision of these guidelines may be necessary.

These guidelines are intended to equally apply to all who perform gastrointestinal endoscopic procedures, regardless of specialty or location of service. Practice guidelines are meant to address general issues of endoscopic practice. By their nature, they cannot encompass all clinical situations. Clinical situations may justify a course of action at variance to these recommendations.

The practice of gastrointestinal endoscopy is dynamic and continues to evolve. Standard endoscopic procedures continually undergo refinement and new major techniques are introduced. In some instances, the acquisition of competence with new technological developments requires little effort because of the endoscopist's prerequisite training, skill and experience. In other cases, however, the acquisition of competency represents a major addition to the endoscopist's skills and knowledge base. In such instances, a vehicle for formal training will be required with documentation of competency.⁽¹⁾ In the initial phases of dissemination of a new technology, few centers of expertise will be available to provide instruction. It is incumbent upon these centers to offer training in new technology in the appropriate setting of fellowship training and advanced fellowship training. Training centers may also consider offering instruction to established endoscopists, based on the complexity of the procedure and the perceived need and applicability of the procedure to general endoscopic practice.

Methods of Privileging for New Technology Purpose

The purpose of these guidelines is to provide a suitable framework for attaining competency and eventual privileging involving new and emerging technologies in gastrointestinal endoscopy. These guidelines apply to newly developed technologies that have left the experimental and developmental stages with demonstrated clinical efficacy and are ready to be adopted into clinical practice. Definitions

"Major skill" describes a new technique or procedure which by its nature involves a high level of complexity, interpretative ability, and/or new type of technology (e.g., endoscopic ultrasound). In their initial phases of dissemination, acquisition of competency would likely be confined to teaching centers and would require formal training.

"Minor skill" describes a new non-experimental development which is a minor extension of an accepted and widely available technique or procedure (e.g., endoscopic variceal band ligation). For the majority of gastrointestinal endoscopists, obtaining competency in a minor skill would

involve limited education and practical exposure such as that obtained from short courses, training videos, CD-ROM, and interactive computer programs.

New Technology Requiring the Development of Major Skills

A preceptorship or other vehicle of formal instruction is mandatory for the acquisition of major new skills. The completion of a short course or workshop that offers limited exposure to cognitive background data or technical skills will not by itself, result in clinical competency and therefore should not be the sole mechanism for the acquisition of new major skills.(2) Persons wishing to learn a new procedure should do so under the supervision of a preceptor, a recognized authority in the new procedure on the basis of extensive clinical experience and/or publications. The preceptor's responsibilities include: setting objectives, developing a curriculum, demonstrating procedural techniques, overseeing the instruction and practice of skills, evaluating the preceptee, and documenting competency of the preceptee for future credentialing.(3) Competency is defined as the minimum level of knowledge, skills and expertise, derived through training required to perform a procedure safely and proficiently. Components of competency include technical, interpretative, and cognitive aspects as previously outlined by the ASGE. The preceptor has primary patient care responsibility and should be involved appropriately in the periprocedural care. Informed consent should document the roles of both the preceptor and preceptee to the patient.

A preceptee is an endoscopist who possesses the sufficient experience to be able to master the new procedure cognitively and technically. Goals of the preceptee include attaining the ability to:

1. understand the indications, contraindications, and alternatives of the procedure
2. perform the procedure proficiently
3. interpret findings correctly
4. integrate findings into therapy or management plans
5. avoid, recognize and manage complications
6. assess preprocedural and plan post-procedural follow-up care

The preceptorship is completed when the preceptee has achieved an acceptable level of competency that will allow for the fully independent performance of the major skill in question, while meeting the six aforementioned goals. The preceptor should supply written documentation of the successful completion of the preceptorship for future credentialing purposes.

New Technology Requiring the Development of Minor Skills

In some instances, new technological developments represent minor extensions or refinements of established endoscopic skills. Utilizing instructive resources such as videotapes, interactive computer programs, CD-ROM and attendance at short courses may be appropriate for attaining competency in these techniques.⁴ The duration of training should not be fixed, but should reflect the time needed for the participant to master the requisite skill. It should be emphasized that short courses do not supply adequate training in endoscopic procedures. Properly designed courses can introduce new techniques to the endoscopist who already has a background and experience in basic endoscopic skills. Technological refinements in equipment, including improvements in commonly used equipment such as endoscopes, biopsy forceps, and snares do

not require formal training, and skill in these techniques can usually be mastered with the aid of videotapes, package inserts, and demonstration of the technique by other endoscopists.

In summary, emerging technologies can be stratified according to their complexity and general applicability. The avenues for attaining competency and privileges in emerging technologies are varied and will depend upon the individual endoscopist's skill, prior training and the complexity of new technology. Some new procedures may require formal hands-on training under supervision followed by written documentation of competency. Other technological developments represent minor extensions of demonstrated skills. Reading, viewing video tapes, or attending short courses may be sufficient training in these technologies.

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Standards of Practice of Gastrointestinal Endoscopy

This statement was prepared by the American Society for Gastrointestinal Endoscopy's Standards of Training and Practice Committee. Modifications resulting in the final statement have been provided by the Patient Care Committees of the American Gastroenterological Association and American College of Gastroenterology and by a group of physicians and surgeons with a broad interest in gastroenterology.

It has been approved by the Governing Boards of the American Society for Gastrointestinal Endoscopy, the American Gastroenterological Association, the American College of Gastroenterology, and the Society for Surgery of the Alimentary Tract.

Physicians and surgeons who practice gastrointestinal endoscopy should meet the following standards. Hospitals should consider these standards in deciding whether to grant or renew privileges in a given gastrointestinal endoscopic procedure.

1. Training

- a. Completion of a residency-fellowship training program as outlined in Guidelines for Training in Gastrointestinal Endoscopy and expanded in the Statement on Endoscopic Training,(1) OR
- b. Attendance in a gastrointestinal endoscopic program until training in the endoscopic procedures he or she wishes to perform is equivalent to that outlined in Guidelines for Training in Gastrointestinal Endoscopy and expanded in the Statement on Endoscopic Training,(1) OR
- c. Experience in the endoscopic procedures he or she wishes to perform equivalent to that obtained in a residency-fellowship training program as outlined in Guidelines for Training in Gastrointestinal Endoscopy and expanded in the Statement on Endoscopic Training. To fulfill this requirement, experience must be documented and skills must be demonstrated.

2. Practice

- a. The endoscopist should provide consultation or direct care in medical or surgical aspects of gastrointestinal disease as they relate to the appropriate use of endoscopy and should not be an individual who provides only a technical service. Independent judgment of the indication for and timing of an endoscopic procedure may lead to a decision against performing endoscopy. Sensitivity to cost-benefit considerations is important in making this decision,
- b. The endoscopist should also:
 1. Evaluate the patient's history of reactions to drugs and associated medical conditions.
 2. Explain the procedure to the patient, including its benefits and risks.
 3. Exercise caution in administration of medications and provide for close monitoring of sedated patients.
- c. The endoscopic procedure should be performed skillfully and expeditiously, and futile efforts should not be prolonged to the detriment of the patient.
- d. A full written report of the procedure and findings should be prepared.
- e. Follow-up should be arranged.

3. Privileges

- a. The decision for granting of privileges in gastrointestinal endoscopy should be based on the applicant's qualifications with appropriate recognition of individual situations and community practice.
- b. This decision can be made by the appropriate Chiefs of Service or by a more broadly-based hospital committee comprised of individuals from various services who have endoscopic training and skills.

4. Continuing Education

- a. It is imperative that the gastrointestinal endoscopist remain current in this rapidly developing field. Attendance at meetings dealing with endoscopy and active participation in postgraduate programs pertaining to advances in endoscopy are necessary to maintain and improve endoscopic skills.
- b. Self-training in new techniques occurs in gastrointestinal endoscopy as in other medical and surgical disciplines, but it must take place on a background of basic endoscopic skills as previously outlined under 1) Training and 2) Practice. The endoscopist should have the integrity and insight to determine when additional training is necessary before undertaking a new procedure.

5. Review of Performance

- a. Performance of the gastrointestinal endoscopist should be reviewed periodically. The numbers of procedures, indications, results, and complications should be made available to the Chief of Service or committee that is responsible for granting privileges. Periodic renewal of privileges is advisable.
- b. Endoscopic complications should be discussed at a periodic conference as a mechanism for review of performance and as an educational device.

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ASGE Publication No. 1004
Revised 3/86

Quality Improvement of Gastrointestinal Endoscopy

This is one of a series of statements discussing the utilization of gastrointestinal endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy prepared this text. A previous guideline on this topic was last revised in 1989. Since that time, new information has been released that requires update of this information and recommendations. In preparing this update, A Medline literature search was performed, and additional references obtained from the bibliographies of the identified articles and from the recommendations of expert consultants.

Gastrointestinal endoscopy guidelines are systematically developed, clinically related evaluations and recommendations. These guidelines are developed with the intent of assisting the practitioner in providing appropriate, cost effective and high quality patient care. The following guideline has been developed specifically for practicing endoscopists. It is not intended as a replacement for accreditation by organizations such as the Joint Commission on Accreditation of Health Organizations (JCAHO) and the American Association of Ambulatory Health Care (AAAHC). Rather, it emphasizes how the ASGE defines quality improvement for gastrointestinal endoscopy.

QUALITY IMPROVEMENT OF GASTROINTESTINAL ENDOSCOPY

Endoscopy is the major diagnostic and therapeutic modality in the care of patients with diseases of the gastrointestinal tract. Prior ASGE guideline statements have outlined standards for establishment of gastrointestinal endoscopy units and for granting of endoscopic privileges (1,2). It is now timely that a standardized quality improvement program be developed to promote high quality in endoscopic practice and care. According to the JCAHO, a quality improvement program should be "designed to objectively and systematically monitor and evaluate the quality and appropriateness of care, pursue opportunities to improve patient care, and resolve identified problems", and must include "a written plan that describes the program's objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and problem-solving activities."(3) The goal of improving an endoscopic unit's performance is to continuously improve patient health outcomes.

