

# ADVANCES IN ENDOSCOPY

Current Developments in Diagnostic and Therapeutic Endoscopy

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## Standard of Care in Endoscopy

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### G&H What is meant by the term standard of care, and why is it important?

**JB** Standard of care is a legal term that refers to what a reasonably prudent physician, with the same or similar experience and training in the same or similar community, would be expected to do. All physicians, not just gastrointestinal endoscopists, need to know the standard of care in their practice, be it general or specialist. Adherence to the standard of care is necessary to ensure patient safety and avoid litigation in the event of a lawsuit for alleged medical malpractice.

### G&H How is standard of care established?

**JB** Standard of care varies on a local, regional, and national level. A local expert may be called upon to review the management of a case handled by another physician, though frequently an expert based at a referral (tertiary) center is consulted. Although the law courts are primarily interested in the standards of a particular community, the Standards of Practice Guidelines promulgated by physicians' professional organizations represent accessible benchmarks. For endoscopists, the Practice Guidelines of the American Society for Gastrointestinal Endoscopy (ASGE) are invaluable. Every endoscopist should be familiar with these guidelines and should practice within them. Defense of alleged malpractice is easier if an endoscopist has adhered to ASGE guidelines. The guidelines can be accessed through the ASGE web site, [www.asge.org](http://www.asge.org). Although it is not necessary to be a member of the ASGE to access their practice guidelines, every endoscopist should consider joining the ASGE for member benefits such as a free subscription to the premier English-

language endoscopy journal, *Gastrointestinal Endoscopy*, reduced registration fees at Digestive Disease Week, local, regional and national courses and workshops, and the Society's political advocacy on behalf of all endoscopists.

### G&H How can community gastroenterologists avoid deviating from the standard of care?

**JB** An endoscopist can often avoid inappropriate or dangerous interventions by calling a local or regional expert to discuss a technically demanding case. Every expert I know is willing to take these calls, which are often made from the endoscopy suite or radiology department when an endoscopist realizes that they are outside of their comfort zone. For example, I have received calls from physicians regarding placement of permanent metal mesh stents for benign biliary strictures, a questionable practice that has not yet undergone clinical trial, or preparation for a needle-knife papillotomy without having prior supervised experience. Endoscopists working in the community should resist the temptation to be "creative." Performing aggressive maneuvers without prior supervised training and experience only invites the possibility of complications that may subsequently prove difficult to defend. Community gastroenterologists are encouraged to develop a working relationship with their local or regional experts to ensure that their endoscopic interventions are appropriate and effective.

### G&H Why is it that professional societies representing gastroenterologists do not have panels of experts available to defend their members in medicolegal cases?

**JB** This is a commonly asked question that has no simple answer. The laws governing medical malpractice litigation are complex and vary considerably across the United

States. States limit who can be accepted by their courts as an expert witness and how much of their time can be spent doing this. Physicians who have retired, or who have not participated in clinical practice for several years (typically 3 or more), may be ruled to be ineligible to offer expert testimony. The court may require the expert to practice within the state where the alleged malpractice occurred or in a contiguous state. As being an expert witness in a medicolegal case can be very time-consuming, many qualified individuals, particularly those with busy practices, do not participate at all; others strictly limit the number and types of cases they will review. Experts from the same professional society often try to avoid being pitted against each other in court (as experts for the plaintiff or defense). The list of issues goes on and on.

The major professional societies help protect their members against malpractice claims by promulgating guidelines for safe practice. As indicated above, in North America, ASGE guidelines are widely regarded as the benchmark for endoscopic procedures and related activities (eg, endoscope disinfection, intravenous sedation). These documents are carefully researched and written by committees of experienced physicians, reviewed and approved by the governing boards of the societies, and promulgated in print publications and via easily accessible web sites. Our professional societies cannot, and do not, provide expert witnesses to review cases and act on behalf of members facing litigation for alleged malpractice. However, endoscopists who adhere to published national practice guidelines can have some confidence that they will meet the local standard of care, deviation from which is the legal litmus test for negligence.

