

Excellence in GI Endoscopy

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The vision and mandate of Surgical Excellence is to recognize Centers that reach and exceed defined standards of performance in several areas of surgery. It is logical now to extend this vision to GI Endoscopy, and I am very pleased to be able to participate in the project.

Gastrointestinal endoscopy has become enormously popular throughout the world because of its tremendous and proven value in diagnosis and treatment. The problem is that the benefits are maximized only when procedures are performed at an optimal level of quality, which is not always the case. Sadly there are practitioners and endoscopy centers whose performance and outcomes are well below acceptable standards. Technical failures and serious complications can occur in the best of hands, but are more likely when procedures are performed by endoscopists with inadequate training and experience, and in unsuitable environments. Practitioners, patients and payers should all be interested in enhancing the quality of endoscopy, and documenting it.

The professional organizations associated with endoscopy and their leaders have increasingly embraced the quality improvement paradigm that is advancing through medicine, as it has through manufacturing industry (1-4). The American Society for Gastrointestinal Endoscopy (ASGE), and the American College of Gastroenterology (ACG) have produced helpful reports and guidelines (5,6). Britain and Australia have taken a step further in setting up authorities which represent all of the stake-holders, ie the Joint Advisory Group (JAG) (7), and the Conjoint Committee in Australia. The problem is that most of the thoughtful conclusions and well meaning documents from these organizations have had little impact so far in the real world. Quality is discussed, but not measured to any extent, and certainly not mandated. Hospital privileging bodies do not always follow published guidelines for credentialing (8).

It is time to develop a data-driven system for recognizing those endoscopists and endoscopy centers which can be proven to excel. We owe it to our patients.

What is quality endoscopy?

Society (ie the informed patient) expects that diagnostic and therapeutic procedures will be appropriate (ie indicated), and that they will be performed expeditiously, skillfully, successfully, safely and comfortably (9). These expectations can be expanded to make a list of desirable characteristics for all types of endoscopic procedures.

- Correct indications – adherence to published guidelines
- Appropriate environment, support team and behavior
- Well prepared and informed patients
- Strategies to minimize risk, including patient preparation and monitoring.
- Appropriate use of medications, including sedation/analgesia when used.
- Correct selection of equipment

- Comfortable intubation
- Complete survey of the target organ(s)
- Recognition of all abnormalities (and photo documentation)
- Appropriate tissue sampling (adherence to published guidelines)
- Application of indicated therapy
- Avoiding, recognizing, and managing, complications
- Reasonable duration
- Smooth recovery, explanation and discharge
- Detailed and clear recommendations and follow-up plans
- Integrated pathology results and communications
- Complete documentation (and billing)
- Positive feedback from patients

Many organizations and groups have explored these quality issues and their metrics (3, 10-18). The ASGE has published guidelines for credentialing physicians and granting privileges to perform endoscopy (19-21). The report from the NIH “state of the science” conference on ERCP made many comments on quality issues (22).

Endoscopy is a team performance, but we will discuss endoscopists and endoscopy units separately.

Excellent endoscopists.

Formal endoscopic training and extensive experience do not guarantee excellent endoscopy practice, but they certainly make it more likely. Thus, documentation of these and related elements should be a part of any assessment of endoscopists. Appropriate metrics could include

- Specialty training and certification (place and dates)
- Training and maintenance of competence in life support and sedation
- Evidence for continuing education in endoscopy
- For each type procedure (eg ERCP, colonoscopy) – lifetime numbers, total last year, and spectrum of practice

The proof of quality comes from documentation of performance. There is no substitute for collecting relevant data (23). Trainees in most countries are now expected to maintain logbooks of their procedural activity during training, and the ASGE and other authorities have recommended that endoscopists should collect data prospectively on their endoscopic practice and performance (3). This translates into “endoscopy report cards” (24).

Report cards and benchmarking performance

Report cards cannot possibly include all of the data elements that have been listed in various well-meaning publications. Items should be selected based on ease of data collection, and by assumed relative importance (25,26). Some items are easily recorded, and already appear in most procedure reports (e.g. indication, anatomical extent, duration, diagnosis, immediate

unplanned events). Other items are more subjective (e.g. lesion interpretation), or more difficult to record (e.g. delayed complications, endoscopist-specific patient satisfaction). Some items would appear to be more important markers of quality than others. For colonoscopy, cecal intubation rates, and minimum withdrawal times, appear to be particularly relevant (15). For ERCP, selective cannulation and complication rates, are obvious key parameters.