This document has been prepared by the ASGE to assist hospitals, outpatient endoscopy centers and endoscopists in establishing a process for quality improvement of endoscopic practice. A prior consensus statement by the ASGE, "Appropriate Use of Gastrointestinal Endoscopy", defines indications, non-indications and contraindications for endoscopic practice and provides a basis for establishing local standards of endoscopic utilization (4). A quality improvement program which evaluates endoscopic practice can be used for re-credentialing and for correcting identified deficiencies and problems. Review of endoscopic treatment against established specified criteria can assist in making cost effective improvements in patient care. Processes for which data should be continually collected include those processes that are high volume, high risk or problem prone (5). All procedures that place patients at risk require systematic data collection and evaluation. The major elements of a program for quality improvement in gastrointestinal endoscopy are: procedure reports; an endoscopic unit record; and multi-disciplinary peer review; as outlined below:

PROCEDURE REPORTS

All endoscopic procedures should be systematically documented by a complete and legible endoscopic report which should include the following elements:

1. date of procedure
2. patient identification data
3. endoscopist(s)
4. assistant(s)
5. documentation of relevant patient history and physical examination
6. indication of informed consent
7. endoscopic procedure
8. indication(s)
9. type of endoscopic instrument
10. medication (anesthesia, analgesia, sedation)
11. anatomic extent of examination
12. limitation(s) of examination
13. tissue or fluid samples obtained
14. findings
15. diagnostic impression
16. results of therapeutic intervention (if any)
17. complications (if any)
18. disposition
19. recommendations for subsequent care

It is expected that written documentation of pertinent procedural related data is available in the patient's record at the time the patient leaves the endoscopic area. This documentation may be the final endoscopic report with all of the data elements listed above or an abbreviated notation with all relevant information that will ensure continuity of care for the patient.

ENDOSCOPIC UNIT RECORD

A record of all endoscopic procedures must be maintained. This may be kept in a log form, in the medical record or entered into a computer database. The information contained in this record can serve as an index for selection of procedures for quality improvement review. Information contained in this record should include the following:

1. date of procedure
2. patient identification data
3. endoscopist(s)
4. assistant(s)
5. endoscopic procedure
6. anatomic extent of procedure
7. duration of procedure
8. findings
9. notation of tissue sampling
10. therapeutic intervention(s) (if any)
11. complications*

12. limitation(s) of examination
13. informed consent document
14. nursing notes of procedure, including pre and post procedural evaluation, procedural sedation record
15. procedure report (as outlined above)

* Elements of procedural complications are

1. they are morbid;
2. they occur as a result of the procedure;
3. they are deviations from an ideal course and tend to impair or delay recovery; and
4. they cause changes in the management of the patient (6).

A process for entering late complications should be devised.

PROCEDURE REVIEW PROCESS

Endoscopic practice should be reviewed regularly by clinicians privileged to perform endoscopic procedures and others who can contribute to quality improvement (i.e., other physicians, endoscopy assistants, QI representatives). The individuals serving on the committee should be representative of those privileged to perform gastrointestinal endoscopy at that institution. The committee will report regularly to relevant medical staff departments and/or committees. Chairmen of appropriate departments are responsible for assuring adequate reviews and actions to assure improvements in the quality of patient care. Results of these monitoring and evaluation activities should be used for continuous improvement of patient care. The data could be considered for reprivilaging and reappointment should not be the responsibility of this committee. Information should be made available to endoscopists to allow for opportunities for improvement. The committee must identify clinical indicators by which records can be reviewed. These might include, but are not limited to one or more of the following: appropriateness of indications, absence of contraindications, technical performance (i.e., full colonoscopic exam, cannulation of desired ducts with ERCP, successful polypectomy), complications and correlations of endoscopic results with desired outcomes and patient benefits. Information from the Endoscopy Unit records can serve as an index for this review. Sentinel events should be reviewed in a timely manner whenever they occur. Accrediting agencies have defined sentinel events as significant adverse events necessitating specific corrective actions. Each unit should develop a policy for the extent and frequency of endoscopic unit reviews. Cases discovered by initial screening should be carefully assessed and evaluated for improved care. In general, prospective evaluations are preferred over those done retrospectively.

The initial screening of cases should usually be performed by a non-physician based on QI indicators chosen by the institution. It is important that patterns of performance, as well as individual cases, be examined. The assessment of cases should incorporate four basic comparisons: with self, with others, with standards and with best practice.

Means of selecting procedures for physician review could include: cases exceeding a predetermined 'threshold for evaluation', based on QI indicators or sentinel events. Those records which indicate a problem suggesting a diminished level of care can be brought to the committee

for evaluation. The committee may also identify problems relating to the endoscopic unit's functioning (i.e., equipment failure/maintenance, infection control / reprocessing issues, scheduling delays). Based on committee deliberations, recommendations may be made to the appropriate person or body.

Organizations should also make efforts to evaluate the quality of outcomes for patients undergoing endoscopic procedures. These measures may include, but not limited to: patient satisfaction, procedural success rates, adequacy of colonoscopic preparation, and incidence of specified complications.

In summary, quality improvement should be multidisciplinary, data driven and systematic; include endoscopy related data collection, undergo a specified review process and lead to improved patient health.

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Appropriate Use of Gastrointestinal Endoscopy

Introduction

Progress in endoscopic technology has advanced the practice of Medicine as it relates to the gastrointestinal tract. Over the last thirty years, scientists and clinicians have acquired unprecedented access to the gastrointestinal lumen and the pancreatic and biliary ductal systems. Direct examination of the mucosal surface provides far greater information than that gained by two dimensional scans and x-rays. Further, endoscopic diagnosis and treatment of conditions have now supplanted many open surgical procedures. Ongoing technical improvements and innovations continue to extend potential endoscopic therapies.

The ASGE has continually promoted safe and responsible endoscopic practice. For more than 20 years, the ASGE with the assistance and support of the American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG), Society for Surgery of the Alimentary Tract (SSAT), The Society of American Gastrointestinal Endoscopic Surgeons (SAGES), and The American Society for Colon and Rectal Surgery (ASCRS) has written guidelines on how endoscopy should be performed, by whom, and for what purposes. These guidelines have been published periodically and are reviewed and updated frequently.

It is critical that the endoscopists receive thorough training in the cognitive aspects of gastrointestinal diseases as well as in the technical aspects of endoscopy. Extensive non-endoscopic training is necessary to provide the endoscopist with the depth of experience, judgement and knowledge necessary to recognize what has been seen and to formulate an appropriate plan for the patient's subsequent care.

Standards of training and practice must be defined and implemented on a national, as well as a local basis. Therefore, the ASGE is continuing to meet with accrediting agencies concerning their mutual interest in quality of care and the peer review mechanisms.

The following information has been prepared for use by national and local procedure review committees to assist them in defining standards of endoscopic practice and training. This information should also be helpful to primary care physicians deciding how best to evaluate their patients.

Definition of Gastrointestinal (GI) Endoscopic Procedures

Esophagogastroduodenoscopy (EGD) affords an excellent view of mucosal surfaces of the esophagus, stomach, and proximal duodenum. Colonoscopy allows examination of the entire colon and rectum and frequently the terminal ileum. Standard diagnostic functions include inspection, biopsy, photography and video recording. Diagnostic observations are made concerning focal benign or malignant lesions, diffuse mucosal changes, luminal obstruction, motility, and extrinsic compression by contiguous structures. The most common therapeutic endoscopic procedures include polypectomy, dilatation of strictures, removal of foreign bodies, gastrostomy, and treatment of gastrointestinal bleeding with injection, banding, coagulation or sclerotherapy.

Endoscopic retrograde cholangiopancreatography (ERCP) employs endoscopy to identify the major and minor papillae. The biliary and pancreatic ductal systems are cannulated and opacified with contrast material to provide diagnostic information. Other diagnostic tools may be used in conjunction with ERCP including brush cytology, biopsy, and endoscopic ultrasound. Therapeutic maneuvers included with ERCP include endoscopic sphincterotomy with or without stent placement and with other ancillary techniques for the treatment of pancreatic and biliary duct disease.

Flexible sigmoidoscopy (FS) employs a flexible instrument to examine the rectum, sigmoid, and a variable length of more proximal colon.

Enteroscopy allows the visualization of a greater extent of the small bowel than EGD. Two types of enteroscopes are available, the push enteroscope, which allows limited tissue sampling and therapy, and the Sonde enteroscope, that potentially visualizes the entire small bowel without the ability of therapy or biopsy.

Endoscopic ultrasonography is a technique where a high frequency is incorporated into the tip of the endoscope. This provides high resolution images of the gastrointestinal wall and adjacent structures. Instruments can be passed under ultrasonographic guidance to obtain tissue samples and perform therapy.

- 1) Laparoscopy is a procedure that allows direct visualization of major portions of the liver, gallbladder, spleen, stomach, large and small intestine, pelvic organs and peritoneum. Directed biopsy increases diagnostic accuracy. Diagnostic laparoscopy is the only gastrointestinal endoscopic procedure that does not use a natural body orifice for access. Access is gained through a small incision in the abdominal wall. Laparoscopy is simple, safe, and well-tolerated under local anesthesia and sedation. General anesthesia is neither necessary nor desirable, except in special circumstances. While sterile conditions are required, laparoscopy need not be performed in an operating room; routine backup by a surgical or anesthesia team is usually not required. The procedure may be performed on an outpatient basis.

The ASGE supports the following statements pertaining to endoscopic training and practice. A more detailed statement is available in the ASGE Principles of Training in Gastrointestinal Endoscopy (Gastrointest Endosc 1992;38:743-736).

1. Those performing gastrointestinal endoscopy should be well trained in endoscopy as part of a broader clinical discipline such as gastroenterology, general, or colorectal surgery.
2. Training in endoscopy is usually acquired during formal residency/fellowship training in an accredited (Accreditation Council for graduate Medical Education) program. Training will include integration of endoscopy with clinical problem-solving and hands on performance of procedures under direct supervision of an experienced endoscopic trainer. Alternative comprehensive training in endoscopy should comply with published guidelines in Alternative Pathways to Training in Gastrointestinal Endoscopy (Gastrointest Endosc 1996;43:658-660).
3. Endoscopic competence is determined and certified by the endoscopic training supervisor.
4. Endoscopic competence will be demonstrated by those seeking privileges in local hospitals.

5. Endoscopic privileges should not be granted to applicants citing attendance in short courses as the principal training experience.
6. Privileges should be granted for each separate procedure for which training has been documented and competence verified. The ability to perform any one endoscopic procedure does not imply competency to perform others.
7. Endoscopic privileges should be reviewed periodically with due consideration to procedure performance and continuing education. A more detailed statement is available in the ASGE, "Maintaining Competency in Endoscopic Skills" (Gastrointest Endosc 1995;42:620-621).

