Ensuring Competence in Endoscopy

Prepared by the ASGE Taskforce on Ensuring Competence in Endoscopy

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Introduction

Endoscopic procedures have become standard tools for evaluation and treatment of gastrointestinal disorders. Diagnostic and therapeutic procedures are widely available and can be performed safely and competently.

Endoscopists have traditionally been trained in the art and science of endoscopy as part of fellowship in gastroenterology, pediatric gastroenterology, or surgery. These procedures have been considered an integral part of the practice of gastroenterology and surgery. Separate specialty boards have not been developed for endoscopy as a discipline. Since there are no boards specific to endoscopy, individuals who have no formal training as part of a specialty in gastrointestinal diseases often apply for, and in some cases are granted, privileges in endoscopy. In some cases, the motivation is to provide services that would not otherwise be available. In others, it is the ability to generate income from these procedures that constitutes the motivation. Even endoscopists who have completed formal training programs may not have received extensive experience and training in more complex endoscopic procedures, such as therapeutic biliary and pancreatic endoscopy (ERCP, endoscopic retrograde cholangiopancreatography) and endoscopic ultrasonography. Additionally, as new endoscopic techniques are developed, trained endoscopists may require additional training in the new procedure prior to utilization in patient care.

American Society for Gastrointestinal Endoscopy (ASGE) with the support of the American College of Gastroenterology (ACG) has long sought to standardize training in endoscopy, and create guidelines that assist privileging institutions in determining who is competent to perform endoscopic procedures. Without specific boards in endoscopy, efforts to help assist hospitals and endoscopy units in establishing guidelines for determining competence may be seen as self-serving and restrictive. Yet the goal of these guidelines is to provide competent endoscopic services to the widest number of patients possible. Endoscopy by poorly trained personnel is not only more likely to result in a complication, the information provided may not be accurate or complete and may, ultimately, lead to misdiagnosis and poor or inappropriate treatment.

Privileging institutions have a responsibility to their patients to be certain that services provided by their staff are of the highest quality and safety. Legal precedent has been established that can hold hospitals and/or endoscopy centers responsible for granting privileges to unqualified medical staff performing the procedure (see Hospital Liability Update on page 15). Establishing guidelines for granting privileges in endoscopy that apply universally to all members of the medical staff can help safeguard against such causes of action. By providing this informational packet, ASGE is continuing its tradition of establishing the highest standards for endoscopic services.

How to Use This Guide

This guide was created by the ASGE Taskforce on Competence in Endoscopy with the support of ACG. It was created to help hospitals, credentialing organizations, insurers and healthcare providers who have questions regarding competence in and privileging for gastrointestinal endoscopy.

ASGE has created several guidelines on privileging, credentialing, and training for GI endoscopy. We have included for you a primer—a guide to the guidelines—to help find the information you need. We have also included examples of credentialing issues to illustrate how the ASGE guidelines might be applied to specific circumstances. Next, we have provided you with an update on hospital liability demonstrating how hospitals can be held liable if undertrained individuals are granted privileges to perform endoscopy. Finally, the *ASGE Policy and Procedure Manual for Gastrointestinal Endoscopy Guidelines for Training and Practice*, available on CD-ROM, includes the full-text version of each of the ASGE guidelines.

It is our intention that these guidelines be used by hospitals and ambulatory endoscopy centers to guide them in creating policies as to who will be allowed to perform procedures in their facilities. Accrediting organizations will find them useful in ensuring that all institutions have appropriate policies that apply equally to all practitioners. And third-party payers should find them useful in setting reimbursement policy so that only the highest quality of care is provided to their patients.

About ASGE and ACG

ASGE is recognized as the premier specialty society dedicated to the education of its physician members in the appropriate use of endoscopic techniques for the diagnosis and treatment of gastrointestinal diseases. ACG was formed in 1932 to advance the scientific study and medical treatment of disorders of the GI tract. The College promotes the highest standards in medical education and is guided by its commitment to meeting the needs of clinical gastroenterology practitioners. Membership in these societies consists of over 8,000 domestic and international gastroenterologists, surgeons, and other medical specialists who utilize endoscopy as a diagnostic and therapeutic method of treatment for diseases of the digestive tract and the clinical practice of gastroenterology more specifically. Eligibility for membership requires formal training in gastrointestinal endoscopy administered by physicians and/or surgeons during a residency/fellowship in an adult or pediatric program. Neither ASGE nor ACG are credentialing organizations but are educational and advocacy societies serving the needs of endoscopists and their patients.

Ensuring Competence in Endoscopy: A Primer

What is competence?

Competence is the minimal level of skill, knowledge, and/or expertise derived through training and experience that is required to safely and proficiently perform a task or procedure. When applied to endoscopy, this means that the endoscopist has gone through a period of training to develop requisite endoscopic skills and acquire the knowledge-base required to safely perform, interpret, and correctly manage findings of endoscopic procedures.

Competence assures that a safe and technically successful procedure is performed and that the observations and results are accurate. When patients come for an endoscopy, they trust that the endoscopist has the skills to perform this procedure without exposing them to more risk than is absolutely necessary. They also trust that the endoscopist will be able to use the information gained from the procedure to promote the patient's health and well-being.

There are several consequences to an incompetently performed endoscopy. Most obvious are the occurrence of patient injury, such as a perforation, bleeding or a sedation-related complication, and incorrect or missed diagnoses. Technically incomplete procedures expose the patients to two kinds of risks: those of a missed or delayed diagnosis, and those of additional procedures and other testing for the same presenting complaint(s).

Even when properly done, endoscopic procedures may result in a complication. The competent endoscopist will have had adequate training in the recognition and prompt treatment of complications. Delays in diagnosis of procedure-related complications lead only to additional morbidity.

How is competence achieved?

There are two aspects to ensuring competence: training and the subsequent assessment of the endoscopist as being competent.

Through training, the endoscopist gains the necessary technical and cognitive skills. The technical skills ensure that safe and technically successful procedures are performed. Cognitive skills take the information gained from the endoscopy, and place it in the appropriate clinical context so that accurate diagnoses are made. An accurate diagnosis is paramount in providing needed therapy, whether that therapy is endoscopic (e.g., polypectomy), medical, or surgical. Additional goals of training include ensuring that only indicated endoscopies are performed, sedation and analgesia are given competently, patient risk factors are identified, and steps are taken to minimize the risks.

ASGE has developed guidelines to ensure that individuals receive adequate training (see Principals of Training in Gastrointestinal Endoscopy, and Guidelines for Training in Patient Monitoring and Sedation and Analgesia) which are supported by ACG.

Training in gastrointestinal endoscopy should take place within the context of a global clinical training program in the fields of adult or pediatric gastroenterology or general surgery. These training programs must be recognized by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association and should exist within institutions where they are supported by the presence of accredited training programs in internal medicine, pediatrics, general surgery, radiology, and pathology. Through hands-on training with adequate case volume and a supporting curriculum, the training program attains its goal of producing competent endoscopists.

While an adequate procedure volume is clearly necessary to achieve competence, performance of an arbitrary number of procedures in no way guarantees competence. ASGE has established threshold numbers of procedures that must be completed before competency can be assessed (see Methods of Granting Hospital Privileges to Perform Gastrointestinal Endoscopy). For example, ASGE recommends that 140 colonoscopies and 130 EGDs be performed before competency can be assessed for these procedures. It must be recognized that these are minimum numbers and that most trainees will require more than this number to achieve competence.

ASGE recognizes that some practitioners will seek training outside of formal training programs. ASGE has developed guidelines for training in these settings (see Alternative Pathways to Training in Gastrointestinal Endoscopy). We emphasize that the content and quality of this training must conform to the SAME guidelines as for formal fellowship or residency training. Short courses on endoscopy deserve special mention. These should be viewed as adjunctive training opportunities or as tools for continuing medical education. However, in no way are these short courses a substitute for adequate formal training (see Statement on Role of Short Courses in Endoscopic Training).

Once training is complete, competency is assessed. Within a training program, competency is assessed by the training program director who should provide written support documenting the individual's competence to perform individual endoscopic procedures. Direct observation of the applicant performing endoscopic procedures by an impartial credentialed endoscopist is also prudent, and is specifically recommended for applicants who received their training outside of a formal program (see Proctoring for Hospital Endoscopy Privileges).

Ensuring competence through privileging.

Privileging is a process by which a local institution authorizes an individual to perform a specific procedure (see Methods of Granting Hospital Privileges to Perform Gastrointestinal Endoscopy). Privileges should be determined separately for each type of endoscopic procedure (sigmoidoscopy, colonoscopy, EGD, ERCP, EUS, capsule endoscopy, and any other endoscopic procedures). Competence in one of these procedures in no way ensures competence in another.