Once several practitioners agree to share their data, they can compare their practices and levels of performance. Benchmarking means comparing the performance of an individual endoscopist with that of his or her peers and “competitors”. This requires an organization as well as motivation.

Further details are discussed in the context of ERCP, which is the most challenging (and risky) of the commonly performed procedures.

The ERCP quality network.

With the support of Olympus America, we set up a pilot project to test the practicality and acceptability of collecting and comparing data on the practice and quality of ERCP procedures by individual endoscopists. Baseline information included the experience and practice environment of the endoscopists. Data on each procedure are loaded onto a secure website, prospectively, either directly or via a single paper data sheet. The data points include the indications, complexity grade, ASA grade, sedation/anesthesia, admission policy, scope and fluoroscopy times, and success rates for individual technical procedures such as deep biliary cannulation, sphincterotomy, stenting, etc. Immediate and delayed complications are noted. There are no patient identifiers. The data are analysed automatically, and results posted immediately on the web site. Contributors can view a summary of their own performance (report card), and compare it with that of all other contributors to the system (benchmarking), not identified by name. Now, more than 150 ERCPists from several countries have entered data on over 25,000 cases. An example of a key metric, biliary cannulation rates, is shown in Figure 1.

What performance level is good enough? Who decides?

The ERCP quality project has confirmed the obvious fact that endoscopists vary in their levels of performance, even amongst those comfortable enough to share their data. Not all patients can be managed by the super-experts. The issue then is how to determine who decides what constitutes acceptable performance and what that should be. Professional organizations initially guessed (far too low) at the “numbers” needed to achieve competence, but have recently concentrated on what might be acceptable performance, ie the skill level that would justify independent practice (completion of formal training). The latest ASGE report on ERCP quality (26) paints a broad canvas “Successful cannulation rates at or above 95% are consistently achieved by experienced endoscopists, and rates at or above 80% are a goal of training programs....Thus, although >90% is an overall appropriate target for successful cannulation, rates of >85% should be achievable for most endoscopists”. It goes on to say that “Technical success for common (biliary) procedures should be achievable in >85% of cases”.

Who is going to do YOUR ERCP?

Are we all comfortable with the fact that a lot of ERCP procedures will continue to be done by marginal endoscopists, especially bearing in mind that the less experienced also have more complications? Would you let your recent trainee loose on your family? Would you yourself submit to an 80-85% ERCPist, or allow your mother to do so? This level of performance would be acceptable, maybe life-saving, in an urgent and remote situation, but certainly not for an elective procedure when experts are available nearby. I would suggest that 95% is an appropriate target, at least for the standard biliary procedures. How can patients make an informed judgment since they have no way of telling the difference between an 85% and a 95% performer. Those of us in health care have ways of knowing who is “good” and who is not, but most of our customers do not. They rely on advice from their primary care givers (and friends), and the honesty and communication skills (sometimes inadequate) of their proposed endoscopists. I believe that we need to do better, and there are only two ways forward. One is for professional societies (and the payers) to set the bar higher, and to press for a certificate or diploma, to be granted only after a formal examination. This would be resource intensive, and not without controversy, but exams are the recognized method for assuring a reasonable level of knowledge and performance in many other fields. The diploma would be based on data from report cards, an examination of core knowledge, observation of a few cases, and, possibly, some work on simulators. This exercise would require agreement on how to “score” the more subjective elements of a procedure. The second method – and a step towards the first - is to encourage or mandate report cards, and to educate the public to ask for them.

Surgical excellence intends, in collaboration with relevant professional societies, to provide a method for recognizing excellent endoscopists and centers.

Benchmarking in Colonoscopy.

Pike in Virginia, USA, has been running an important voluntary benchmarking project focusing on the quality of colonoscopy procedures (27). This has the same main goal as the ERCP study, to allow individuals to benchmark their performance against colleagues and guidelines, but differs in that there were many more data points, entry was on paper, delayed data were required (pathology reports), and that the analyses were not done on-line, and reported only intermittently.