Endoscopic Privilege Granting

A guideline addressing methods of granting hospital privileges to perform gastrointestinal endoscopy has been published by the ASGE (Gastrointest Endosc 1992;38:765-767). Local hospital committees wishing to apply the foregoing criteria may find the following credentialing guidelines helpful.

1. The hospital staff should have minimal standards which uniformly apply to all endoscopists.
2. Privileges should be granted to applicants based upon completion of a training program that certifies that the applicant has successfully completed a gastrointestinal endoscopy training program (as detailed by ASGE Publication No.1001,"Principles of Training in Gastrointestinal Endoscopy" (Gastrointest Endosc 1992;38:743-746).
 - A. Must be able to integrate gastrointestinal endoscopy into the overall clinical evaluation of the patient.
 - B. Should have sound general medical or surgical training.
 - C. Must have a thorough understanding of the indications, contraindications, individual risk factors and benefit-risk considerations for the individual patient.
 - D. Must be able to clearly describe an endoscopes procedure and obtain informed consent.
 - E. Must have a knowledge of endoscopic anatomy, technical features of endoscopic equipment, accessory endoscopic techniques, including biopsy, cytology, photography, thermal and non-thermal endoscopic therapy.
 - F. Must be able to accurately identify and interpret endoscopic findings.
 - G. Must have a thorough understanding of the principles, pharmacology and risks of conscious sedation/analgesia.
 - H. Must be able to document endoscopic findings and therapy, and communicate with referring physicians and integrate endoscopic findings in patient care.
 - I. The applicant for privileges to performing endoscopic techniques must perform competently the procedure for which he is credentialed.
3. Endoscopic short courses are unacceptable as the principal evidence of competence for granting of privileges.
4. Credentialing for all procedures, except sigmoidoscopy, should require the ability to perform associated therapeutic modalities.
5. Privileges should be granted on a procedure specific basis. Credentialing in one area of endoscopy does not necessarily apply to another endoscopic procedure.

6. Training requirements for non-endoscopists seeking to be privileged in flexible sigmoidoscopy while less rigorous than that for other endoscopic procedures still requires supervised hands on experience.
7. The renewal of privileges should be based on demonstration of continued endoscopic skills, participation in continuous quality improvement, and evidence of ongoing educational activities.
8. New endoscopic procedures or significant advances in existing procedures may occur. Endoscopists who have not received conventional formal training may wish to acquire privileges to perform these procedures. The degree of training, direct supervision and proctoring will vary with the experience of the endoscopist and the nature of the procedure. When possible, objective criteria of competence should be developed and met.
9. Subspecialty board certification or membership in regional/ national societies does not, per se, indicate competence to perform GI endoscopic procedures and should not be the sole or primary criterion for granting procedure privileges.

General Indications Statements

The indications and relative contraindications for doing each of the endoscopic diagnostic procedures are listed on the following pages. These guidelines are based on a critical review of available information and broad clinical consensus, and are as specific and definitive as possible.

Clinical considerations may occasionally justify a course of action at variance with these recommendations.

GI endoscopy is generally indicated:

- A. If a change in management is probable based on results of endoscopy.
- B. After an empiric trial of therapy for a suspected benign digestive disorder has been unsuccessful.
- C. Often as the initial method of evaluation as an alternative to x-ray studies.
- D. When a primary therapeutic procedure is contemplated.

GI endoscopy is generally not indicated:

- A. When the results will not contribute to a management choice.
- B. For periodic follow-up of healed benign disease unless surveillance of a premalignant condition is warranted.

GI endoscopy is generally contraindicated:

- A. When the risks to patient health or life are judged to outweigh the most favorable benefits of the procedure.
- B. When adequate patient cooperation or consent can not be obtained.
- C. When a perforated viscus is known or suspected.

1. Esophagogastroduodenoscopy (EGD) is generally indicated for evaluating:

- A. Upper abdominal distress which persists despite an appropriate trial of therapy
- B. Upper abdominal distress associated with symptoms and/or signs suggesting serious organic disease (e.g., anorexia and weight loss) or in patients over 45 years of age.

- C. Dysphasia or odynophagia.
- D. Esophageal reflux symptoms which are persistent or recurrent despite appropriate therapy.
- E. Persistent vomiting of unknown cause.
- F. Other system disease in which the presence of upper GI pathology might modify other planned management. Examples include, patients who have a history of ulcer or GI bleeding who are scheduled for organ transplantation, long-term anticoagulation or chronic non-steroidal therapy for arthritis and those with cancer of the head and neck.
- G. Familial adenomatous polyposis.
- H. For confirmation and specific histologic diagnosis of radiologically demonstrated lesions:
 1. Suspected neoplastic lesion.
 2. Gastric or esophageal ulcer.
 3. Upper tract stricture or obstruction.
- I. Gastrointestinal bleeding:
 1. In patients with active or recent bleeding.
 2. For presumed chronic blood loss and for iron deficiency anemia when the clinical situation suggests an upper GI source or when colonoscopy is negative.
- J. When sampling of tissue or fluid is indicated.
- K. In patients with suspected portal hypertension to document or treat esophageal varices.
- L. To assess acute injury after caustic ingestion.
- M. Treatment of bleeding lesions such as ulcers, tumors, vascular malformations (e.g., electrocoagulation, heater probe, laser photocoagulation or injection therapy).
- N. Sclerotherapy or banding of varices.
- O. Removal of foreign bodies.
- P. Removal of selected polypoid lesions.
- Q. Placement of feeding or drainage tubes (peroral, percutaneous endoscopic gastrostomy, percutaneous endoscopic jejunostomy).
- R. Dilation of stenotic lesions (e.g., with transendoscopic balloon dilators or dilation systems employing guide wires).
- S. Management of achalasia (e.g., botulinum toxin, balloon dilation).
- T. Palliative treatment of stenosing neoplasms (e.g., laser, multipolar electrocoagulation, stent placement).

2. EGD is generally not indicated for evaluating:

- A. Symptoms which are considered functional in origin (there are exceptions in which an endoscopic examination may be done once to rule out organic disease, especially if symptoms are unresponsive to therapy).
- B. Metastatic adenocarcinoma of unknown primary site when the results will not alter management.
- C. X-ray findings of:
 1. Asymptomatic or uncomplicated sliding hiatal hernia.
 2. Uncomplicated duodenal ulcer which has responded to therapy.
 3. Deformed duodenal bulb when symptoms are absent or respond adequately to ulcer therapy.

3. Sequential or periodic EGD may be indicated:

- A. In patients requiring periodic surveillance of proven Barrett's esophagus or familial adenomatous polyposis.
- B. For follow-up of selected esophageal, gastric, or stomal ulcers to demonstrate healing.
- C. In patients with prior adenomatous gastric or duodenal polyps.
- D. For follow-up of prior sclerotherapy or banding of esophageal varices.

4. Sequential or periodic EGD is generally not indicated for:

- A. Surveillance for malignancy in patients with gastric atrophy, pernicious anemia, or prior gastric operations for benign disease.
- B. Surveillance of healed benign disease such as esophagitis, gastric or duodenal ulcer.
- C. Surveillance during repeated dilations of benign strictures unless there is a change in status.

5. Colonoscopy is generally indicated in the following circumstances

- A. Evaluation of an abnormality on barium enema which is likely to be clinically significant, such as a filling defect or stricture.
- B. Evaluation of unexplained gastrointestinal bleeding.
 1. Hematochezia in absence of convincing anorectal source.
 2. Melena after an upper GI source has been excluded.
 3. Presence of fecal occult blood
- C. Unexplained iron deficiency anemia.
- D. Surveillance for colonic neoplasia
 1. Examination to evaluate the entire colon for synchronous cancer or neoplastic polyps in a patient with treatable cancer or neoplastic polyp.
 2. Clearing colonoscopy at or around time of curative resection of cancer followed by colonoscopy at three years and 3-5 years thereafter to detect metachronous cancer.
 3. Following adequate clearance of neoplastic polyp(s) survey at 3-5 year intervals.
 4. Patients with significant family history.
 - a. Hereditary non polyposis colorectal cancer: colonoscopy every two years beginning at the earlier of age 25, or five years younger than the earliest age of diagnosis of colorectal cancer. Annual colonoscopy should begin at age 40.
 - b. Sporadic colorectal cancer before the age of 60: colonoscopy every five years beginning at age 10 years earlier than the affected relative or every three years if adenoma is found.
 5. In patients with ulcerative pancolitis eight or more years "duration or left sided colitis 15 or more years" duration every 1-2 years with systematic biopsies to detect dysplasia.
- E. Chronic inflammatory bowel disease of the colon if more precise diagnosis or determination of the extent of activity of disease will influence immediate management.
- F. Clinically significant diarrhea of unexplained origin.
- G. Intraoperative identification of a lesion not apparent at surgery (e.g., polypectomy site, location of a bleeding site).
- H. Treatment of bleeding from such lesions as vascular malformation, ulceration, neoplasia, and polypectomy site (e.g., electrocoagulation, heater probe, laser or injection therapy).
- I. Foreign body removal.
- J. Excision of colonic polyp.
- K. Decompression of acute nontoxic megacolon or sigmoid volvulus.
- L. Balloon dilation of stenotic lesions (e.g., anastomotic strictures).

- M. Palliative treatment of stenosing or bleeding neoplasms(e.g., laser, electrocoagulation, stenting).
- N. Marking a neoplasm for localization.

6. Colonoscopy is generally not indicated in the following circumstances:

- A. Chronic, stable, irritable bowel syndrome or chronic abdominal pain; there are unusual exceptions in which colonoscopy may be done once to rule out disease, especially if symptoms are unresponsive to therapy.
- B. Acute diarrhea.
- C. Metastatic adenocarcinoma of unknown primary site in the absence of colonic signs or symptoms when it will not influence management.
- D. Routine follow-up of inflammatory bowel disease (except for cancer surveillance in chronic ulcerative colitis).
- E. Upper GI bleeding or melon with a demonstrated upper GI source.

7. Colonoscopy is generally contraindicated in:

- A. Contraindications listed under General Indications statements
- B. Culminant colitis.
- C. Documented acute diverticulitis.