This process begins with a review of the credentials provided by the training program. The training director should provide, in writing, the curriculum of the program and confirm the training, experience (including the number of cases for each procedure for which privileges are requested), and an actual observed level of competency (see Principles of Privileging and Credentialing for Endoscopy and Colonoscopy, and Proctoring for Hospital Endoscopy Privileges).

Each institution should have specific guidelines regarding privileging, and apply these guidelines uniformly to all applicants across all disciplines. The institution may, and in many cases should, require independent verification of competence through direct observation of the applicant by an independent, unbiased, credentialed endoscopist. The institution's guidelines should specify the level of training, threshold numbers of procedures, and the types of credentials supplied by training programs needed (see Methods of Granting Hospital Privileges to Perform Gastrointestinal Endoscopy).

Ensuring continued competence.

Maintaining clinical and endoscopic skills requires an ongoing effort. This includes familiarity with the GI literature, continuing medical education (CME) activities, and familiarity with new developments in endoscopic technologies. The endoscopist must also maintain an adequate case volume to maintain procedural skills (see Position Statement on Maintaining Competency in Endoscopic Skills).

In order to ensure competence of their endoscopy staff, institutions should have guidelines on recredentialing and reprivileging. Ideally, an endoscopist that wants to renew privileges should document an adequate case volume with specific documentation of the number of procedures, procedural success, therapeutic interventions, and complications. These statistics should be reviewed as part of a continuous quality improvement program. The applicant should also document continued cognitive training through participation in CME activities (see Position Statement on Maintaining Competency in Endoscopic Skills, and Quality Improvement of Gastrointestinal Endoscopy).

Endoscopy by non-physicians.

The decision to utilize non-physician endoscopists should be based on competence in endoscopy, availability of physician resources, and volume of procedural demand as dictated by local conditions. While physician endoscopists undergo extensive formal training in gastrointestinal diseases 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 patient care.

The safety and efficacy of non-physicians performing flexible sigmoidoscopy (i.e., the direct visual examination of a portion comprising the lower 30–40% of the entire colon) as part of colon cancer screening programs has been established. Non-physician sigmoidoscopy for the evaluation of symptoms has not been assessed and cannot currently be recommended. Some non-physicians have also performed upper endoscopy and colonoscopy. For these more complex sedated procedures, non-physicians require supervision by qualified physician endoscopists. However, currently, the medical literature supports the utilization of non-physician endoscopists for screening flexible sigmoidoscopy only (see Endoscopy By Non-physicians), and never for therapeutic procedures (e.g., removal of a polyp).

Competence in advanced endoscopic procedures.

Complex diagnostic and therapeutic procedures are used less frequently than standard procedures and are more likely to have complications and adverse outcomes. Therefore, their performance requires greater skill that is concentrated in fewer individuals. These procedures include, but are not limited to, ERCP, EUS, and endoscopic surgical techniques such as endoscopic mucosal resection (EMR). It is not possible for all training programs to teach all of these procedures to all trainees, nor is it necessary for optimal patient care.

ASGE recommends that trainees wishing to acquire skills in advanced endoscopic techniques first have completed standard endoscopy training during an approved GI fellowship (or demonstrably equivalent training) and have documented competence to perform standard endoscopic techniques (see Guidelines for Advanced Endoscopic Training). Competence and privileges to perform these advanced procedures should be determined separately from other endoscopic procedures. Once threshold numbers of procedures have been reached (as previously established by ASGE), competency can be assessed. Assessment of competence should, whenever possible, include objective measures of competence (such as success rates) and direct observation of the trainee (see Methods of Privileging and Credentialing for Endoscopy and Colonoscopy, and Proctoring for Hospital Endoscopy Privileges).

Competence in new endoscopic technologies.

The field of gastrointestinal endoscopy is dynamic and increasingly more complex. ASGE recognizes that new endoscopic techniques and procedures will be developed and that endoscopists may wish to incorporate them into their practices (see Methods of Privileging for New Technology in Gastrointestinal Endoscopy).

New techniques require new skills. These skills can be roughly divided into major and minor. *Major skill* describes a new technique or procedure that, by its nature, involves a high level of complexity. These techniques require formal training within a training program or through the guidance of a preceptorship before competence can be assessed. *Minor skill* describes a new nonexperimental development that is a minor extension of an accepted and

widely available technique or procedure. For the majority of established endoscopists, obtaining competence in a minor skill would require limited education and practical exposure, such as that obtained from short courses, training videos, CD-ROMs, and interactive computer programs. Granting privileges for new major skills should be viewed as establishing privileges for new surgical techniques and handled in a similar fashion.

Competence in wireless capsule endoscopy.

A capsule endoscope is a self-contained videoendoscopy device that is swallowed and is able to transmit images of the GI tract to an external receiver. While the technical skills to administer the capsule and operate the software to review the images are not major, the cognitive skills are similar to that required for standard endoscopy. For that reason, ASGE recommends that the use of capsule endoscopy be limited to practitioners already competent and privileged to perform standard upper and lower endoscopy and who have extensive experience viewing gastrointestinal mucosa. ASGE recommends additional specific training in capsule endoscopy as well as review of the initial 10 procedures to verify competence (see Methods of Privileging and Credentialing for Capsule Endoscopy).

Competence in sedation for gastrointestinal endoscopy.

The majority of endoscopic procedures in the United States are performed under sedation. Competence in sedation is necessary to perform safe, comfortable, and technically successful procedures.

Competence in sedation includes the ability to recognize the various levels of sedation from anxiolysis (minimal sedation) to general anesthesia. The endoscopist must understand the pharmacology of each sedative they intend to use, as well as the appropriate reversal agents. The endoscopist must be able to apply appropriate monitoring techniques (see Conscious Sedation and Monitoring During Gastrointestinal Endoscopy).

Of paramount importance is the ability to recognize complications of sedation (chiefly cardiorespiratory depression) and be able to rescue the patient. For moderate (conscious) sedation, the endoscopist must have the skills to rescue the patient from deep sedation. These skills are similar to those taught in Basic Life Support (BLS) but also include the use of reversal agents. For deep sedation (including all uses of propofol), the endoscopist must have the ability to rescue the patient from general anesthesia, including managing a compromised airway (see Practice Guidelines for Sedation, and Analgesia by Non-Anesthesiologists).

Out-of-hospital endoscopy.

Endoscopy can be done in a variety of settings, including the physician's office or in freestanding endoscopy centers. ASGE supports seeking accreditation for these facilities. Standards for out-of-hospital endoscopy units (whether they be freestanding or in-office endoscopy units) should be identical to those recognized guidelines followed in the hospital. The endoscopist's training should in all ways be equivalent to those practicing endoscopy in the hospital setting (see Establishment of Gastrointestinal Endoscopy Areas). Endoscope reprocessing must adhere to established

guidelines (see Multisociety Guidelines for Reprocessing Flexible Gastrointestinal Endoscopes).

ASGE and ACG's position has always been that the decision of site for an endoscopic procedure should be the sole prerogative of the patient and his/her physician, on the sole criteria of what is best for that patient. Gastroenterologists have steadfastly resisted the site of service policy to create a financial incentive to shift patients from one setting to another. Even more disconcerting than the incentive to change doctor behavior, are the emerging policies of some private payers to fully abrogate to themselves the decision of the site of service, without any consultation whatsoever with either patient or doctor and our societies reject this policy as not in the interest of patients. As noted in the attached legal memorandum, such a policy also carries with it potential liability consequences for the payer.

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.

Colonoscopy

A physician currently on staff at your hospital applies for privileges in colonoscopy. The physician was trained in flexible sigmoidoscopy by a local gastroenterologist and has been performing sigmoidoscopy for 12 years. Lately, he has been using a colonoscope on selected patients and has been reaching the cecum in many of these patients. He attended a two-day course on colonoscopy that provided him a certificate of attendance upon completion of the course. The department of internal medicine has granted him privileges, and the chief of staff is being asked to sign-off on his request. Should he be granted privileges?

Comment

The applicant does not meet ASGE requirements, and privileges should be denied. He has not completed a formal training program in gastroenterology or surgery. While this individual has completed training and has substantial experience in a related procedure (flexible sigmoidoscopy), the requisite cognitive and procedural skills necessary to perform colonoscopy safely and competently have not been documented. Competence to perform colonoscopy cannot be acquired in a brief or short course. ASGE has recommended that a minimum of 140 supervised colonoscopy procedures be performed in a training program before an individual is qualified to perform colonoscopy without supervision. Even this minimum number does not assure competence, and training is individualized within an appropriate residency program.