#### **G&H** How is the standard of care determined for a new endoscopic procedure?

**JB** Until a new endoscopic procedure has been shown in carefully designed research studies to be safe and effective, reports in the endoscopic literature typically conclude with a warning that the procedure should be regarded as experimental and that evaluation is ongoing. If the procedure is associated with potentially severe complications (eg, endoscopic debridement of pancreatic necrosis), it will likely be identified as “for experts only.” When it appears likely that a new procedure, or a modification of an existing procedure, will be widely adopted, practice guidelines are developed and promulgated by the ASGE. Even an extension to an existing procedure requires practice guidelines. Care must be taken to avoid competence creep. For example, the ability to perform flexible sigmoidoscopy safely and competently does not entitle a physician to bypass the additional supervised training necessary for colonoscopy. Adding a therapeutic inter-

vention to an established diagnostic procedure usually requires some mentoring or additional supervised training. When in doubt, a call to a local expert will usually clarify the situation. It is wise not to make assumptions when extending the range of one’s endoscopic skills.

#### **G&H** What other steps can physicians take to guard against the appearance of negligence, particularly when guidelines do not exist for a particular procedure?

**JB** In a court of law, the opinions of expert witnesses carry significant weight. Hopefully, these experts are reasonable and prudent individuals who will take a balanced view of the events involved. However, the adversarial nature of the process means that the experts for the plaintiff and defendant will usually disagree. At the end of the day, the better-prepared, more impressive witness will often determine a jury’s decision. In everyday practice, it is helpful to consider how deviations from the normal routine may appear to outside assessors or a jury. For example, I am not aware of any practice guideline that mandates the use and retention of radiograph images during endoscopic retrograde cholangiopancreatography (ERCP), but when medicolegal cases revolve around failed procedures, the question often arises whether the failure to obtain or keep images was a deviation from the standard of care. Most endoscopists have experienced, at least on occasion, technical difficulties during endoscopy that resulted in lost images or tissue specimens. This is not malpractice. However, to avoid the impression of carelessness or disinterest, an endoscopist should always document and explain such untoward events carefully in the permanent record. Records are always carefully scrutinized in legal cases, and failure to document actions may be considered evidence that they were not performed. Of course, if an endoscopist has a habit of failing to document their activities, losing biopsies, and so on, and these findings come to light during a trial, a competent lawyer will have little difficulty convincing a jury that the endoscopist is not a reasonable or prudent physician. Procedure reports should always be dictated or entered into a database in a timely fashion. When serious complications occur, reports prepared much later, with the benefit of hindsight, are usually exposed in court for what they really are: attempts to avoid blame (exculpatory statements) for acts of omission or commission.

#### **G&H** When does a new procedure or modification of an existing one become the standard of care?

**JB** This is a thorny issue. Some real, and more self-styled, experts are quick to declare their published research



findings to be the new standard of care. Wise journal editors discourage this, as the term standard of care highlights the issue in terms of the medicolegal radar screen. The pendulum of expert opinion swings back and forward frequently in the years following such declarations, and some of them prove to be plain wrong. More often, however, the declarations need significant modification and qualification. This is why practice guidelines that become standard of care should be forged by committees of experts after review of a body of literature. A good example of the rush to standard of care is the use of prophylactic pancreatic duct stents to minimize post-ERCP pancreatitis. After a number of studies showed the benefit of these stents in high-risk cases, some commentators declared that they were now standard of care and that it might well be negligent not to use them. The fact is that it is sometimes technically difficult, or even dangerous, to

place pancreatic duct stents due to unfavorable local anatomy, and stents certainly do not need to be placed after every ERCP. Lawyers avidly read our literature and know that failure to place a pancreatic duct stent in a patient who subsequently develops severe post-ERCP pancreatitis is a chink in our medicolegal armor. If an endoscopist performs ERCP in a high-risk setting and tries, but fails, to place a prophylactic pancreatic duct stent, or elects not to do so for whatever reason, it is wise to document this at the time in the written record, as the endoscopist will surely be asked about it in the event of future litigation.

*Dr. Baillie is a member of the Governing Board of the ASGE, but the views expressed in this article are his own and do not necessarily reflect the position of the ASGE or any other professional society regarding any of the subjects discussed.*