CURRENT ENDOSCOPIC PRACTICES – THE EXPERTS SPEAK

Canadian credentialing guidelines for endoscopic privileges: An overview

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A series of credentialing guidelines for gastrointestinal (GI) endoscopic procedures has been developed by the Canadian Association of Gastroenterology (CAG) Endoscopy Committee, approved by the Clinical Affairs Committee, and

reviewed and endorsed by the Executive Board. The individual guidelines will address credentialing for upper GI endoscopy (esophagogastroduodenoscopy), flexible sigmoidoscopy, colonoscopy, endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS), with reference to diagnostic procedures as well as interventional or therapeutic manoeuvres such as polypectomy, dilation, hemostasis and endoscopic mucosal resection. However, there are many issues that are common to all types of endoscopic procedures, and this introductory article will address these common and general principles.

Overall, the credentialing guidelines are designed as general reference documents; they

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are not strict 'rule books' and it should be recognized that there will be exceptions to the guidelines for some aspects of endoscopic practice. However, in the best interest of patients and physicians, it is appropriate and, in fact, expected that all spe-

cific elements of the guidelines should be considered during endoscopic training and, subsequently, when documenting training and experience for individuals applying for endoscopic privileges at an institution.

The CAG does not credential individuals for GI endoscopic procedures; that is the responsibility of the institution or facility at which the individual will undertake his or her endoscopic practice. Therefore, the purpose of these guidelines is to provide a framework that will allow institutions, organizations and departments to assess the training and competence of applicants to perform endoscopy, as part of the credentialing process for the granting of endoscopic privileges. Currently, physicians constitute the

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overwhelming majority of applicants for endoscopic privileges but, in Canada, as in other jurisdictions, one can foresee the training of nonphysician endoscopists, and the principles of credentialing for endoscopic procedures should be consistent for all applicants.

Anecdotal accounts indicate a significant variation among institutions in the credentialing process. This is, in part, because many institutions do not have formal methods for evaluating endoscopic credentials. However, it should also be noted that there are few well-designed prospective trials that are relevant to endoscopic credentialing, and the criteria for assessment of competence are based, largely, on expert consensus opinion combined with large case series or case-controlled studies. Furthermore, decisions on credentialing may be influenced by other factors such as perceived health care needs in under-serviced health care regions. To further complicate matters, endoscopic practice has changed markedly over the past decade, with increased requirements for more technically challenging endoscopic procedures such as colonoscopy, ERCP and EUS, and a greater expectation that endoscopists will perform interventional or therapeutic procedures. Thus, credentialing procedures that were sufficient for determining competence to perform diagnostic upper GI endoscopy may be inadequate for determining competence to perform interventional endoscopic procedures including photoablation or endoscopic mucosal resection.

Regrettably, although many aspects of medical practice are defined by clear, evidence-based standards, this is not the case for endoscopic practice and there are few high-quality data that can be used to underpin credentialing standards for endoscopy. Nonetheless, there are many guidelines and recommendations and, although many of the issues are determined by a lower level of scientific evidence (mainly expert opinion), there are some data that can be used to define standards for specific aspects of training and credentialing.

Methods of privileging for GI endoscopy have been addressed in the United States in the form of guidelines published through the American Society for Gastrointestinal Endoscopy (1,2). The CAG guidelines will address competence in the cognitive and technical aspects of each endoscopic procedure, as well as training issues in endoscopy; when possible, the guidelines will focus on issues relevant to Canadian practice but they will, in general, closely follow the practices established in the United States, the United Kingdom and Australia (1-4).

The credentialing criteria reviewed in the forthcoming guidelines have been evaluated with respect to the performance of endoscopic procedures in adult patients (18 years of age or older), regardless of whether the procedure is performed by endoscopists who have been trained in a formal GI or general surgical residency program, by nonphysician endoscopists or by nonendoscopist physicians. The basic principles of credentialing also apply to the performance of endoscopy by pediatric gastroenterologists in children but the absolute numbers of procedures required to achieve and maintain competence may differ; guidance on credentialing for pediatric endoscopy is, therefore, considered to be the responsibility of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition.