Colonoscopy by a physician assistant

A local family practice group has hired a physician assistant to perform colonoscopy. This individual has spent more than a year being trained in colonoscopy with a GI group in another state. He can provide documentation of having done more than 200 supervised colonoscopies, as well as letters from his supervising GI physicians attesting to his competence. He is requesting unrestricted privileges to perform colonoscopy in your hospital's endoscopy suite. None of the family practitioners in the practice currently have endoscopic privileges.

Comment

The safety and efficacy of non-physicians performing flexible sigmoidoscopy as part of colon cancer screening programs has been established. For more complex and sedated procedures, there is inadequate literature to support this practice. For this reason, ASGE does not currently endorse colonoscopy by non-physician endoscopists. It is recognized that some non-physicians have been trained to perform these procedures. In these rare instances, ASGE recommends that the non-physician be closely supervised by a trained physician endoscopist.

In this scenario, the physician assistant is requesting unrestricted privileges to do unsupervised colonoscopies, and this request should be denied.

Endoscopy by a foreign medical graduate

A graduate of a non-U.S. foreign medical school is seeking privileges to perform endoscopy in a U.S. hospital. She completed training in internal medicine at the same institution where she attended medical school. She completed a university affiliated and accredited three-year gastroenterology fellowship in the United States and can document more than 500 EGDs and colonoscopies, along with a letter from her program director attesting to her competency. She has an unrestricted medial license in the same state as the hospital to which she is applying for privileges and is a permanent resident-alien (she has a green card). Because of her foreign medical training, she is not eligible to take the American Board of Internal Medicine examination in gastroenterology and is, therefore, not board certified.

Comment

This applicant meets all the requirements of training in endoscopy having completed an accredited fellowship, performed more than the recommended minimum number of procedures, and was deemed competent by her program director (see Methods of Granting Hospital Privileges to Perform Gastrointestinal Endoscopy). ASGE does not require board certification, and the fact that she is not board certified should not be used to deny privileges.

ERCP

A physician has just finished three years of endoscopic training. The second year of training was dedicated to research and involved no endoscopic experience. During the third year of fellowship training, the fellow was involved with 133 ERCP cases, the vast majority of which were completed by the staff physician. The trainee's competency evaluations during his ERCP rotation specifically commented that the trainee was not competent to

independently perform ERCP. Upon completion of fellowship training, the physician accepted a position at another institution; he is applying for privileges to perform ERCP.

Comment

ERCP is considered by ASGE to be an advanced endoscopic procedure that is complex, technically demanding to perform, and carries a relatively higher risk of complications. Serious life-threatening short-term and long-term complications may arise as a result of ERCP. Providing brief exposure to an advanced procedure is no longer appropriate.

Few studies of the rate at which proficiency is attained have been performed, but available data suggest that at least 180 to 200 ERCPs are required for the usual trainee to achieve competence (see Jowell PS, et al. *Ann Intern Med.* 1996;125:983-9). In the scenario mentioned, the fellow has not performed the minimum 200 procedures recommended by the ASGE before competency can be assessed, and his training program specifically did not feel he was competent.

A trainee's overall numbers are not in and of themselves adequate to ensure competency in ERCP. The following are suggested objective performance criteria for the evaluation of technical skills in ERCP (see Principles of Training in Gastrointestinal Endoscopy): cannulation of desired duct, opacification of desired duct, stent placement, sphincterotomy, and stone extraction. Expert endoscopists are generally expected to perform at a 95% to 100% technical success level, and current research supports establishing a standard of 80% to 90% technical success before trainees are deemed competent in a specific skill. In a given program, small variations in the standard of expected proficiency that is set from one procedure to the next may be appropriate, especially among procedures of varying complexity; however, the expected performance level should be uniform among all trainees. The principles of training and credentialing in endoscopy that have been outlined by ASGE were not met in this case (see Methods of Granting Hospital Privileges to Perform Gastrointestinal Endoscopy). Should an adverse event during ERCP occur after the trainee, in this case, performs ERCP, the hospital granting privileges may be held accountable.

Reclaiming privileges after a leave of absence

A gastroenterologist who was formerly on staff has recently returned to your city and is requesting readmission to the medical staff with privileges in liver biopsy, flexible sigmoidoscopy, upper endoscopy (EGD), colonoscopy, and ERCP. The physician left your staff five years ago to become the medical director of an insurance company out of state. He has not been involved in direct patient care while employed by the insurance company. He has, however, continued to attend national meetings and has kept his license and CME credits current. Should you grant privileges in these procedures?

Comment

The physician has had formal training in gastroenterology and has had experience and training in these procedures. He has not, however, performed these procedures in the last five years, and there is good evidence that proficiency in endoscopic procedures is dependent upon continued practice and performance of adequate numbers of procedures (ASGE. *Gastrointest Endosc.* 1999;49:823-5. See Renewal of Endoscopic Privileges and Position Statement on Maintaining Competency in Endoscopy Skills). It would be necessary for this physician to demonstrate competence through proctoring prior to granting privileges. While this is true for any of the requested procedures, it is particularly true for the more complex and technically demanding procedures, such as ERCP. This request should be treated in a similar manner to a newly trained physician who is seeking initial privileges, with proctoring by someone acceptable to both the privileging body and the applicant (see Proctoring for Hospital Endoscopy Privileges).

Capsule endoscopy

A 52-year-old gastroenterologist requests permission to offer small-bowel capsule endoscopy in the outpatient endoscopy suite at the hospital. He currently has privileges to perform EGD, enteroscopy, and colonoscopy. He has attended a hands-on course in capsule endoscopy and received eight hours of CME credit. He had his first 10 capsule exams reviewed by an experienced capsule endoscopist and is able to produce a letter from this colleague attesting to his good accuracy rate.

Comment

ASGE recommends that the use of capsule endoscopy be limited to practitioners already competent and privileged to perform standard upper and lower endoscopy and who have extensive experience viewing gastrointestinal mucosa. ASGE recommends additional specific training in capsule endoscopy, as well as review of the initial 10 procedures to verify competence. The practitioner in question has met all of these requirements, and privileges should be granted.

New technology

A company develops a new technology for gastroesophageal reflux. It is an implantable device using a proprietary insertion tube and is performed under endoscopic guidance. The technology has been studied in a multicenter trial and is cleared for marketing by the FDA. The technology is then presented at a national meeting at an evening dinner program. Having attended the meeting, a local gastroenterologist returns to his hospital and wishes to start offering this service in the endoscopy suite.

Comment

The new technology requires a major skill since the new procedure involves a high level of complexity. According to ASGE guidelines, this technique requires formal training within a training program or through the guidance of a preceptorship before competence can be assessed. Granting privileges for new major skills is viewed as establishing privileges for new surgical techniques and handled in a similar fashion. The gastroenterologist is told

to contact the manufacturer who is sponsoring hands-on training courses, and privileges should not be granted in the absence of documented training proficiency.

Endoscopic Ultrasound (EUS)

A physician has applied for privileges to perform endoscopic ultrasound. She has privileges to perform standard upper and lower endoscopy as well as ERCP. She has completed a two-week hands-on course that included an animal lab and direct involvement in performing supervised EUS in 20 patients. She supplies a letter and a CME certificate documenting this training. She states that for someone with her level of endoscopic skills, EUS represents a minor skill and privileges should be granted.

Comment

ASGE recognizes EUS as a technically demanding procedure and has specific recommendations as to adequate training. Privileging for EUS should be considered separately from other endoscopic procedures. Competence in other endoscopic procedures (e.g., ERCP) does not automatically indicate competence in EUS. ASGE does recommend at least 24 months of formal GI or surgical training or equivalent and competence in standard GI endoscopy. ASGE recognizes that some physicians may not wish to perform all aspects of EUS. Before competency can be assessed, we recommend that the trainee complete the following minimum number of procedures:

Mucosal tumors:	**75**	
Submucosal lesions only:	**40**	
Mucosal and submucosal lesions:	**100**	
Pancreaticobiliary:	**75**	
EUS-guided FNA		
Non-pancreatic:	**25**	
Pancreatic:	**25**	
Comprehensive competence:	**50**	(including at least 75 pancreaticobiliary and 50 FNA)

These numbers do not guarantee competence but are thresholds at which competence can be assessed.

The physician in this example does not meet the ASGE guidelines, and privileges should not be granted.