8. Endoscopic Retrograde Cholangiopancreatography (ERCP) is generally indicated in:

- A. The jaundiced patient suspected of having biliary obstruction (if therapeutic ERCP maneuvers can be performed during the procedure).
- B. The patient without jaundice whose clinical and biochemical or imaging data suggests pancreatic or biliary tract disease.
- C. Evaluation of signs or symptoms suggesting pancreatic malignancy when results of direct imaging (e.g., US, CT or MRI) are equivocal or normal.
- D. Evaluation of pancreatitis of unknown etiology.
- E. Preoperative evaluation of the patient with chronic pancreatitis and/or pseudocyst.
- F. Evaluation of the sphincter of Oddi by manometry.
- G. Endoscopic Sphincterotomy

1. Choledocholithiasis
2. Papillary stenosis or sphincter of Oddi dysfunction causing significant disability
3. To facilitate placement of biliary stent or balloon dilatation of biliary stricture
4. Sump syndrome
5. Choledochocele involving the major papilla
6. Ampullary carcinoma in patients who are not candidates for surgery
7. Facilitate access to the pancreatic duct

- H. Stent placement across benign or malignant strictures, fistulae, postoperative bile leak or in high risk patients with large irremovable common duct stones.
- I. Balloon dilation of ductal strictures.
- J. Nasobiliary drain placement for prevention of or treatment of acute cholangitis or infusion of chemical agents for common duct stone dissolution, for decompression of an obstructed common bile duct or postoperative bile leak.
- K. Pseudocyst drainage in appropriate cases.
- L. Tissue sampling from pancreatic or bile ducts.
- M. Therapy of disorders of the pancreatic duct.

9. ERCP is generally not indicated in:

- A. Evaluation of abdominal pain of obscure origin in the absence of objective findings which suggest biliary or pancreatic disease.
- B. Evaluation of suspected gallbladder disease with out evidence of bile duct disease.
- C. As further evaluation of proven pancreatic malignancy unless management will be altered.

10. ERCP is generally contraindicated for:

- A. Contraindications listed in General Indications statements.

11. Flexible sigmoidoscopy (FS) is generally indicated for:

- A. Screening of asymptomatic patients at risk for colon neoplasia.
- B. Evaluation of suspected distal colonic disease when there is no indication for colonoscopy.
- C. Evaluation of the colon in conjunction with barium enema.
- D. Evaluation for anastomotic recurrence in rectosigmoid carcinoma.
- E. Patients with a family history of familial adenomatous polyposis

- 1. Annually from age 10-12 years with colectomy when polyps develop
- 2. Annually to age 40 years if no polyps found then every 3-5 years there after.

12. FS is generally not indicated:

- A. When colonoscopy is indicated.

13. FS is generally contraindicated for:

- A. Contraindications listed in General Indications statements.
- B. Documented acute diverticulitis.

14. Therapeutic FS may be indicated for:

- A. All colonoscopic procedures under special circumstances, (e.g. polypectomy in patient with subtotal colectomy, laser photo-coagulation of a rectal carcinoma). However, colonoscopy and not FS is generally indicated for therapeutic colonic procedures (e.g. polypectomy).

15. Enteroscopy is generally indicated for:

- A. Evaluation of the source of gastrointestinal bleeding not identified by EGD or colonoscopy.
- B. Evaluation of an abnormal radiographic imaging study of the small bowel.
- C. Localization of known or suspected small bowel lesions.
- D. Therapy of small bowel lesions beyond the reach of a standard endoscope.

E. Tissue sampling from the small bowel.

16. Enteroscopy is generally not indicated:

- A. When the source of gastrointestinal bleeding has been identified by EGD or colonoscopy.
- B. When the findings of the procedure will not alter therapy.

17. Enteroscopy is generally contraindicated:

- A. Contraindications listed in General Indications statements.

18. Endoscopic ultrasound is generally indicated for:

- A. Staging tumors of the gastrointestinal tract, pancreas and bile ducts.
- B. Evaluating abnormalities of the gastrointestinal tract wall or adjacent structures.
- C. Tissue sampling of lesions within, or adjacent to, the wall of the gastrointestinal tract.
- D. Evaluation of abnormalities of the pancreas, including masses, pseudocysts and chronic pancreatitis.
- E. Evaluation of abnormalities of the biliary tree
- F. Providing endoscopic therapy under ultrasonographic guidance.

19. Endoscopic ultrasound is generally not indicated:

- A. When the results will not alter patient care
- B. Staging of tumors shown to be metastatic by other imaging methods (unless the results are the basis for therapeutic decisions)

20. Endoscopic ultrasound is generally contraindicated:

- A. Contraindications listed in General Indications statements.

21. Laparoscopy is generally indicated for:

- A. Evaluation of focal liver disease (benign and malignant) particularly when image directed biopsies are non diagnostic
- B. Staging of intra-abdominal malignancies (e.g., liver, pancreas, stomach, esophagus)
- C. Suspected intra-abdominal malignancy (e.g., hepatic/peritoneal metastasis) when imaging studies are negative
- D. Suspected cirrhosis with non-diagnostic percutaneous biopsy
- E. Cirrhosis when blind percutaneous biopsy may be hazardous (e.g., small shrunken liver, marked as cists, overlying intestinal loops, coagulopathy)
- F. Ascites of unknown cause
- G. Disorders of the peritoneum (e.g., mesothelioma, metastatic disease, tuberculous peritonitis)

22. Laparoscopy is generally not indicated:

- A. When direct percutaneous or image directed biopsies are diagnostic
- B. When open surgery is indicated despite the results of laparoscopy

23. Laparoscopy is contraindicated in:

- A. Abdominal wall infections
- B. Acute, cardio-pulmonary disease
- C. History of generalized peritonitis or perforated viscus resulting in extensive adhesions

- D. Intestinal obstruction
- E. Severe coagulopathy

The Committee on Training of the American Society for Gastrointestinal Endoscopy prepared the text of this statement. It was reviewed and concurred in by the Patient Care Committee of the American Gastroenterological Association and by other physicians and surgeons with expertise in gastroenterology. Additionally, it has been approved by the Governing Boards of the American Society for Gastrointestinal Endoscopy, the American Gastroenterological Association and the American College of Gastroenterology.

Statement on Role of Short Courses in Endoscopic Training

This statement concerns the role that short courses play in the training of physicians and other professionals who perform gastrointestinal endoscopic procedures. The statement also deals with certain problems that hospital committees may face in setting guidelines for the granting of privileges to perform gastrointestinal endoscopy by their staff physicians. For purposes of this statement, a short course is defined as an organized teaching program lasting less than several weeks, and often only a few days.

Issues of what constitutes appropriate endoscopic training, practice and utilization have been addressed by this Society in great detail. The American Society for Gastrointestinal Endoscopy, through its Standards of Practice Committee, Committee on Training, and Governing Board, has developed Standards of Practice of Gastrointestinal Endoscopy¹ and a Statement on Endoscopic Training.² These documents have been approved by the Governing Boards of other Digestive Disease organizations and represent a consensus of a broad-based group of gastroenterologists, surgeons and other specialists. The requirements for training in gastrointestinal endoscopy are described in these publications, and entail either residency-fellowship training or equivalent endoscopic training. If experience is acquired outside a formal training program, it must be equivalent to that obtained within such a program. Competence must be documented and skills demonstrated. These principles, which have been accepted by organizations representing both medical and surgical specialties, have been very useful to hospital committees who are responsible for defining criteria for and granting of endoscopic privileges.³

The rapid development of endoscopic instruments and their widespread distribution to physicians who have not received formal supervised endoscopic training has been associated with a proliferation of short courses on gastrointestinal endoscopy. Such courses usually lack supervised "hands on" training experience with patients; rather, they are limited to didactic instruction and the use of artificial models. Attendees of such courses are sometimes granted certificates of attendance and these, with or without supporting letters, are used inappropriately by those applying for endoscopic privileges as sufficient evidence of competence to perform endoscopy. Those physicians whose training in gastrointestinal endoscopy has been acquired largely or entirely through courses of this type pose a particularly difficult problem for hospital staff committees concerned with the granting of privileges to perform endoscopy.

Although endoscopic short courses have been utilized as a primary learning modality, it is the consensus of the American Society for Gastrointestinal Endoscopy that these courses, by themselves, do not provide adequate training in standard endoscopic procedures such as esophagogastroduodenoscopy, colonoscopy, endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasound (EUS), endoscopic laser therapy, endoscopic photodynamic therapy, or laparoscopy. Such courses do not allow the attendee to gain experience, interpretive

as well as technical, equivalent to that in a residency-fellowship program and do not, therefore, fulfill accepted requirements for training. There is no rationale for partially trained physicians. The granting of hospital privileges to physicians whose training does not meet established requirements is no longer tenable³ and may lead to poor patient care. It may also raise potential liability issues for medical staffs and hospital boards.

Short courses do have an appropriate place in endoscopic training. When properly designed, they can serve to augment the trained endoscopist's technical and clinical skills in studies with which he or she is already experienced. They may also, in the proper setting, introduce new techniques to the physician who already has a background of basic endoscopic skills and experience. Finally, the introduction of flexible sigmoidoscopy to the non-endoscopist may be facilitated by a short course format, but cannot assure competence in that procedure.⁴

The purpose of previously published guidelines^{1, 2} and of this statement is to assure that the patient is receiving appropriate, safe and competent care. In order to provide such assurance, the training and experience of the physician-endoscopist must be documented and his or her skills demonstrated. Privileges should not be granted solely on the basis of training in short courses.

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Alternative Pathways to Training in Gastrointestinal Endoscopy

Physicians who have not received conventional formal training in gastrointestinal endoscopy may wish to acquire privileges to perform endoscopy. The conventional route for acquiring skills in endoscopy is via a two or three year gastroenterology fellowship or five to six year surgery residency. The following recommendations have been developed by the ASGE Committee on Training for individuals who have not completed one of the conventional routes for acquiring endoscopic skills and who wish to acquire competency adequate to obtain endoscopic privileges. These guidelines are intended to ensure the quality, cost-effectiveness and safety of patient care, and to help protect health care providers from legal liability resulting from granting privileges to inadequately trained physicians who wish to perform endoscopy. These guidelines are based on the principle that universal standards of endoscopic training should apply to all physicians regardless of their specialty background or training.