Competence in performing pediatric endoscopy requires three components, just as in adult endoscopy: cognitive, technical and communication. The endoscopist must not only have the technical skills to perform endoscopy, especially in those under the age of 12 years, but they also need to understand the indications for and significance of the endoscopic findings. Unlike in adult endoscopy, there are no studies looking at threshold numbers of endoscopy and outcomes such as reaching the cecum or complication rates. Although some have tried to assign a minimal number of procedures, these numbers are not drawn from reported data. The same difficulty exists with assigning a number of endoscopies needed to maintain competence in pediatric endoscopy.

The pediatric endoscopist must also have experience in sedating younger patients. Even if sedation during endoscopic procedures is provided by personnel who are trained in pediatric anesthesia, the endoscopist must clearly understand the sedation risks of each patient, many of whom may have comorbid problems. In pediatrics, the endoscopist also needs to understand the various bowel cleansing regimens in preparation for colonoscopy and be able to decide which is appropriate for each patient, depending on age and underlying disease. The pediatric endoscopist must be able to communicate results in an age-appropriate manner to children and their parents. Finally, it is best if the procedures can be done in a setting that is accustomed to seeing and managing pediatric patients.

DEFINITION OF TERMS

Privileges

The granting of privileges refers to authorization by a local institution to perform a particular procedure or clinical service. Privileging includes consideration of the applicant's current competence and other factors, including the applicant's scope of practice and the availability of institutional resources.

Competence

Competence is defined as the minimum level of skill, knowledge and expertise, derived through training and experience, that is required to perform a task or procedure safely and proficiently; thus, competence includes the interpretation and management of initial results and the management of complications, in addition to the technical aptitude needed to complete a procedure safely (5).

Competence thresholds

A competence threshold indicates the minimum number of procedures required before the technical component of competence can be assessed reliably. The achievement of the threshold itself does not imply competence. The selected threshold may not guarantee technical proficiency for all endoscopists; some will require more experience while others will achieve competence after fewer cases (6-10). In addition, the definition of a competence threshold, based on the number of procedures performed, will generally only address the technical component of overall competence; it will not necessarily address competence with respect to the cognitive components, such as lesion recognition and procedure-related management decisions.

Currently, the number of procedures completed is the only objective measure that is widely available to assess competence during training and, subsequently, it provides a measure for evaluating maintenance of competence in practice. Complication rates can also be monitored but, although they are clearly important, they are infrequent and they are rarely recorded routinely or in a standardized manner. Other factors

are considered important, but there are no validated objective measures of their magnitude or effect; thus, they will be reviewed in the credentialing documents with the caveat that they are difficult to assess and that they cannot, at the present time, be incorporated into measures of competence.

CREDENTIALING PROCESS

In Canada, it is the applicant's local institution that grants privileges for an endoscopic procedure or clinical service to be performed within that same institution. Privileges should not be granted broadly to permit all endoscopic procedures; instead, credentials should be evaluated independently for each of the individual types of procedures that the applicant wishes to perform. Credentials are documents demonstrating successful completion of a period of education and training, and, when appropriate, maintenance of competence or absence of any impediment to continued endoscopic practice. Credentials are provided by the practitioner for assessment and verification according to the standards set by the institution. As part of the credentialing process, candidates may also undergo proctoring. The proctor is an impartial, qualified endoscopist (see below) who observes the candidate during a specified number of procedures and evaluates the candidate's competence.

There is a clear obligation on the part of the trainee and the training institution to ensure competence in endoscopic procedures, from both a technical and a cognitive point of view (1). In general, competence for a particular endoscopic procedure implies both the ability to perform diagnostic procedures and the ability to perform any appropriate, procedure-related therapeutic intervention. One possible exception to this general rule is flexible sigmoidoscopy, if performed by nonphysician endoscopists, for colorectal cancer screening; under these circumstances, the endoscopists might not be expected or credentialed to perform a polypectomy with cautery or to remove large (1 cm in size or larger) polyps. In addition, not all endoscopists would be expected or credentialed to perform certain advanced techniques, such as endoscopic mucosal resection.