The following is a legal memorandum prepared by the prominent litigation firm Williams & Connolly regarding the responsibilities of those granting privileges to perform gastrointestinal endoscopy, commissioned by the American College of Gastroenterology. The research and authorship of the initial legal memorandum were prepared by Williams & Connolly in 1992. Recently ACG commissioned a complete review and updating of the same topic, again performed by Williams & Connolly resulting in the following new 2005 legal memorandum. It should be noted that the neither ASGE nor ACG has indicated board certification as part of its requirements to perform gastrointestinal endoscopy.

Hospital Liability Update

Introduction

Hospitals have a duty to exercise due care in granting privileges to physicians. 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.[1] This memorandum examines the standard of care that governs the extension of hospital privileges and considers how that standard applies to endoscopic procedures in particular. To help protect themselves from liability, the memorandum concludes, hospitals should extend endoscopic privileges only to board-certified gastroenterologists or general surgeons, or physicians/surgeons with knowledge, training, and experience in gastroenterology or gastrointestinal surgery comparable to that required for board certification.

Analysis

I. Hospital Liability for Corporate Negligence Extends to "Negligent Credentialing."

In the landmark case of *Darling v. Charlestown Community Memorial Hospital*, 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.[2] This decision marked a departure from the previous rule that hospitals could be held liable only vicariously for the negligence of their agents—which generally did not include physicians with staff privileges. Following *Darling*, a clear majority of jurisdictions adopted some form of what has come to be called the "corporate negligence" theory of hospital

1. A clear majority of jurisdictions that have addressed the issue adhere to the rule that a hospital owes an independent duty to patients to exercise reasonable care in, *inter alia*, granting privileges to physicians. *See infra*, note 3. However, it should be noted that the duty, *vel non*, and/or the applicable standard of care may vary depending on the jurisdiction.
2. 211 N.E.2d 253 (Ill. 1965), *cert. denied*, 383 U.S. 946 (1966).

liability.[3] The moniker "corporate negligence" encompasses at least four distinct duties: "(1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within [a hospital's] walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients."[4] Thus, corporate negligence applies directly against hospitals for general failure to ensure patient safety and does not hinge on negligent conduct by health care providers themselves. For example, in *Welsh v. Bulger*, the defendant hospital granted a physician obstetrical but not surgical privileges.[5] Without a surgeon present, the physician had to deliver an infant vaginally when caesarean section was indicated for variable decelerations. The hospital also failed to staff the delivery with a pediatrician who could perform resuscitation. Although provider negligence contributed to the baby's eventual death, the court held the hospital directly liable for failing to ensure quality of care.

Liability for "negligent credentialing" applies when hospitals extend privileges to unqualified physicians who then commit actual malpractice.[6] At least thirty-four jurisdictions impose such liability.[7] Even when jurisdictions do not impose all four of the above corporate-negligence duties on hospitals, the law requires, at least, that hospitals comply with the duty to exercise due care in granting privileges to physicians.[8]

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3. *See, e.g.*, *Tucson Medical Center, Inc. v. Misevch*, 545 P.2d 958 (Ariz. 1976); *Elam v. College Park Hosp.*, 183 Cal. Rptr. 156 (Cal. App. 1982); *Kitto v. Gilbert*, 570 P.2d 544 (Colo. App. 1977); *Insinga v. LaBella*, 543 So.2d 209 (Fla. 1989); *Mitchell County Hosp. Auth. v. Joiner*, 189 S.E.2d 412 (Ga. 1972); *Ferguson v. Gonyaw*, 236 N.W.2d 543 (Mich. App. 1975); *Gridley v. Johnson*, 476 S.W.2d 475 (Mo. 1972); *Foley v. Bishop Clarkson Memorial Hosp.*, 173 N.W.2d 881 (Neb. 1970); *Moore v. Board of Trustees*, 495 P.2d 605, *cert. denied*, 409 U.S. 879 (Nev. 1972); *Corleto v. Shore Memoria1 Hosp.*, 350 A.2d 534 (N.J. Super. L. 1975); *Raschel v. Rish*, 488 N.Y.S.2d 923 (N.Y.A.D. 4 Dept. 1985); *Blanton v. Moses H. Cone Memorial Hosp., Inc.*, 354 S.E.2d 455 (N.C. 1987); *Benedict v. St. Luke's Hosps.*, 365 N.W.2d 499 (N.D. 1985); *Albain v. Flower Hosp.*, 553 N.E.2d 1038 (Ohio 1990), *overruled on other grounds by Clark v. Southview Hosp. & Family Health Ctr.*, 628 N.E.2d 46 (Ohio 1994); *Thompson v. Nason Hosp.*, 591 A.2d 703 (Pa. 1991); *Pedroza v. Bryant*, 677 P.2d 166 (Wash. 1984); *Utter v. United Hosp. Center, Inc.*, 236 S.E.2d 213 (W.Va. 1977); *Johnson v. Misericordia Community Hosp.*, 301 N.W.2d 156 (Wis. 1981). Additionally, at least one state has codified the duty of hospitals to exercise reasonable care in, *inter alia*, granting privileges to physicians. *See* Fla. Stat. Ann. § 766.110 (West 2004).
4. *Thompson*, 591 A.2d at 707.
5. 698 A.2d 581 (Pa. 1997).
6. For example, the court in *Hiroms v. Scheffey*, No. 14-00-0424, 2002 WL 245959 (Tex. App. Houston Feb. 21, 2002), summarily dismissed the plaintiff's negligent credentialing claim because the codefendant physician performed competently.
7. States that impose liability include Alabama, Alaska, Arizona, California, Colorado, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maine, Michigan, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Texas, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. Oregon and Vermont have left open the possibility of negligent credentialing actions but have not directly addressed the issue. *See Wheeler v. Central Vermont Med. Ctr.*, 582 A.2d 165 (Vt. 1989) (citing with approval *Darling* and *Johnson*); *Huffaker v. Bailey*, 540 P.2d 1398 (Ore. 1975) (approving *Darling*).
8. *See, e.g.*, *Albain*, 553 N.E.2d at 1046 (adopting the corporate negligence theory but stressing that a hospital's duty "is limited to the exercise of due care in the granting of privileges.").

II. The Standard of Care Required of Hospitals.

At the most general level, hospitals must "exercise[] that degree of care and skill as the average hospital exercises in selecting its medical staff," *i.e.*, "ordinary care under the circumstances."[9] This includes thoroughly investigating a physician's declarations[10] and contacting other hospitals that granted privileges to the applicant physician.[11] Other courts have proffered similarly vague statements of the applicable standard of care.[12] This lack of specificity may stem from the inherently difficult task of legally defining the "reasonable man" standard. Accordingly, it is helpful to consider several benchmarks to which courts look when considering whether a hospital has breached the applicable standard of care.

The National Standard of Care. Although hospitals always should adhere to their own credentialing bylaws as minimum requirements,[13] community norms may establish a standard of care more rigorous than a hospital's internal regulations.[14] In the corporate negligence context, many courts abandoned the "locality" standard of care several years ago in favor of a uniform, national standard.[15] This change is attributable, in large part, to the establishment of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[16] Specifically, courts mandate that hospitals exercise the same degree of care that other similarly situated hospitals exercise; and, because many hospitals are now accredited by JCAHO, a nationwide organization, courts often consider all accredited hospitals to be "similarly situated."[17] Hence, compliance with the accreditation standards promulgated by JCAHO is particularly germane to the issue of whether a hospital has exercised due care in granting privileges to physicians. Likewise, in the medical malpractice context (where liability for negligent credentialing can arise), "the applicable standard of care for general practitioners is that of the local community or similar communities**,** while the standard of care for a

9. *Johnson*, 301 N.W.2d at 171.
10. *E.g.*, *Ferguson*, 236 N.W.2d 543.
11. *E.g.*, *Rule v. Lutheran Hosps. & Homes Soc'y of Am.*, 835 F.2d 1250 (8th Cir. 1987).
12. *See Blanton,* 354 S.E.2d at 458 (holding that a hospital has a duty to act as a "reasonable man of ordinary prudence … to ascertain that a doctor is qualified to perform an operation before granting him the privilege to do so"); *Insinga*, 543 So.2d at 214 (finding a hospital liable when it fails to exercise "due care" in selecting and retaining physicians).
13. *E.g.*, *Brandt v. U.S. Dept. of Veterans Affairs*, No. 99-197, 2000 WL 1879806 (D. Me Dec. 22, 2000).
14. *E.g.*, *Call v. Chambers*, No. 218865, 2001 WL 740588 (Mich. Ct. App. Feb. 16, 2001), *appeal denied*, 636 N.W.2d 140 (Mich. 2001).
15. *See Washington v. Washington Hosp. Center*, 579 A.2d 177, 181 (D.C. App. 1990) (rejecting the locality rule in favor of a national standard, with respect to hospitals); *Shilkret v. Annapolis Emergency Hosp. Ass'n*, 349 A.2d 245, 254 (Md. 1975) (adopting a national standard of care for accredited hospitals); *Darling*, 211 N.E.2d at 257 (Ill. 1965) (allowing a jury to consider, *inter alia*, national standards adopted by the Joint Commission on Accreditation of Healthcare Organizations); Koehn, Note, *Hospital Corporate Liability: An Effective Solution to Controlling Private Physician Incompetence?*, 32 RUTGERS L. REV. 342, 368 (1979) (hereinafter Note, *Hospital Corporate Liability*) ("the trend [in hospital corporate negligence cases] has been away from local standards to national or regional ones"); 1 David W. Louisell & Harold Williams, MEDICAL MALPRACTICE, ¶ 15.02, at 15-8 (1988).
16. *See Shilkret*, 349 A.2d at 254.
17. *See, e.g.*, *Pedroza*, 677 P.2d at 170-71 (citing, Note, *Hospital Corporate Liability*, at 369-70); Shilkret, 349 A.2d at 254.