Competency in performing endoscopic procedures requires competency in the technical, interpretive and cognitive aspects of endoscopy, and the capability to integrate endoscopic findings into clinical practice. The six principles of endoscopic training, as previously outlined by ASGE(1), include understanding of indications, expeditious performance of procedures, correct interpretation of findings, integration of these findings into therapeutic management plans, avoidance and management of complications, and recognition of personal limitations in performing endoscopic procedures. The training period should be long enough to allow substantial experience in endoscopy but not so prolonged that newly acquired skills are lost. Training should be comprehensive and provide a working knowledge of the pathophysiology, diagnosis, and management of digestive diseases for which endoscopic procedures are indicated.

Guidelines for formal training in endoscopy established by the ASGE include performance under supervision of at least 100 upper endoscopies or colonoscopies to acquire competency in either procedure. These recommended numbers are twice those proposed by the American College of Physicians (50 each)(2,3). The following available data support the more conservative guidelines of the ASGE: 1) Formally trained and experienced colonoscopists consistently achieve a cecal intubation rate of over 95% (4,5); 2) after 100 supervised colonoscopies, the cecal intubation rate of trainees is only 84%, and learning curves are similar regardless of subspecialty background training(6); and 3) family physicians with limited training report cecal intubation rates varying from 54% to 83%(7,8). For upper endoscopy, experienced endoscopists approach 100% success with esophageal and pyloric intubation (6), whereas family practitioners report that the pylorus be traversed in 93% of cases (9).

Performance of an arbitrary number of procedures does not guarantee competency. Training in endoscopy must include recognition of lesions and proper interpretation of findings, understanding of gastrointestinal disease pathophysiology, and development of appropriate clinical management strategies. Endoscopists performing diagnostic procedures such as colonoscopies must be capable of performing appropriate therapeutics such as polypectomy at the same setting. Short (two or three day) courses or self-instruction in endoscopy without additional supervised experience do not provide adequate training in these or other aspects of endoscopy.

Inadequate endoscopic examinations may result not only from failure to insert the endoscope completely, but also from failure to recognize pathology, formulation of inappropriate management strategies, or failure to accomplish necessary therapeutic interventions such as polypectomy at the time of the diagnostic study. The implications of such examinations include missed diagnoses, the need for endoscopy to be repeated, or the need for alternative procedures such as barium enema. Such outcomes are neither desirable nor cost-effective.

It is recommended that physicians desiring training in endoscopic procedures other than flexible sigmoidoscopy, regardless of specialty, receive formal, supervised, "hands on" training in endoscopy. This may take the form of a preceptorship, sabbatical, or education in a practice setting by a qualified endoscopic instructor. This type of formal training is most readily available in a timely fashion in gastroenterology fellowships or surgical residencies (11). Training in endoscopy must occur in the context of cognitive education in lesion recognition and gastrointestinal disease pathophysiology. Endoscopic training should conform with ASGE guidelines (1), and should include performance under supervision of the minimal numbers of procedures currently recommended by the ASGE, including 100 diagnostic upper endoscopies and 100 total colonoscopies. Proficiency in one procedure (such as flexible sigmoidoscopy or upper endoscopy) does not imply proficiency in another (such as colonoscopy), because of differences in anatomy, pathology, and technique. Training in colonoscopy must include polypectomy. Additionally, endoscopists must receive training in the techniques of conscious sedation. Competency in performing elective procedures does not imply competency in performing emergency therapeutic procedures.

As espoused previously by the ASGE (12), it is recommended that health care facilities grant endoscopic privileges only to physicians who have training and experience that meet the recommended criteria. Prior to being granted privileges, an endoscopist should demonstrate competency by undergoing proctoring by an impartial qualified endoscopist. It is also suggested that prior to undergoing endoscopic procedures, patients have access to information regarding the level of training of the endoscopist.

These guidelines for training are based on the available data in the literature that pertain to the attainment of competency in endoscopy. Organizations that disagree with these recommendations should provide objective data to support their positions. Assurance of adequate training has implications with respect to both quality and legal liability.

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Guidelines for Training in Patient Monitoring and Sedation and Analgesia

Introduction

The ability to provide sedation and analgesia safely and effectively and to ensure patients clinical stability by appropriate monitoring during gastrointestinal endoscopy are skills that endoscopic trainees must develop. In the past decade, the introduction of new medications and the widespread dissemination of a variety of automated monitoring devices has transformed the practice of endoscopy. Although both upper endoscopy 8 and colonoscopy 9 may successfully be performed in the absence of systemic medication, randomized prospective trials involving gastroscopy 10 suggest that sedation enhances patient tolerance of endoscopic examination. Similar data regarding colonoscopy is not yet available.

At present, the vast majority of patients undergoing gastrointestinal endoscopy in the United States receive intravenous medication, usually a combination of a narcotic and benzodiazepine, with a very low reported incidence of sedation-induced complications 11. Despite an excellent overall safety record, cardiopulmonary complications, likely due in large part to sedative and analgesic medications, are believed to account for 50% and 60% of procedure-related morbidity and mortality, respectively 12. Appropriate training in these skills is thus essential to the provision of patient safety and comfort before, during and after each endoscopic examination. This statement defines the cognitive and procedural skills that must be conveyed to the trainee and the optimal setting and methods for conducting such training.

Contents of Training

The goal of training in patient monitoring and sedation techniques is to enable the trainee to provide maximal patient safety and comfort uniformly during each type of endoscopic procedure, and to optimize concurrently the diagnostic and therapeutic success of the procedure. To achieve this, the trainee must achieve mastery of a broad variety of information. The curriculum of the training program should incorporate the following critical concepts and practices.

1. Trainees must be able to provide the patient with adequate pre-procedure education regarding the sedation/analgesia aspects of the examination.
2. The trainee endoscopist must obtain appropriate patient information in the pre-procedure clinical assessment (history and physical). It should be stressed that this initial evaluation may identify cases, such as uncooperative patients or patients with instability due to co-morbid conditions, where the use of general anesthesia as an alternative to conscious sedation and analgesia constitutes the safest and most prudent approach.
3. The trainee must be instructed in the precise definitions of the various levels of sedation, such that the trainee understands both the physiologic characteristics and the clinical and medico-legal implications of conscious (light) sedation, deep sedation, and general anesthesia.

4. The trainee must develop a thorough understanding of the pharmacology of all drugs used for sedation/analgesia, including mechanisms of action, appropriate dosing intervals, the potential for drug-drug interactions¹³, the effects of patient co-morbidity and patient age¹⁴ on the process of sedation, and the rational usage of reversal agents. The advantages and disadvantages of topical pharyngeal anesthesia and the use of careful incremental drug dosing, titrated to achieve specific clinical end-points, should be taught.
5. Endoscopists in training must understand basic cardiopulmonary physiology and pharyngeal anatomy and be able to establish and maintain an adequate airway.
6. Trainees must comprehend the essential role of the well-trained gastrointestinal nurse or assistant in providing optimal patient monitoring and must be aware of the circumstances in which additional personnel are required, such as ERCP and complex therapeutic interventions, so that one assistant may remain primarily focused on monitoring the patient.
7. Clinical parameters to be monitored during the procedure and appropriate standards of intra-procedure documentation must be understood. The trainee, who initially will be focused on mastering the technical basics of endoscopy, must appreciate that, although the assistant plays an essential role, ultimate responsibility for all aspects of the monitoring process rests with the endoscopist.
8. The trainee must learn a rational approach to the provision of supplemental oxygen during endoscopic procedures¹².
9. The appropriate role of automated monitoring devices should be conveyed, including routine pulse oximetry and selective employment of continuous electrocardiographic and blood pressure monitoring. It is essential that trainees appreciate that the use of pulse oximetry and other monitoring devices do not replace direct clinical assessment and observation of ventilatory function, in particular given the potential for severe hypoventilation and hypercapnia in patients on pulse oximetry receiving supplemental oxygen¹⁵.
10. The trainee should understand the significant risk of post-procedure complications of sedation and analgesia and learn appropriate standards of post-procedure monitoring and pre-discharge assessment.
11. The trainee should be familiar with antagonistic agents of those sedative and analgesic drugs in common use, including their pharmacology, duration of action, and indications. The trainee should also be knowledgeable about the necessity for monitoring of patients following use of these antagonists to detect spontaneous re-sedation and unexpected respiratory depression.
12. Trainees in pediatric gastrointestinal endoscopy will often require special training and experience in sedation and monitoring techniques beyond that needed for endoscopy in adults, due in part to highly unpredictable drug metabolism in children and a much greater reliance on deep sedation and general anesthesia¹⁷. The curriculum for trainees in this field

should additionally reflect established guidelines 18 pertaining to the monitoring of children during procedures.

Methods and Setting of Training

Training in patient monitoring and the administration of sedatives and analgesics should occur within the context of a global training program in gastrointestinal endoscopy, which in turn should be conducted at accredited residency training programs within the disciplines of gastrointestinal medicine, pediatric gastroenterology, or surgery. Much of the training process occurs within the endoscopy suite, with trainees learning appropriate sedation and monitoring practices while performing endoscopic procedures under the close supervision of an expert endoscopy instructor. Simultaneously, trainees learn through practice the technical and cognitive aspects of endoscopy. Clinical training must be complemented by a comprehensive didactic review of pharmacology, cardiopulmonary physiology, principles of anesthesiology and other relevant areas. This must be achieved through a combination of supervised independent study, lectures, and topic reviews at academic conferences. A periodic morbidity and mortality conference or some other forum to review complications also is essential. Each endoscopy instructor should be an accomplished endoscopist with well-established clinical skills and a thorough mastery of all aspects of current practice in sedation/analgesia and patient monitoring. Ultimate responsibility for the training program lies with the Training Program Director. Training in patient monitoring and sedation outside of such traditional residency pathways is theoretically possible but in most cases impractical. Weekend or "short" courses may provide useful information and serve as valuable refreshers, but are inadequate as the sole source of training.

Assessment of Skills

Objective data quantifying the experience needed to achieve competence in gastrointestinal endoscopy are sparse 19-20, and no studies specifically address trainees' acquisition of skills in sedation and patient monitoring. In this setting, as with other aspects of endoscopic training, the determination of each trainee's competence in these areas rests on the subjective, expert assessment of the endoscopy instructor and the Training Program Director. Maintenance of ongoing competence remains the responsibility of hospital credentialing bodies.