Documentation for credentialing should include evidence of appropriate education and training, as well as documentation of technical and cognitive competence for the particular type of procedure. The specific indicators of competence for colonoscopy, flexible sigmoidoscopy, upper GI endoscopy (esophagogastroduodenoscopy), ERCP and EUS are discussed in a series of companion articles. However, some general principles are outlined below, based on a recognition that credentialing for an endoscopic procedure must address the applicant's preliminary training and cognitive skills. Cognitive aspects of endoscopy include knowledge of indications for and contraindications to the procedure, informed consent, endoscopic anatomy, technical aspects of the procedure, sedation and analgesia, reporting and documentation, integration of the procedure and its results into the patient's care, endoscopic skills, technical skills, the number of procedures performed, the endoscopist's success rates and complication rates, interpretation of the results, therapeutic intervention, and overall patient care (1).

Appropriate training

Typically, training is conducted through a preceptor (recognized authority) and it should be assessed at various levels. The actual technical performance of the procedure may, in some cases, constitute the most rudimentary level of care provided. An understanding of the indications, contraindications and alternatives, including their role in the overall management schemata, as well as postprocedural follow-up care, are critical components of the procedure process.

Credentialing should require appropriate documentation of the completion of a formal training program (residency or fellowship), or equivalent training in other settings (7,11-13). As technology advances, and the complexity and demands of endoscopic procedures increase, retraining in various modalities will be required.

The American Society for Gastrointestinal Endoscopy has recommended that, once an applicant has been granted privileges to perform one or more endoscopic procedures, renewal of privileges should be based on adherence to recredentialing guidelines; this would require documentation that the applicants have maintained their endoscopic skills by requiring them to report the number of procedures performed, along with the associated success rate and complication rates, and a record of their educational activity and participation in continuous quality improvement (1).

Technical and cognitive aspects

Competence requires both cognitive and technical components. For example, to perform a safe and effective colonoscopy, the practitioner must determine whether colonoscopy, rather than fecal occult blood testing, radiography, flexible sigmoidoscopy or computerized tomography, is the most appropriate procedure. The decision to offer colonoscopy must then account for the patient's personal characteristics and wishes, the likelihood of complications balanced against the probability of benefit, and the practitioner's assessment of his or her own technical skills in completing the procedure and performing any necessary interventions.

Technical skills refer to the ability to perform the procedure proficiently. For credentialing, this can be assessed by using the numbers of procedures performed by the applicant (including findings and interventions), the success rate (eg, proportion of colonoscopies completed) and complication rate (5). Cognitive skills refer to an understanding of indications for and contraindications to the procedure, management alternatives, the nature, location and importance of any findings, consent, sedation, reporting and documentation, recognition and management of complications, and integration of findings into patient care (including early management, appropriate referral and appropriate follow-up) (5).

An understanding of appropriate indications is critical to the performance of all endoscopic procedures. Complications are rare but, in the event that a 'sentinel event' (an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof) (14) is identified, the indication for the procedure is often an important consideration when assessing an endoscopist's performance and skill in the overall management of the patient. The acquisition of cognitive skills may be as important as the acquisition of technical skills in determining the appropriate duration of training for endoscopic procedures.

Proctoring

A proctor is an impartial, qualified endoscopist who observes or supervises the candidate while he or she performs a predefined number of endoscopic procedures. Proctoring is not a substitute for training; the role of the proctor is to evaluate, not to teach and not to help with the procedure. Proctoring should occur after the candidate's competence has been assessed. There is no mechanism to define how many procedures should be proctored directly for all individuals, and it is unlikely that a specific number of supervised procedures can be defined because the indications for proctoring will vary between practitioners. However, because the proctor must assume considerable responsibility for the competence decisions, it may be reasonable for the burden of evaluation to be shared with one or more additional proctors. In addition, regardless of the proctor's assessment, it is highly recommended that the practitioner's technical and cognitive performance continue to be monitored for several months after privileges have been granted.