specialist is nationwide."[18] The criteria of medical specialty societies also become highly relevant, since they not only provide reliable indicia of national consensus, but also define the very class of "specialists" who are uniquely capable of performing certain procedures and maintaining the required standard of care. The following sections examine JCAHO standards and pertinent specialty society guidelines.

JCAHO Accreditation Standards. JCAHO, established in 1952, acts as a nationwide accreditation board for hospitals. While hospitals need not be accredited by JCAHO to provide health care, a large majority of hospitals seek JCAHO accreditation because participation in Medicare and Medicaid, as well as recognition of intern and residency programs, generally depends on JCAHO accreditation.[19] The purpose of JCAHO is "to establish minimum hospital standards for patient care."[20]

JCAHO annually publishes a manual that contains a plethora of guidelines addressing many hospital functions, from administrative organization to specific forms of care.[21] Each section of the manual sets forth broad "Standards," and every Standard is further defined by a "Rationale" as well as "Elements of Performance," *i.e.*, what it means to comply with the Standards. Of particular relevance is the section dealing with the credentialing, privileging, and appointment of medical staff.[22]

Credentialing is the first step in the process that leads to privileging. It involves "processing applications, verifying credentials, evaluating applicant-specific information, and making recommendations to the governing body for appointment and privileges."[23] The purpose of verifying credentials data is to ensure the following: (1) the individual requesting privileges is in fact the same individual who is identified in the credentialing documents; (2) the applicant has attained the credentials as stated; (3) the credentials are current; and (4) there are no challenges to any of the credentials.[24] Required information includes "data on qualifications such as licensure and training or experience."[25] Relevant training or experience "is defined by the specific circumstances of the applicant, requiring that the hospital believes there is sufficient information on which to base a reasoned decision."[26] Ideally, such information should come from a "primary source," which is "the original source of the specific credential that can be used to verify the accuracy of a credential reported by the practitioner," such as "for example, the specialty certifying boards approved by the American Dental Association for a dentist's board certification, and letters from professional schools . . . and from residency or postdoctoral programs for

18. Cudnik *v. William Beaumont Hosp.*, 525 N.W.2d 891, 894 (Mich. Ct. App. 1994).
19. *See Johnson*, 301 N.W.2d at 159 n. 8 (1981).
20. Note, *Hospital Corporate Liability*, at 369 n. 194.
21. *See* JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK (2004) (hereinafter JCAHO MANUAL).
22. *See id*. at MS-3.
23. *Id*. at MS-16.
24. *Id*. at MS-17.
25. *Id*. at MS-16.
26. *Id*. at MS-17.

completion of training."[27] Current competence must be verified in writing "by peers knowledgeable about the applicant's professional performance."[28] The written documentation should address two specific aspects of current competence:

(a) for applicants in fields performing operative and other procedures, the types of operative procedures performed as the surgeon of record, the handing of complicated deliveries, or the skill demonstrated in performing invasive procedures, including information on appropriateness and outcomes; in the case of applicants in nonsurgical fields, the types and outcomes of medical conditions managed by the applicant as the responsible physician; and

(b) the applicant's clinical judgment and technical skills.[29]

The following Standards govern the next step in the process—the actual extension of hospital privileges:

MS.4.20 There is a process for granting, renewing, or revisiting setting-specific clinical privileges.[30]

MS.4.40 At the time of renewal of privileges, the organized medical staff evaluates individuals for their continued ability to provide quality care, treatment, and services for the privileges requested as defined in the medical staff bylaws.[31]

MS.4.70 Peer recommendations from peers in the same professional discipline as the applicant are used as part of the basis for the initial granting of privileges. Peer recommendations are used to recommend individuals for the renewal of clinical privileges when insufficient peer review data are available.[32]

The Rationale for MS.4.20 explains the standard as follows:

Essential information needs to be gathered in the process of granting, renewing, or revising clinical privileges. The information will dictate the type(s) of care, treatment, and services or procedures that a practitioner will be authorized to perform. Privileges are setting-specific because they require consideration of setting characteristics, such as adequate facilities, equipment, number, and type of qualified support personnel and resources. Setting-specific decisions mean that privileges granted to an applicant are based not only on the applicant's qualifications, but also on consideration of the procedures and types of care, treatment, and services that can be performed or provided within the proposed setting.[33]

27. *Id.* (parenthetical examples omitted).
28. *Id.*
29. *Id.* at MS-17 to MS-18.
30. *Id.* at MS-19.
31. *Id.* at MS-22.
32. *Id.* at MS-24.
33. *Id.*

The Elements of Performance for Standard MS.4.20 mandate that "[c]riteria are developed that determine an applicant's ability to provide patient care, treatment, and services within the scope of privileges requested."[34] Specifically, the criteria must include "evidence of current competence" and "peer recommendations when required."[35] Current competence is established in the same manner as required for credentialing.[36] As for peer recommendations, Standard MS.4.70 states that such information supplements peer review data. Peer recommendations may come from/consist of (1) a hospital performance improvement committee, the majority of whose members are the applicant's peers; (2) reference letters, written documentation, or documented phone conversations about the applicant from peers who are knowledgeable about the applicant's professional performance and competence; (3) a department or major clinical service chairperson who is a peer; or (4) the medical staff executive committee.[37] Peer recommendations must address (1) relevant training and experience and (2) current competence—as previously described—as well as "any effects of health status on privileges being requested."[38]

In addition, the Elements of Performance for Standard MS.4.20 demand that, before granting privileges, the hospital medical staff must evaluate:

(a) challenges to any licensure or registration;

(b) voluntary and involuntary relinquishment of any license or registration;

(c) voluntary and involuntary termination of medical staff membership;

(d) voluntary and involuntary limitation, reduction, or loss of clinical privileges;

(e) any evidence of an unusual pattern or an excessive number of professional liability actions resulting in a final judgment against the applicant;

(f) documentation as to the applicant's health status;

(g) relevant practitioner-specific data compared to aggregate data, when available; and

(h) morbidity and mortality data, when available.[39]

Renewal or revising of privileges involves the same process as the initial extension of privileges, as well as assessment of the applicant's ability to perform the requested privileges based upon his or her previous performance.[40]

As noted above, JCAHO itself has been responsible for a shift to a national standard of care. Further, as explained below, compliance with the pertinent standards is extremely important for hospitals seeking to avoid liability.

34. *Id*. at MS-20.
35. *Id*.
36. *Id*. at MS-17.
37. *Id*. at MS-24.
38. *Id*.
39. *Id*. at MS-20.
40. *Id*. at MS-24.

III. Application of the Standard of Care.

Although standard-of-care analysis in individual cases is fact-specific, case law and JCAHO standards parallel one another.