These projects, and the rising tide of professional opinion, led the ASGE and ACG to initiate a joint national system for benchmarking, called GIQUic (28). This opened for enrollment in July 2010, and focuses on colonoscopy. ERCP will be incorporated along with other procedures eventually, and the ERCP Quality Network will cease at that point. In the meantime, it remains available as a viable resource for personal quality assessment and improvement.

Conclusion

No one involved in endoscopy doubts the importance of ensuring the highest possible quality of our processes and procedures. Many patients assume that any doctor offering a

procedure is competent to do it, and that all facilities are equally safe (although some may look less appealing). The very simplicity of endoscopy as a “walk-in, walk-out” procedure can lull patients and practitioners alike into a sense of false security. Bad things can and do happen. Our profession must work harder to encourage the collection and dissemination of performance data. The fact that some endoscopists will be reluctant to document and advertise their performance should not stop us from doing the right thing. We should wear our data plainly and proudly as badges of quality. It will pay huge dividends eventually.

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Excellent endoscopy units

Patients are concerned about their safety, comfort and dignity during endoscopy, and the efficiency of the process. Whilst endoscopists have responsibility for these elements, and can influence the way the rest of the team functions, there are important quality elements of the endoscopy unit and staff that can be considered separately. Endoscopists (however talented) cannot work without good facilities, equipment, and a team of well-trained and motivated staff. Whilst most healthcare facilities pay some attention to “quality improvement”, the extent to which this percolates down to the endoscopy unit is variable. There has been no national quality improvement program specific for endoscopy units in the United States, and the agencies which accredit them do not have comprehensive guidelines.

Metrics of quality in endoscopy units

It is not difficult to list features of endoscopy units which may impact the quality of the procedures being performed in them.

- 1) Years unit existed
- 2) Nature; hospital, freestanding endoscopy clinic, or office
- 3) Accreditation agency (and most recent rating)
- 4) Name of medical director
- 5) Name of nurse manager
- 6) Volumes last calendar year (uppers, colons, ERCP, EUS)
- 7) Number of procedure rooms and patient bays.
- 8) Total number trained nursing staff (levels)
- 9) Written policies and systems for
 - sedation and monitoring

- cleaning and disinfection
 - risk reduction
 - patient recall for surveillance
 - tracking pathology results
 - quality improvement
- 10) Safety data
- Infection rates
 - Unplanned intubations
 - Unplanned admissions
- 11) Communications and feed-back
- No-show rates
 - Patient satisfaction data
 - Staff satisfaction data

An “Endoscopy Unit Report Card” could be developed by picking a selection of these criteria (1).

Measurement of Endoscopy unit Quality

As part of the Endoscopy Modernization process in Britain, a “Global Rating Scale” for endoscopy units was developed by Dr Roland Valori (2). The system is backed-up with a comprehensive knowledge base, and useful improvement tools. Sequential measurements in almost all the British endoscopy units over six years have shown gratifying and progressive improvement in the results.

In USA, the ASGE has initiated a system for “recognizing units” (3). To obtain recognition, a representative from the unit (doctor or senior nurse) must attend a 2 day seminar on key quality topics, and agree (in writing) to comply with the comprehensive ASGE guidelines in this context. The majority of endoscopists in the applying unit must be ASGE members. This program has been popular and many hundreds of units are now officially recognized. Emphasis is placed on quality improvement projects and processes.

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New endoscopy reporting metrics

Performance assessment must be data-driven, a fact that has stimulated many people and professional groups to develop appropriate quality metrics (as detailed in the first section). The ASGE Quality Committee recently sponsored three working parties to work on different aspects.

Complexity scales. It is self evident that some endoscopy procedures are more difficult than others. In general ERCP is trickier than EGD, but there are large variations within each main class. We recently published new complexity scales for all of the main procedures (1). This will make it easier to stratify results.

Adverse events. Complications occur, and must be documented in a way that allows meaningful comparisons between practitioner and time periods. The latest recommendations are published (2).

Predicting adverse events. The likelihood of adverse events is influenced by the complexity of the procedure, the skill of the endoscopist, and the health status of the patient. Data on the importance of patient risk factors and suggestions for a basket of metrics, are published (3,4).

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Figure 1. Comparison of deep biliary cannulation rates of individual providers in the ERCP Quality Network.

Deep Biliary Cannulation Success Rate