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The Committee on Training of the American Society for Gastrointestinal Endoscopy prepared the text. It has been approved by Governing Boards of the American Society for Gastrointestinal Endoscopy, the American Gastroenterological Association and the American College of Gastroenterology. This document is intended to establish guidelines for appropriate training of endoscopists in the techniques of patient monitoring and the administration of sedative and analgesic medications for gastrointestinal endoscopy. Such training, which focuses on the role of the endoscopist as not only clinician and proceduralist but also anesthetist, is invariably delivered as a component of a global training program in gastrointestinal endoscopy. The foundation for these training guidelines is derived in part from previous ASGE statements on principles of training in gastrointestinal endoscopy (1) and practice guidelines for patient

sedation and monitoring (2), as well as from published practice guidelines for sedation and analgesia by non-anesthesiologists (3) endorsed by the ASGE. The principles conveyed in this document complement previous efforts made in other health care disciplines (4-7) to establish standards for training in patient sedation and monitoring.

The following is a legal opinion regarding the responsibilities of those granting privileges to perform gastrointestinal endoscopy, commissioned by the American College of Gastroenterology. It should be noted that the American Society for Gastrointestinal Endoscopy has not indicated Board Certification as part of its requirements to perform gastrointestinal endoscopy.

Hospital Liability Update

from the American College of Gastroenterology¹

Developments in the law indicate that hospitals continue to have a growing legal duty to exercise due care in granting privileges to physicians, and they expose themselves to liability for granting specialized privileges (including the privilege to perform endoscopic procedures) to physicians/surgeons who are poorly trained, inexperienced with specific procedures, or insufficiently knowledgeable about the relevant disease areas.

This memorandum examines the standard of care with which hospitals must comply; it considers how that standard should be applied in the particular situation of granting privileges to perform endoscopic procedures; and it concludes that, to protect themselves from liability, hospitals should grant endoscopic privileges only to either board-certified gastroenterologists or physician/surgeons with knowledge, training, and experience in gastroenterology or gastrointestinal surgery that is commensurate and comparable to that required to secure board certification.

¹ This Update was prepared with the assistance of Williams & Connolly LLP, a law firm in Washington, D.C. The Update presents an overview of legal developments, and the law of any given jurisdiction should be thoroughly researched in order to assess the liability risks from specific facts in that jurisdiction.

“Negligent Credentialing” and “Corporate Negligence”

In the landmark case of *Darling v. Charlestown Community Memorial Hospital*, 33 Ill.2d 326, 211 N.E.2d 253 (1965), *cert. denied*, 383 U.S. 946 (1966), the Illinois Supreme Court upheld a lower court ruling that a hospital owes an independent duty directly to its patients to exercise reasonable care in granting surgical privileges to and monitoring the competence of its physicians. Thereafter, many courts across the United States decided that hospitals are subject to liability for “negligent credentialing” and, more generally, for theories of “corporate negligence.” The theory of corporate negligence is applied directly against hospitals for failure to use sufficient care generally in the selection, retention, and supervision of medical staff; negligent credentialing arises where hospitals extend privileges to a physician to perform procedures for which he or she is not adequately qualified.

Roberts v. Stevens Clinical Hospital, 345 S.E.2d 791 (W.Va. 1986), for example, involved a suit by parents of a deceased child against a doctor who had negligently performed a sigmoidoscopy on the boy and had perforated his colon, and also against the hospital for, among other things, granting full surgical privileges to the physician. In upholding the jury verdict against the hospital, the court stated that there was sufficient evidence of negligence by the hospital. Specifically, the court noted evidence that the hospital had failed to comply with state regulations and JCAHO standards. Furthermore, the court stated that there was evidence that “the hospital was negligent in granting [the doctor] full surgical privileges in light of the fact that before coming to [the hospital] he had been primarily a family practitioner and has never previously been granted full surgical privileges.” *Id.* at 798.

Such theories are being deployed with increasing frequency against hospitals and other medical institutions in a majority of American jurisdictions.

Research discloses that tort liability for improper credentialing and corporate negligence generally has been affirmatively recognized in at least thirty jurisdictions, including: Alabama, Arizona, California, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Kentucky, Michigan, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, Tennessee, Texas, Washington, West Virginia, Wisconsin, and Wyoming.²

Applicable Standards

Regarding the degree of care that a hospital must exercise in credentialing, courts now mandate that it must use as much care as do other similarly situated hospitals. Because many hospitals are now accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), a nation-wide organization, courts often consider all accredited hospitals to be “similarly situated,” and JCAHO standards become highly relevant.

JCAHO annually publishes a manual that contains numerous guidelines addressing many hospital functions, and it sets minimum standards for, among other things, the delineation of clinical privileges:

² Two other States—Oregon and Vermont—have left open the possibility of adopting negligent credentialing causes of action, by remarking on a hospital’s legal responsibility for the competence of the physicians to whom they extend privileges, but they do not appear to have directly ruled on the question. See *Wheeler v. Central Vermont Med. Ctr.*, 582 A.2d 165 (Vt. 1989)(citing with approval *Darling v. Charleston Community Mem. Hosp.* 211 N.E.2d 253 (Ill. 1965), and *Johnson v. Misericordia Community Hosp.* 301 N.W.2d 156 (Wis. 1981)); *Huffaker v. Bailey*, 540 P.2d 1398, 1402 (Ore. 1975)(also citing with approval *Darling, supra*). The Oregon court noted “the possibility of independent tort liability being imposed upon [hospitals] for the actions of doctors practicing therein, including liability for mere selection and admission of physicians whose subsequent negligence injures a hospital’s patients.” 540 P.2d at 1402.

MS.5.15.2. *Board certification is an excellent benchmark and is considered when delineating clinical privileges.*

JCAHO, *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*, 2000 ed. (“*JCAHO Manual*”), at MS-11 (emphasis in original).

Of course, hospitals often cannot grant privileges only to physicians who are board certified in a particular subspecialty. *See Thomas v. Solon*, 121 A.D.2d 165, 502 N.Y.S.2d 475, 476 (1st Dep’t 1986) (simply because a physician was not board certified in a particular subspecialty did not establish that he was unqualified to practice in that field; state law prohibited hospitals from granting privileges only to board-certified physicians). JCAHO guidelines do make provision for this situation when they speak of “privilege delineation . . . based primarily on experience.” On the other hand, there is a good argument that the JCAHO guidelines place less emphasis on “experience” (as opposed to certification) as the primary basis for granting privileges, and as the only basis when privileges come up for renewal.³ Instead, the JCAHO seems to be moving toward board certification as the preferred minimum requirement—but not the sole criterion—when granting privileges to practice within a subspecialty. Thus, hospitals would seem best insulated from liability if they granted staff privileges in subspecialties only to either board-certified physicians/surgeons or physicians/surgeons with such knowledge, training, and experience in the

³ See MS 5.15.3 and “Intent of MS.5.15 through MS.5.15.3,” in the *JCAHO Manual*, at MS-44: “Granting, renewal, or revision of privileges is *also* based on the individual’s current competence. For renewal or revision of privileges this may be determined, *in part*, by a review of the relevant results of medical staff performance improvement activities. Specific instances of treatment outcomes and the results of other assessment and improvement activities may *also* be included.” (Emphasis added.) Compare “Intent of MS.5.4 through MS.5.4.3,” *JCAHO Manual*, at MS-34 (competence “cannot be determined on the basis of board certification or admissibility *alone*”)(emphasis added).

subspecialty that is commensurate and comparable to those who are board certified.

The American Board of Internal Medicine (ABIM) is alone responsible for deciding which candidates are eligible for admission to the examination for certification in gastroenterology. The requirements to sit for the exam include:

- (a) prior certification in Internal Medicine;
- (b) substantiation of a minimum of three years of training in an accredited program; and
- (c) evaluation and substantiation of the candidate's clinical competence and moral and ethical behavior by the subspecialty program director and internal medicine department chairman.

During the residency period, clinical competence includes the following categories: (1) clinical judgment, (2) medical knowledge, (3) clinical skills, (4) humanistic qualities, (5) professional attitudes and behavior, (6) medical care, (7) commitment to scholarship, and (8) moral and ethical behavior. *See ABIM Memoranda: "Attending Physicians" & "Residents"; ABIM "Policies and Procedures 2000"* (all available at www.abim.org). Thus, candidates for board certification in gastroenterology must demonstrate: (1) superior and current medical knowledge of the relevant disease areas, (2) refined diagnostic and procedural skills, and (3) high moral, ethical, and professional standards. *See ABIM Memorandum: "Information Regarding the Examinations"* (available at www.abim.org).

The ABIM has stated that superior and current medical knowledge includes: knowledge of common and uncommon gastroenterologic disease including cancer of the digestive system; the natural history of digestive diseases in adults and children; factors involved in managing nutritional problems; surgical

procedures employed in relation to digestive system disorders; and judicious use of special instruments and tests in the diagnosis and management of gastroenterologic disorders. It now also requires specialized skill in “[p]roctology and/or flexible sigmoidoscopy.” *“Policies and Procedures 2000,” supra.*

The foregoing establishes that certification in the subspecialty of gastroenterology requires (1) *broad cognitive expertise with respect to the diagnosis and treatment of gastrointestinal conditions, and (2) a substantial amount of training and practical experience in a number of complex procedures, including endoscopy.* Perhaps more importantly, the stringent requirements for board certification in gastroenterology – which are outlined in the ABIM publications cited above – would likely be admissible in court on the question what is the standard of care in granting privileges to gastroenterologists.

The American Board of Surgery (“ABS”), which regulates the requirements for board certification in general surgery and its recognized subspecialties, also maintains requirements that are similar to those of the ABIM in the cognitive and procedural aspects of endoscopy. To be eligible for board-certification in general surgery, a candidate must acquire a significant level of knowledge of procedures in the “nine components of Surgery,” of which two are the “alimentary tract” and the “abdomen and its contents.” American Board of Surgery, *Booklet of Information, July 2000- June 2001*, at 10. Furthermore, the ABS clearly mandates that a candidate “must be capable of employing endoscopic techniques,” including, specifically, protosigmoidoscopy, colonoscopy, and esophagogastroduodenoscopy, in order to qualify for certification. *Id.* at 11.