Case law. In *Johnson v. Misericordia Community Hospital*, a physician negligently attempted to remove a pin fragment from the plaintiff's leg.[41] The court found that, had the defendant hospital conducted a thorough investigation of the doctor's qualifications before extending privileges, it would have discovered that his peers in the medical community considered him unqualified to perform orthopedic surgery.[42] Also, an administrator from another hospital where the doctor had previously been granted orthopedic privileges testified that the doctor was "*neither board certified, nor board eligible* in the field of orthopedic surgery."[43] Furthermore, the doctor's privileges in another hospital had been limited to only uncomplicated operations, and those privileges were eventually revoked.[44] After upholding the jury's verdict of negligence on the part of the hospital, the court set out, in detail, what it considered the necessary components of a proper background investigation:

The credentials committee (or committee of the whole) must investigate the qualifications of applicants. The facts of this case demonstrate that a hospital should, at a minimum, require completion of the application and verify the accuracy of the applicant's statements, especially in regard to his medical education, training and experience. Additionally, it should: (1) solicit information from the applicant's peers, including those not referenced in his application, who are knowledgeable about his education, training, experience, health, competence and ethical character; (2) determine if the applicant is currently licensed to practice in this state and if his licensure or registration has been or is currently being challenged; and (3) inquire whether the applicant has been involved in any adverse malpractice action and whether he has experienced a loss of medical organization membership or medical privileges or membership at any other hospital. The investigating committee must also evaluate the information gained through its inquiries and make a reasonable judgment as to the approval or denial of each application for staff privileges. The hospital will be charged with gaining and evaluating the knowledge that would have been acquired had it exercised ordinary care in investigating its medical staff applicants and the hospital's failure to exercise that degree of care, skill and judgment that is exercised by the average hospital in approving an applicant's request for privileges is negligence.[45]

In *Ferguson v. Gonyaw*, the question was whether the trial court erred in directing a verdict in favor of the defendant hospital on plaintiff's claim that

41. 301 N.W.2d 156 (Wis. 1981).
42. *Id*. at 161.
43. *Id*. at 162 (emphasis original).
44. *Id*. at 161.
45. *Id*. at 175 (emphasis added).

the hospital had been negligent in granting surgical privileges to an osteopathic neurosurgeon.[46] The appellate court held that the hospital could be held liable for failure to exercise reasonable care in extending privileges to a physician. The court also noted that the hospital had breached the standard of care by failing to corroborate the physician's credentials prior to granting him privileges. For example, the hospital failed to follow the American Osteopathic Association's guidelines for checking a physician's credentials, and, in fact, failed to follow its own procedures in vetting the doctor.[47] Nevertheless, the court held that the hospital was not liable because, had it completed a proper background check of the physician, it would have found that he was competent to perform the procedures for which he was granted privileges.[48] Specifically, the court noted that the doctor had completed a training program for which the American Osteopathic Association gave him credit towards certification as an osteopathic neurosurgeon.[49]

In *Blanton v. Moses H. Cone Memorial Hospital*, plaintiff sued the defendant hospital for alleged negligence in granting mastectomy privileges to a physician without first determining whether that doctor was competent to perform the procedure.[50] The court held that evidence of the hospital's failure to enforce JCAHO standards could be admitted as evidence of negligence.[51]

In *Rohe v. Shivde*, plaintiffs sued the defendant doctor and hospital for negligent treatment of an infant.[52] The court noted the hospital's duty to delineate privileges on the basis of a physician's particular qualifications and stated, "The standard to which the hospital must conform its conduct is the accepted standard of care in the medical community."[53] The use of expert testimony to establish the standard of care was not necessary because "the use of hospital licensing regulations, [JCAHO] accreditation standards, and [hospital] bylaws to establish a hospital's standard of care remains one of the few judicially recognized exceptions to the general requirement of expert testimony to establish the applicable standard of care in medical malpractice cases."[54] There was evidence that the hospital's regulations and state licensing laws required a qualified neonatologist to staff the neonatal ward. The court, however, found no breach of the standard of care because there was no evidence that the doctor in question was either not eligible for board certification in the subspecialty of neonatal/perinatal medicine or not qualified in neonatology.[55]

A case particularly pertinent to the standard of care applicable when a hospital grants privileges to perform gastrointestinal diagnostic and therapeutic procedures such as endoscopy and colonoscopy, *Roberts v. Stevens Clinic*

46. 236 N.W.2d 543 (Mich. App. 1976).
47. *See id*. at 550.
48. *See id*. at 550-51.
49. *See id*. at 551.
50. 354 S.E.2d 455, 458 (N.C. 1987).
51. *Id*.
52. 560 N.E.2d 1113, *appeal denied*, 564 N.E.2d 848 (Ill. App. 1990).
53. *Id*. at 1125.
54. *Id*.
55. *Id*. at 1128.

Hospital, Inc., involved a suit by the parents of a deceased child against the defendant hospital for granting full surgical privileges to a physician who negligently performed a sigmoidoscopy on the child and perforated his colon.[56] In upholding the jury verdict against the hospital, the court stated that the hospital failed to comply with state regulations and JCAHO standards. Furthermore, the court found 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 had never previously been granted full surgical privileges."[57]

To summarize, certain specifics concerning the applicable standard of care in extending staff privileges can be culled from these and other representative cases. First, hospitals should establish and invariably comply with procedures that require thorough vetting of potential staff physicians' qualifications. Such procedures should conform to JCAHO standards for staffing hospitals, as well as any applicable state licensing regulations and hospital bylaws. Second, privileges should be granted on a procedure-specific basis. For example, granting full surgical privileges to a physician qualified to perform only a particular procedure may expose a hospital to liability.[58] Third, the importance of compliance with JCAHO standards, state regulations, and hospital bylaws should not be underestimated. Almost every court will admit evidence of these standards on the issue of compliance with the standard of care.[59] And with the emergence of what appears to be a national standard of care (at least for accredited hospitals), JCAHO standards arguably define the applicable standard of care. Courts may hold that failure to comply with JCAHO standards, alone, is negligence. At least one court appears to have adopted this view.[60] Fourth, even though hospitals cannot extend privileges only to physicians who are board-certified,[61] hospitals best insulate themselves from liability if they grant staff privileges in subspecialties only to either board-certified physicians/surgeons or physicians/surgeons with knowledge, training, and experience in the subspecialty that is commensurate with board-certification.

To illustrate the high level of expertise necessary for privileges to perform gastrointestinal procedures, the next sections survey pertinent subspecialty certification prerequisites.

56. 345 S.E.2d 791 (W.Va. 1986).
57. *Id*. at 798.
58. *E.g*., *Roberts*, 345 S.E.2d at 798.
59. *See, e.g*., *Albain*, 553 N.E.2d at 1045 n. 7; *Blanton*, 354 S.E.2d at 458; *Roberts*, 345 S.E.2d at 798; *Rohe*, 560 N.E.2d at 1125; *Andrews v. Northwestern Memorial Hosp*., 540 N.E.2d 447, 489-51 (Ill. App. 1989).
60. *See Rohe*, 560 N.E.2d at 1125-26.
61. *See Thomas v. Solon*, 502 N.Y.S.2d 475, 476 (N.Y. App. Div. 1986) (pointing out that state law prohibited hospitals from granting privileges only to board-certified physicians, and finding that simply because a physician was not board-certified in a specific subspecialty did not establish that he or she was unqualified to practice in that field).

Certification in Gastroenterology. The American Board of Internal Medicine (ABIM) sets the requirements for board certification in gastroenterology. It alone decides which candidates are eligible for admission to the subspecialty examination. The requirements to sit for the exam include:

(a) certification in internal medicine, which entails a minimum of three years of training in a program accredited by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada, or the Professional Corporation of Physicians of Quebec, as well as substantiation of the candidate's clinical competence and moral and ethical behavior by the program director;[62] and

(b) a minimum of three additional years of training with experience in proctoscopy and/or flexible sigmoidoscopy; diagnostic upper gastrointestinal endoscopy; colonoscopy, including biopsy and polypectomy; esophageal dilation; therapeutic upper and lower gastrointestinal endoscopy; and liver biopsy.[63]

Thus, candidates for board certification 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. 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.[64]

As to diagnostic and procedural skills, ABIM has required that, at the completion of their residency, candidates for certification demonstrate satisfactory procedural skills in, at least, the following procedures: (1) proctoscopy and/or flexible sigmoidoscopy; (2) esophagograstroduodenoscopy; (3) colonoscopy, including biopsy and polypectomy; (4) esophageal dilation procedures; (5) therapeutic upper and lower gastrointestinal endoscopy; and (6) percutaneous aspiration liver biopsy.[65] Successful mastery of these skills included "an understanding of their indications, contraindications,

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62. Clinical competence encompasses (1) patient care (medical interviewing, physical examination, and procedural skills), (2) medical knowledge, (3) practice-based learning and improvement, (4) interpersonal and communication skills, (5) professionalism, and (6) systems-based practice.
63. *See* AMERICAN BOARD OF INTERNAL MEDICINE, POLICIES AND STANDARDS FOR CERTIFICATION (2004), at www.abim.org (hereinafter ABIM POLICIES AND STANDARDS).
64. AMERICAN BOARD OF INTERNAL MEDICINE, Memorandum at 5, at http://www.utmem.edu/ID/documents/SSGENERI.pdf.
65. *Id*. at 8. While ABIM emphasized the need for residents to demonstrate a high degree of competence in, at least, these procedures, it also dispensed with the requirement of a minimum number of procedure repetitions. The ABIM Memorandum stated:

> The Board does not prescribe the number of times a procedure must be done to ensure competency. It recognizes that trainees' manual dexterity and confidence vary, and procedures should be applied for the patient's benefit and not to fulfill some arbitrary quota.