MEDICO-LEGAL ISSUES

Although there are regional variations in access to care, maintaining a uniform minimum quality of care requires that competence be evaluated in a standard manner, independently of any considerations as to the perceived effect of the evaluation on an institution's or a population's access to a

specific procedure. Endoscopists, like other health care practitioners, are expected to practice to a standard of care and this standard pertains to routine care, regardless of the availability of local resources. The 'standard of care' is a legal concept that defines the limits of an endoscopist's practice. Practicing within the standard of care is the endoscopist's best legal defence in the event of complications or problems, and failure to do so is considered a breach of duty and one of the elements of proof that a plaintiff requires to win a malpractice claim (1).

As previously indicated, there are only limited data that can be used to define evidence-based standards for endoscopic practice. Consequently, the standard of care in endoscopy can be described as the practice that is customary among competent gastroenterologists who are in good professional standing and are practicing with reasonable diligence. Guidelines (ie, practice parameters) are available for endoscopy in several jurisdictions and they typically form the basis for the legal standard of care. From a risk management perspective, endoscopists must be aware of guidelines and they should document any deviations in their practice from the published standards, including the reasons for any specific deviation.

Responsibility of the institution

The endoscopist is responsible for ensuring that he or she practices to the standard of care. However, the institution that grants privileges also has a responsibility. In the 1965 case of Darling versus Charlestown Community Memorial Hospital (15), the Illinois Supreme Court upheld a lower court ruling that a hospital owes an independent duty in granting privileges and monitoring the competence of its physicians. As a result, a majority of American jurisdictions adopted the concept of 'corporate negligence' for hospitals (1). Liability for 'negligent credentialing' applies when hospitals "extend privileges to unqualified physicians who then commit actual malpractice" (7). The 'reasonable' credentialing process for a hospital involves ensuring that the applying physician is indeed the person referred to in the credentialing documents, that the credentials claimed are actually held and that the credentials have not been previously challenged; the institution should also ensure that it obtains relevant data on training, experience, board certification and licensure (7). Current competence should be documented by peers who are knowledgeable about the applicant's professional performance (7). An effort should be made to incorporate into the accreditation assessment the endoscopist's success rates in procedures and, when available, a comparison of practitionerspecific data to aggregate data, including morbidity and (if appropriate) mortality (7).

SUMMARY AND CONCLUSIONS

GI endoscopy comprises a variety of endoscopic procedures that include both diagnostic and therapeutic or interventional components. The ability to perform these procedures proficiently requires both technical and cognitive skills, which are generally acquired through formal training with subsequent consolidation or improvement of skills in clinical practice. Documentation of these skills is the basis of acquiring credentials for one or more endoscopic procedures and it is these credentials that permit the granting of privileges such that an endoscopist may undertake these procedures in clinical practice. The CAG has developed a series of guidelines for credentialing in endoscopic procedures

to aid practitioners and institutions in the process of acquiring or granting privileges; however, it is the individual institution or facility, not the CAG, who grants these privileges.

The guidelines are consistent with those developed by other national professional bodies and, like other endoscopic credentialing guidelines, they are based predominantly on the application of expert opinion regarding the numbers of procedures required to achieve competence. As such, the current guidelines provide a consistent basis for all institutions that may wish to grant privileges for endoscopic procedures and it is hoped that this will lead to a greater degree of uniformity in evaluating credentials and granting privileges. However, it should also be recognized that there are a number of deficiencies in the current process. There is a need for a more standardized and comprehensive evaluation process to document the competence of trainees at the completion of their training program; this process should include formal documentation of trainees' technical skills in completing procedures proficiently and performing appropriate therapeutic interventions, as well as their cognitive skills in determining appropriate indications, lesion recognition and management

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consequences. There is also a need for continuing evaluation processes, which will allow practicing endoscopists to document maintenance of competence as a basis for renewed granting of privileges at the same or another institution. Development of these evaluation processes is no small undertaking but it is critical to the continued development of a safe and effective endoscopic practice in Canada, particularly with the prospect of widespread colorectal cancer screening and surveillance, and the continued development of new endoscopic techniques and standards.

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