Undoubtedly, there are individuals whose training and experience match or exceed the board certification requirements, but who, for a variety of reasons, have not obtained this qualification. Physicians who train in Internal Medicine outside the United States but subsequently complete a Gastroenterology

Fellowship here, for example, are not allowed to sit for the ABIM Subspecialty Board Examination; these physicians are “board eligible,” but under the present ABIM rules will never be “board certified.” Many excellent foreign medical graduates of US GI Fellowship training programs request and receive privileges to perform endoscopy. In granting such privileges, however, hospitals should recognize that, in the absence of the “objective badge” of board certification, the likelihood increases of being called upon to explain and justify why they deemed that candidate’s qualifications to be comparable and commensurate to those of the physician who holds board certification.

The American Society for Gastrointestinal Endoscopy (ASGE) recommends that competence in gastrointestinal endoscopy can be established by completion of a residency-fellowship training program, or by other “comprehensive training in endoscopy [which] should comply with published guidelines.” ASGE, *Statement: Appropriate Use of Gastrointestinal Endoscopy*, 52 *Gastrointestinal Endoscopy* 831, 832 (2000). The ASGE furthermore recognizes that competence in one particular endoscopic procedure does not indicate that a physician is proficient in other such procedures. *Id.* at 832. Finally, in several publications, the ASGE has criticized the use of short endoscopy courses which “usually lack supervised ‘hands on’ training experience with patients.” ASGE, *Statement on Role of Short Courses in Endoscopic Training*, 50 *Gastrointestinal Endoscopy* 913 (1999). In a lawsuit about granting privileges, the ASGE’s publications, or expert opinion based upon them, probably would be admissible on the standard of care question.

Do Minimum Standards Protect Hospitals where the Physician/Surgeon Is Not Board-Certified?

In some jurisdictions, the scope of legally sustainable pro-patient verdicts in negligent credentialing cases seems to have become so broad that simple reliance on JCAHO guidelines may not be enough, particularly if injury occurs at the hands of a physician/surgeon who is not board-certified. Consider, for example, the North Carolina case of *Carter v. Hucks-Folliss*, 505 S.E.2d 177 (N.C. App.), *rev. denied*, 526 S.E.2d 173 (N.C. 1998). There, a hospital had allowed a surgeon not certified by the American Board of Neurological Surgery to perform neurosurgery, and injury occurred. Summary judgment in favor of the hospital in the trial court was reversed. The appeals court held that the jury could decide – and the hospital could well be found liable on – a negligent credentialing claim, even though the hospital thought that it had met JCAHO requirements by noting (along with more positive factors) a doctor’s lack of board certification before it had extended privileges. The hospital had argued that this was sufficient to meet the JCAHO standard requiring that certification status be “considered.” But in the end it proved not to be enough, and the hospital lost the appeal. The *Carter* court held that a jury could well decide that the hospital had not properly “considered” the lack of certification by merely “noting” it along with the surgeon’s other experience. Hospitals clearly need to be prepared to justify their conclusions in terms of the non-board certified physician’s skills and training being commensurate and comparable to those of a board certified individual.

Thus, lack of board certification, and failure to articulate a rationale in terms of comparable and commensurate training/experience, can fatally flaw a hospital’s defense against negligent credentialing claims. An approach similar to that in *Carter* was used successfully in California, where a hospital settled for

\$200,000 with an injured former patient, after it emerged that a doctor continued to hold staff privileges after she had failed her OB/GYN board certification exam. *See “Doe Newborn v. Roe Doctor/Hospital”*, CRA No. 9830 (Los Angeles Cty 1998), Confidential Report for Attorneys, May 5, 1998 (available on Lexis). Similarly, in a case from Pennsylvania, a jury found a hospital 27.5 per cent liable for a \$22,400,000 total verdict, on a theory of negligent credentialing, even though it was apparent from post-verdict interviews that the jurors thought that the hospital actually had met national standards relating to the issuance of physicians’ credentials and privileges. *See Calli v. Episcopal Hosp.*, No. 97-08-0251 (Philadelphia Cty 2000), Medical Litigation Alert, Sept. 2000; *id.*, Nat’l Jury Verdict Rev. & Analysis, Oct. 13, 1999 & Mar. 1, 2000; *id.*, Penn. Jury Verdict Rev. & Analysis, Oct. 13, 1999 & Mar. 1, 2000.

Another quite recent development that should be noted is the extension of the corporate negligence theory (and, with it, negligent credentialing) to a variety of medical institutions, such as HMOs. The case law is scattered, but the trend of increasing liability risk seems not to have abated. *See, e.g., Jones v. Chicago HMO Ltd*, 730 N.E.2d 1119 (Ill. 2000); *see generally* Michel, *Credentialing Liability in the Managed Care Arena*, 35-1 Tort & Liability Ins. L.J. 137 (1999).

Conclusion

The number of States in which there is a favorable basis for bringing negligent credentialing claims has risen to at least thirty. Only two jurisdictions have squarely rejected the cause of action.⁴ Moreover, in at least some States

⁴ A third State, Texas, has modified but clearly not eliminated it when its court made a legally controversial decision requiring that a plaintiff prove “malice.” There is little indication of any other State following Texas’s example.

where the legal theory is used, it is being applied more vigorously, with outcomes adverse to hospitals—even where JCAHO and other appropriate standards arguably had been met—in cases where physicians had failed to obtain board certification for the in-house procedures that they performed, and where hospitals have not sufficiently addressed and documented a rationale for the absence of boards. Finally, the trend is for corporate negligence theories to be applied not only against hospitals but also against other medical institutions, like HMOs and managed care programs.

In sum, negligent credentialing claims are very much alive, and growing. The prudent hospital administration should assess this threat when reviewing their policies for credentialing. Hospitals can be held liable for breaching their duty to vet thoroughly physicians applying for clinical privileges. If privileges are granted to an unqualified physician, and the hospital should have known that the physician was not competent to perform the particular procedure, then it may be held to have breached its legal duty. Courts may admit, on the issue of negligence, evidence of compliance with JCAHO standards, applicable state regulations, and hospital by-laws.

As minimum standards, these guidelines provide prophylaxis, but not immunity, against negligent credentialing claims. Although privileges cannot be granted solely on board certification, hospitals will find themselves with the strongest objective documentation in cases where they have granted privileges for gastrointestinal endoscopy to board-certified physicians or surgeons, or where the hospital can document that medical staff members have attained both the cognitive expertise required to diagnose and treat gastrointestinal conditions, and experience in the specific procedures which is commensurate and comparable to the ABIM's prerequisites for board eligibility in gastroenterology, or to the ABS's prerequisites

for board eligibility gastrointestinal surgery, and which conforms to ASGE guidelines.

Examples of Endoscopy Credentialing Issues

The following is a set of examples designed to illustrate how credentialing guidelines may be used to address common issues in granting endoscopic privileges.

Case 1: The new gastroenterologist has a problem

Dr T is appointed to be the sole gastroenterologist for a small community hospital. She requests and is granted privileges to perform diagnostic and therapeutic EGD*, colonoscopy and ERCP** based on her self-reported training in these procedures at a respected academic center in the US Midwest. She submits a letter from a senior faculty member at that institution which states that “Dr T is a well-rounded gastroenterologist with solid endoscopic skills”. The necessary privileges to perform the requested procedures are granted without further discussion. Several months later the Chairman of the Credentialing Committee calls an Extraordinary Meeting to discuss concerns voiced to him regarding Dr T’s competence to perform ERCP. The Risk Management Officer for the hospital reports that in two months, out of 13 patients who underwent ERCP by Dr T, six suffered complications requiring hospitalization for more than 48 hours, four with pancreatitis (one severe), one with a retroperitoneal perforation after sphincterotomy, requiring surgery, and one with post-sphincterotomy hemorrhage requiring a total of 4 units’ blood transfusion. The Head Nurse of the Day Case Procedures Unit reports that Dr T’s ERCPs often last 2-3 hours or more, and that she (Dr T) frequently asks the nursing staff how equipment works and what they think she should do next. As a result, some of the nurses request not to be on duty when Dr T has an ERCP scheduled. Dr T is invited to respond to the Credentialing Committee’s concern that her complication rate for ERCP is excessive by accepted national standards. The Committee also requests more detailed information regarding Dr T’s endoscopic training. This is solicited – with Dr T’s written agreement – from the Endoscopic Training Director at the center where she did her GI Fellowship. The information provided is reviewed by the Credentialing Committee. Dr T’s original career “trajectory” as a fellow had been bench research, but after 6 months in the laboratory she switched to a clinical track with emphasis on nutrition. She received “basic training” in diagnostic EGD and colonoscopy, but was noted to have “consistent difficulty intubating the pylorus during EGD and reaching the cecum during colonoscopy”. Dr T observed “20-25” ERCPs during her third year of fellowship

but received no “hands on” training in this technique. The physician whose letter was accepted by the Committee as proof of Dr T’s training runs the Irritable Bowel Clinic; he does not perform endoscopy or teach fellows to perform endoscopic procedures. Dr T submitted a statement to the Credentialing Committee indicating that she had personally performed “more than 50” ERCPs without significant complications in her previous post. She asked the Committee to allow her to continue to perform ERCP in return for her agreement to limit her work to “diagnostic cases only”.