Id. at 5.

and complications, and the ability to interpret their results."[66] Furthermore, ABIM prohibits candidates who have received an unsatisfactory rating "in [any] of the components of clinical competence during the final year of required (residency or fellowship) training" from taking the subspecialty examination.[67] Any candidate who does not receive a satisfactory evaluation in his or her overall clinical competence must complete an additional twelve months of training for each unsatisfactory year.[68]

The foregoing clearly indicates 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. Perhaps more importantly, the stringent requirements for board certification in gastroenterology—outlined in ABIM's Procedures and Policies and elsewhere—would likely be admissible in court on the issue of the standard of care in granting privileges to gastroenterologists. This is because JCAHO standards for delineating clinical privileges indicate that hospitals must consider an applicant's relevant training.[69] As previously stated, courts are eager to consider compliance with JCAHO standards.

Certification in Gastrointestinal Surgery. For general surgery, the American Board of Surgery (ABS) grants certification and demands qualifications similar to those of ABIM with respect to endoscopy. To be eligible for board certification, a candidate must acquire a significant level of knowledge of those disease areas that "relate[] to disorders of a surgical nature."[70] During a minimum of five years of training in a program accredited by ACGME or the Royal College of Physicians and Surgeons of Canada, trainees must log a minimum of 500 procedures spanning ten "essential content" areas, including "alimentary tract" and "abdomen and its contents," that provide experience with endoscopic techniques, particularly proctosigmoidoscopy, colonoscopy, esophagogastroduodenoscopy, and laryngoscopy.[71] Therefore, board certification in gastrointestinal procedures, for either internists or surgeons, requires (1) specialized medical knowledge of relevant disease areas, (2) extensive and refined diagnostic and procedural skills, and (3) high moral, ethical, and professional character. These stringent prerequisites would likely be admissible in court to establish the standard of care in extending privileges for gastric procedures.

Thus, granting privileges in gastroenterology or gastrointestinal surgery to physicians/surgeons who lack either board certification or the specialized medical knowledge and technical expertise commensurate with board eligibility poses liability risks for hospitals. In theory, a particular physician could be qualified to perform a particular procedure even though the physician lacks the training and experience required for board certification. If a

66. *Id*. at 4.
67. ABIM Policies and Standards.
68. *Id*.
69. JCAHO Manual at MS-16.
70. American Board of Surgery, Booklet of Information 12 (2003-2004) (hereinafter ABS Booklet).
71. ABS Booklet at 10-12.

hospital grants endoscopic privileges to such a physician who later commits malpractice, however, the hospital runs the risk of having to explain to a jury why it extended such privileges in the absence of experience commensurate with that obtained in the subspecialty certification process.

Non-Certified Physicians. As mentioned, hospitals may not be able to limit privileges to physicians who are board-certified.[72] Furthermore, quality of care may improve with physicians whose training and experience exceed board certification requirements but who, for a variety of reasons, have not obtained certification. For example, physicians who trained outside North America and subsequently completed a gastroenterology fellowship in the United States cannot take the ABIM Subspecialty Board Examination. They would first have to repeat their training in an accredited internal medicine residency program, which may prove unacceptable.

Accordingly, both the courts and accreditation agencies have moved away from reliance on board certification alone as a badge for competence. For example, JCAHO eliminated its former focus on board certification as "an excellent benchmark . . . when delineating clinical privileges."[73] It now endorses hospitals where "[p]eer recommendations from the peers in the same professional discipline as the applicant are used as part of the basis for the initial granting of privileges."[74] This shift occurred after cases such as *Greene v. Marchyn*, which held that JCAHO accreditation (with its former emphasis on board certification) does not give rise to a presumption of non-negligence in credentialing.[75] Such precedent suggests that board certification helps to show—but does not alone establish—threshold skills and training. Nonetheless, the burden upon the hospital to establish absence of negligence in credentialing is almost certainly greater when it cannot point to the physician's having attained board certification in the appropriate specialty for the procedure being performed.

Thus, while board certification is a very strong and generally admissible indicator of compliance with the requisite standard of care, certification alone may no longer suffice to absolve hospitals of liability. For example, the jury in *Calli* v. *Episcopal Hospital*[76] found a hospital 27.5 percent liable for a $22,400,000 verdict, even though post-trial interviews revealed that the jurors believed the hospital had met national standards for issuance of credentials and privileges.[77] Thus, certification—and the specialty society guidelines that serve as the basis for certification—may represent the *minimum* qualifications physicians must possess for hospitals to grant privileges. To that extent, specialty society criteria remain significant. They prescribe the baseline level of expertise with which to compare a non-certified applicant's credentials.

72. *E.g., Thomas,* 121 A.D.2d 165.
73. JCAHO MANUAL at MS-11 (2000).
74. JCAHO MANUAL at MS-24.
75. No. 99 CA 2662, 2000 Ohio App. Lexis 4699 (Ohio Ct. App. Sept. 27, 2000).
76. No. 97-08-0251 (Philadelphia County 2000).
77. Medical Litigation Alert (Sept. 2000).

Standards of the American Society of Gastrointestinal Endoscopy. The American Society for Gastrointestinal Endoscopy (ASGE), a professional society of specialists in endoscopic procedures for digestive disease indications, issues publications concerning qualifications for practicing gastrointestinal endoscopy. According to ASGE, "[i]t is critical that the endoscopist receive thorough training in the cognitive aspects of gastrointestinal diseases as well as in the technical aspects of endoscopy."[78] Furthermore, ASGE stresses that "[t]hose performing gastrointestinal endoscopy should be well trained in endoscopy as part of a broader clinical discipline such as gastroenterology, general or colorectal surgery."[79] While ASGE does not insist upon formal residency and fellowship training, alternative methods of skill acquisition must impart a commensurate level of expertise.[80] In particular, alternative pathways must adhere to the "six principles" of endoscopic training: "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."[81] In addition, "[t]raining should be comprehensive and provide a working knowledge of the pathophysiology, diagnosis, and management of digestive diseases for which endoscopic procedures are indicated."[82]

To help assess adequacy of training, ASGE has proposed specific requirements that may be admissible in court to address the standard of care question for gastrointestinal procedures. According to ASGE, competent endoscopists:

(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 knowledge of endoscopic anatomy, technical features of endoscopic equipment, and accessory endoscopic techniques, including biopsy, cytology, photography, and thermal and nonthermal endoscopic therapy;

78. American Society of Gastrointestinal Endoscopy, Appropriate Use of Gastrointestinal Endoscopy (2000) (hereinafter ASGE, Appropriate Use of Endoscopy), at http://www.askasge.org/pages/misc/misc_appropriate_use_endo_00.cfm.
79. *Id.*
80. *See* American Society of Gastrointestinal Endoscopy, alternative Pathways to Training in Gastrointestinal Endoscopy (hereinafter ASGE Alternative Pathways), at http://www.askasge.org/pages/guidelines/tg_alternative.cfm.
81. *Id.*
82. *Id.*

(f) must be able to accurately identify and interpret endoscopic findings; and

(g) must have a thorough understanding of the principles, pharmacology, and risks of sedation/analgesia.[83]

Furthermore:

> 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. . . . Recent prospective studies using objective measures of endoscopic competence . . . have demonstrated that the published threshold numbers are not adequate for most trainees to achieve competence.[84]

For example, one study found that at least 180 supervised procedures were necessary for trainees to achieve competency in endoscopic retrograde cholangio-pancreatography, a much higher number than the previously published minimum of 75 procedures.[85] Therefore, although it recognizes that objective measures of skill have not been developed for all endoscopic procedures, ASGE stresses the use of objective criteria—like board certification—as opposed to "an arbitrary number of procedures." For instance, ASGE believes that flexible sigmoidoscopy—the least complicated endoscopic procedure—may be performed by physicians who are not qualified gastroenterologists but who have received a certain amount of supervised training in the procedure. Nonetheless, ASGE emphasizes the complexity of, and variations among, other endoscopic procedures and asserts that privileges to perform those procedures should be granted on a procedure-specific basis, and only to qualified gastroenterologists or surgeons.[86] Indeed, ASGE recommends that "[p]rior to being granted privileges, an endoscopist should demonstrate competency by undergoing proctoring by an impartial qualified endoscopist."[87]

Finally, ASGE, in several publications, has criticized the use of short endoscopy courses as substitutes for comprehensive training. For example, ASGE has stated outright that "[e]ndoscopic short courses are unacceptable as the principal evidence of competence for granting of privileges. Attendance in short courses should not be considered a substitute for training acquired during a formal residency/fellowship in an accredited training program."[88] These "short courses" neither train physicians adequately to perform complex endoscopic procedures nor raise their level of cognitive expertise with respect to diagnosing and treating gastrointestinal conditions.

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83. ASGE, Appropriate Use of Endoscopy.
84. American Society for Gastrointestinal Endoscopy, Methods of Granting Hospital Privileges To Perform Gastrointestinal Endoscopy (hereinafter ASGE, Methods of Granting Privileges), at http://www.askasge.org/pages/guidelines/pc_methods.cfm.
85. Paul S. Jowell et al., *Quantitative Assessment of Procedural Competence: A Prospective Study of Training in ERCP*, 125 Annals of Internal Medicine 937 (1996).
86. ASGE, Methods of Granting Privileges.
87. ASGE, Alternative Pathways.
88. ASGE, Appropriate Use of Endoscopy.

Such pronouncements by a professional subspecialty association may also impact the issue of the applicable standard of care. JCAHO's Rationale for Standard MS.4.10 provides that in extending privileges, primary sources for the verification of relevant training or experience include "for example, the specialty certifying boards approved by the American Dental Association" and lists the following institutions/associations as "designated equivalent sources" for confirmation: the American Medical Association, the American Board of Medical Specialties, the Educational Commission for Foreign Medical Graduates, the American Osteopathic Association, and the Federation of State Medical Boards.[89] The reference to these organizations appears to be illustrative only, not exclusive, as the Rationale further states that "[o]ther designated equivalent sources may exist for certain applicants."[90] Thus, publications by other associations, such as ASGE and other specialty societies, are also relevant to the decision to grant privileges. As such, it would appear that ASGE's publications would be admissible on issues such as defining the standard of care. Furthermore, courts have held that publications by trade associations that discuss safety standards within an industry are admissible on standard-of-care issues.[91]

Application Beyond Hospitals. Liability for negligence in credentialing/privileging and similar functions is not limited to hospitals. To the extent that other health care entities such as insurance plans, health maintenance organizations, and others assume responsibilities in setting standards, publishing lists of physicians eligible or recommended for specific services, or defining policies about acceptable site(s) for specific medical or surgical procedures, these entities must exercise reasonable behavior and should meet a standard of care analogous to that for hospital credentialing. For example, if an insurance plan contracted primarily or solely with practitioners who were neither board eligible nor board certified in an area of surgery or procedural practice (such as gastroenterology), and encouraged subscribers to utilize one or more such under-qualified practitioners—by listing them as eligible or recommended providers of specialized services, for instance—courts may hold the plan liable for negligent or even intentional misrepresentation. Under Florida, New Jersey, and Pennsylvania law, for example, insurance plans can be found liable for intentional or negligent misrepresentation. These torts require proof only of (1) false representation or omission of a material fact (2) made with knowledge of its falsity or with recklessness/negligence as to its truth or falsehood, (3) that induces plaintiff's reasonable and justifiable reliance.[92] Similarly, in Massachusetts plaintiffs can prevail against insurance carriers/health plans if they show that

89. JCAHO Manual at MS-17 to MS-18.
90. *Id.*
91. *See Andrews v. Burke*, 779 P.2d 740, 742 (Wash. App. 1989) ("[S]tandards adopted by . . . trade associations are admissible on the issue of negligence where shown to be reliable and relevant. . . .").
92. *See, e.g., Gibbs v. Ernst*, 647 A.2d 882, 889 (Pa. 1994); *Huddleston v. Infertility Center of America, Inc.*, 700 A.2d 453, 461 (Pa. Super. 1997); *Wittekamp v. Gulf & Western, Inc.*, 991 F.2d 1137, 1142 (3d Cir.1993); *City of Rome v. Glanton*, 958 F. Supp. 1026, 1039 (E.D. Pa.1997); *Amoco Oil Co. v. McMahon,* 1997 WL 50448 (E.D. Pa.1997); *Carroll v. Cellco Partnership*, 713 A.2d 509, 516 (N.J. App. Div. 1998); *Butterworth v. Quick & Reilly, Inc.*, 171 F.R.D. 319, 321 (M.D. Fla.1997).

"the defendant . . . supplied false information for the guidance of another upon which the plaintiff justifiably relied to his . . . detriment and that the defendant failed to exercise reasonable care or competence in obtaining or communicating the information."[93] Falsity of information can consist of the failure "to divulge all the material facts . . . that lie within [the defendant's] knowledge"—such as the fact that non-board certified providers often lack skills and experience commensurate with their certified counterparts—and "half-truths may be as actionable as whole lies."[94] Alternatively, if an HMO or health plan implicitly or explicitly recommends that its subscribers have surgical or invasive procedures performed in facilities that do not meet JCAHO or Medicare certification standards and lack (1) necessary equipment for resuscitation or for addressing reasonably foreseeable complications or (2) controls on the training of all personnel participating in such procedures, a finding of negligence is also possible.[95]

Conclusion

Hospitals can be held liable for breaching their duty to conduct thorough investigations of physicians applying for clinical privileges. If privileges are granted to an unqualified physician and the hospital should have known, at the time it granted the privileges, that the physician was incompetent to perform the particular procedure, the hospital will have breached its duty. More than half of the states now recognize negligent credentialing and/or corporate negligence as causes of action against hospitals that allow physicians to perform procedures for which they are not qualified. Moreover, the threat of liability under each theory continues to grow. Courts have extended corporate negligence to a variety of medical institutions, including health insurance companies and health maintenance organizations.[96] Concomitantly, it has become more difficult to justify privileges for both board-certified and non-certified physicians.

Courts will admit, on the issue of negligence, evidence of compliance with JCAHO standards, applicable state regulations, and hospital bylaws. Of particular importance are JCAHO standards, as courts, more and more, look to them as providing a national standard of care. JCAHO standards for delineating clinical privileges emphasize training and experience. The subspecialties of gastroenterology and gastrointestinal surgery require a significant amount of training and experience, both in their cognitive and procedural aspects, prior to board certification. ABIM and ABS requirements for board certification in these fields provide an excellent model for judging the knowledge, training, and experience of physicians who are not board-

93. *Cole v. New England Mutual Life Insurance Co*., 729 N.E.2d 319, 323 (Mass App. Ct. 2000).
94. *Golber v. BayBank Valley Trust Co*., 704 N.E.2d 1191, 1193 (Mass. App. Ct. 1999) (citing *Kannavos v. Annino,* 247 N.E.2d 708, 712-13 (Mass. 1969)).
95. Recognizing that certificate of need issues arise in some jurisdictions to preclude actual certification, demonstrated capacity to meet all the stated certification requirements for facility structure, available equipment, and personnel training may be more important than holding the actual certification document.
96. *See, e.g*., *Grobman v. Posey*, 863 So.2d 1230 (Fla. Dist. Ct. App. 2003); *Jones v. Chicago HMO Ltd*., 730 N.E.2d 1119 (Ill. 2000). *See generally* C.P. Michel, *Credentialing Liability in the Managed Care Arena*, 35(1) TORT & LIABILITY INS. L.J.137-53 (1999).

certified. Indeed, although board certification does not confer liability immunity, it serves as an objective and convenient benchmark of training and skill. Courts search for thresholds of expertise and may admit medical society guidelines such as those published by ASGE, accreditation agency regulations, and similar consensus norms to determine the applicable standard of care. These regulations and guidelines either embody certification requirements or reference certification criteria as minimum necessary qualifications. Certification thus attests to a baseline level of competence and helps protect against liability.

To best insulate themselves from liability, therefore, hospitals should extend privileges only to board-certified physicians or to physicians with the degree of experience consistent with and comparable to the standards for board certification in a given, appropriate medical specialty. With respect to endoscopy in particular, this translates into granting privileges only to ABIM-certified gastroenterologists, ABS-certified general surgeons, or non-certified physicians who have attained (1) the cognitive and technical repertoire required to diagnose and treat gastrointestinal conditions, and (2) experience in specific procedures commensurate with (a) either ABIM prerequisites for board eligibility in gastroenterology or ABS prerequisites for general surgery, and (b) ASGE measures of expertise.

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The ASGE guidelines referenced in this document can be accessed on the *ASGE Policy and Procedures Manual for Gastrointestinal Endoscopy: Guidelines for Training and Practice* on CD-ROM. The CD-ROM is available for purchase at www.asge.org/store.

All guidelines are also available online, free of charge, at www.asge.org.

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