Comment: This is a difficult situation that could have been avoided: the competence of a physician who has already received privileges to perform diagnostic and therapeutic ERCP is being questioned by experienced endoscopy nurses who have worked with her. It is important to identify such deficiencies in training and/or practice quickly: a Quality Improvement (QI) program that tracks indicators of competence, such as duration of procedures and incidence of complications, is a valuable tool for those monitoring physician competence (see Quality Improvement of Gastrointestinal Endoscopy). In this case, the Head Nurse of the Endoscopy Unit voiced concern to the hospital’s Risk Manager, who appropriately brought the issue to the attention of the Credentialing Committee. Although complications are often unpredictable, a series of complications following prolonged procedures naturally raises a “red flag”. Expected complication rates for specific procedures are available in the published literature. Also, when questions arise about these, expert endoscopists at regional or national level can be consulted. The Credentialing Committee in this case failed to exercise due diligence in confirming that Dr T had the necessary training and experience to perform specific endoscopic procedures. The ASGE document “Methods of Granting Hospital Privileges to Perform Gastrointestinal Endoscopy” states that “credentials and privileges should be determined independently for each type of endoscopic procedure (sigmoidoscopy [flexible and rigid], colonoscopy, EGD, ERCP, endoscopic ultrasound [EUS], etc). It also states that “appropriate documentation should be required in the determination of competence in each procedure”. In certain procedures, such as colonoscopy and ERCP, published studies have indicated minimum levels of success in specific tasks (e.g. reaching the cecum at colonoscopy, selective cannulation at ERCP) before competence can be certified. Normally, these data would be supplied to a Credentialing Committee by the Endoscopic Training Director at the applicant’s site of residency or

fellowship. In Dr T's case, the hospital Credentialing Committee erred in accepting a "generic" letter of support from a faculty member at her training institution, a letter that did not contain specifics of training in individual procedures and that did not originate from the endoscopic training director. The source of this letter should have been questioned: was this faculty member asked to write a letter of recommendation because the applicant knew that the endoscopic training director could not certify credentialable training? This seems likely. Many hospitals ask each applicant for endoscopy privileges to identify his or her endoscopy training director, to whom they send a detailed form requesting procedure totals and an opinion regarding the applicants' suitability to perform specific procedures without supervision. In Dr T's case, this would likely have exposed her lack of credentialable ERCP training before privileges were granted. Observational experience – watching but not performing procedures – is no substitute for properly supervised hands-on training. In her previous post, Dr T admits to performing over 50 ERCPs with no formal training in this specialized endoscopic procedure. Under the circumstances, her claim to have done these without a significant complication must be regarded with skepticism, and one wonders what her failure rate must have been. Her request to continue to perform ERCPs as long as they are only diagnostic is further evidence of her inexperience in this field. As many ERCPs lead to therapeutic intervention (e.g. stone removal, stent placement), there is no place in modern endoscopic practice for the solely "diagnostic ERCP endoscopist". Based on the endoscopic training director's comment about Dr T's difficulties reaching the cecum at colonoscopy, the Credentialing Committee solicited feedback from the Endoscopy Unit Head Nurse regarding these procedures. Several nurses had expressed concern about the level of discomfort experienced by patients undergoing colonoscopy by Dr T, the prolonged duration of these procedures, and frequent failure to reach the cecum. The Credentialing Committee revoked Dr T's privileges to perform all endoscopic procedures pending further review. Dr T immediately threatened to bring a law suit against the hospital, but then abruptly resigned her position and moved out of the area.

[*EGD: esophagogastroduodenoscopy ; **ERCP: endoscopic retrograde cholangiopancreatography]

Case 2: A graduate of the "West Coast College of Colonoscopy"

Dr W, a relatively recent recruit to the medical staff, an internist without formal training in gastroenterology, gastrointestinal (GI) surgery or pediatric gastroenterology, requests privileges to perform colonoscopy in the hospital's Day Case Procedure Unit. In support of his application, he reports that he has attended a weekend course in colonoscopy and received hands-on training, including colonoscopy and simulated polypectomy in anesthetized pigs. He provides the Credentialing Committee with a certificate received at the end of this course, certifying that he has received 10 hours of Category I Continuing Medical Education (CME) credit, and that he has been "thoroughly familiarized with the indications and contraindications for colonoscopy and all technical aspects of the procedure". He has successfully completed colonoscopy in three pigs and performed snare electrocautery to remove five simulated colon polyps. The certificate, provided by the "West Coast College of Colonoscopy" states that Dr W completed his colonoscopy training "Magna Cum Laude" and exhorts him to gain further experience of colonoscopy to maintain his "already excellent skills".

Comment: Dr W, the applicant in this case, has no formal training in gastroenterology or GI endoscopy. He is requesting privileges to perform colonoscopy on the basis of a short weekend course during which he practiced colonoscopy and simulated polypectomy on anesthetized pigs. Applying the ASGE's "General Principles of Credentialing and Granting of Privileges" (in "Methods of Granting Hospital Privileges to Perform Gastrointestinal Endoscopy"), it is evident that this physician does not have the training or experience to undertake any endoscopic procedure, let alone colonoscopy. He has not completed a formal training program in gastroenterology or any allied specialty, nor has he had structured training in endoscopy involving real patients. The ASGE's "Statement on the Role of Short Courses in Endoscopic Training" is quite clear on this subject: "these courses, by themselves, do not provide adequate training in standard endoscopic procedures..The granting of hospital privileges to physicians whose training does not meet established requirements is no longer tenable, and may lead to poor patient care. It may also raise potential liability issues for medical staffs and hospital boards". There is no "quick fix" available for Dr W: supervised experience of colonoscopy under the guidance of a proctor would not compensate for the lack of formal training in gastroenterology and GI endoscopy. The Credentialing Committee should decline this physician's request for privileges to perform colonoscopy in the hospital Endoscopy Lab.

Case #3: The Photodynamic Therapy (PDT) Program

Dr M, one of two gastroenterologists at a small community hospital, petitions the Credentialing Committee to approve his performance of photodynamic therapy (PDT) for dysplasia in Barrett's esophagus. He tells the Committee that the equipment has been purchased (at considerable cost) and what looks like a lucrative program for the hospital is "ready to go". Dr M had not intended "to bother" the Credentialing Committee with a formal request for privileges, as he is already an experienced endoscopist, but the hospital's Radiation Safety Officer heard of his plans and brought the issue to the Committee Chairman's attention. Dr M tells the Committee that there are no formal training guidelines for gastroenterologists wishing to perform laser therapy. Dr M feels "well qualified" to do laser procedures because he has been performing endoscopy for 20 years and has seen PDT demonstrated by experts at national meetings.

Comment: This gastroenterologist, who has no formal training in laser techniques, is requesting privileges to perform photodynamic therapy (PDT). In fact, he had planned to initiate a PDT program to treat dysplasia in Barrett's esophagus without formal approval from the hospital Credentialing Committee. Dr M has been performing diagnostic EGD and colonoscopy for many years, and feels that PDT is a minor extension of his existing endoscopic skills. However, he has had no formal training in laser techniques in GI endoscopy. The critical issue in this case is whether or not Dr M is requesting privileges to perform a "major skill" – "a new technique or procedure which by its nature involves a high level of complexity, interpretative ability and/or new type of technology" – or a "minor skill" – "a new, non-experimental development which is a minor extension of an accepted and widely available technique or procedure". The ASGE document, "Methods of Privileging for New technology in Gastrointestinal Endoscopy", states that "a preceptorship or other vehicle of formal instruction is mandatory for the acquisition of major new skills. The completion of a short course or workshop that offers limited exposure to cognitive background data or technical skills will not by itself result in clinical competency, and therefore should not be the sole mechanism for the acquisition of major new skills". The endoscopic use of laser energy within the GI tract for photocoagulation or ablation of dysplasia or tumor should be regarded as a "major skill" requiring specific training. The ASGE guidelines state: "Persons wishing to learn a new procedure should do so under the supervision of a

preceptor, a recognized authority in the new procedure on the basis of extensive clinical experience and/or publications”. When it comes to a “minor skill”, the ASGE guidelines state that: “..for the majority of gastrointestinal endoscopists, obtaining competency in a minor skill would involve limited education and practice exposure such as that obtained from short courses, training video(tapes), CD-ROM (programs) and interactive computer programs”.

The Credentialing Committee ruled that Dr M must seek specific training in laser physics and the practical applications of laser in the GI tract before he can start his PDT program for dysplasia in Barrett’s esophagus. An arrangement was made for an expert in the use of lasers in endoscopy to come from the regional endoscopy center one afternoon every two weeks to act as a preceptor for Dr M while he gained experience of laser techniques in his own patients. Dr M and his endoscopy nurse were required to attend one hour of instruction on laser physics and safety provided by the hospital’s Radiation Safety Officer. The Credentialing Committee agreed that PDT could be added as a “Minor Skill” once Dr M was certified by his preceptor as competent to perform endoscopic laser therapy unsupervised. After five months, Dr M had performed a total of six laser photocoagulation sessions under supervision, four for obstructing esophageal cancers and two for rectal cancers. Towards the end of that period, he attended a weekend course designed to render endoscopists already familiar with GI laser techniques “PDT capable”. Based on the recommendation of his preceptor and his documented attendance at an accredited weekend course on PDT, Dr M was granted permission to initiate his PDT program for dysplasia in Barrett’s esophagus six months after the credentialing process began. In response to Dr M’s written complaint that this process had “taken too long” and had “deprived (him) of significant income”, the Credentialing Committee Chairman pointed out that performing endoscopic laser therapy without appropriate (certifiable) training and experience creates a “medicolegal exposure” for the physician as well as the hospital. Dr M’s extensive prior experience of EGD and colonoscopy did not excuse him from the need to learn all about the new technique he was planning to employ. After a slow start, Dr M’s PDT program became quite successful, attracting referrals from around the state and beyond. The volume of procedures was such that he was able to act as preceptor for his partner, who learned general GI laser techniques and PDT and was subsequently credentialed to deputize for Dr M when he was away.

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John Baillie, MB ChB, FACG (Chairman)
Duke University Medical Center
Durham, NC

Paul Jowell, MD
Duke University Medical
Center, Durham, NC

Steven Bickston, MD
UVA Health Sciences Ctr
Charlottesville, VA

Kristine Krueger, MD
University of Kentucky Med
Center, Lexington, KY

David Bjorkman, MD, FACG
University Medical Center
Salt Lake City, UT

Irving Pike, MD, FACG
1020 Independence Blvd
Virginia Beach, VA

Steven Edmundowicz, MD
Graduate Hospital
Philadelphia, PA

David Raines, Jr., MD
Gastroenterology Clinic
Monroe, LA

Richard Erickson, MD, FACG
Scott and White Clinic
Temple, TX

Jerome Siegel, MD, FACG
Beth Israel Med Center
New York, NY

Ira Flax
919 Frostwood
Houston, TX

Milton Smith, MD, FACG
619 Concerto Lane
Silver Springs, MD

Christopher Gostout, MD, FACG
Mayo Clinic
Rochester, MN

Jacques Van Dam, MD, PhD., FACG
Stanford University Medical Center
Stanford, California

Glenn Gross, MD
University of Texas HSC
San Antonio, TX

Karen Woods, MD, FACG
Baylor College of Medicine
Houston, TX

Joseph Hancock, MD
500 Chestnut St.,
Abilene, TX

Greg Zuccaro, Jr, MD, FACG
The Cleveland Clinic
Cleveland, OH

Ira Jacobsen, MD,FACG
50 E 69th St., New York, NY