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QUALITY ASSURANCE AND QUALITY IMPROVEMENT

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Efforts to maintain and enhance quality in medicine have evolved significantly in the last several generations. Systematic efforts to improve quality, with attention to structure, process and outcomes of delivery began in the 1960s. Following the lead of quality gains in manufacturing, the health care industry subsequently embraced a number of all-encompassing and proactive concepts, including *continuous quality improvement (CQI)*, best described as a systematic approach to ongoing measurement, evaluation and improvement of all products and services throughout an organization, and *total quality management*, emphasizing CQI as well as strategic planning, innovation and involvement of all members of a team or organization. Three reports by the Institute of Medicine (IOM) influenced the current environment by defining national problems with errors, safety, variation in practice and lack of accountability in health care. The IOM defined three parameters of quality, including (1) *safety*, or freedom from accidental injury, (2) *practice consistent with present medical knowledge*, or use of evidence-based medicine, and (3) *customization*, or meeting customer specific values and expectations.

This focus on quality improvement now encompasses all areas of medicine. Endoscopists are not exempt from this process. Indeed, the American Society for Gastrointestinal Endoscopy (ASGE) and its sister societies have taken leadership roles in developing tools for endoscopic quality assessment. Quality measures for the technical performance of colonoscopy were published by the US Multi-Society Task Force on Colorectal Cancer in 2002. In 2006, collaborative guidelines were published recommending quality indicators for endoscopic care in general and for specific issues pertinent to colonoscopy, upper endoscopy, endoscopic ultrasound and endoscopic retrograde cholangiopancreatography (ERCP).

Management for Quality Improvement

Managing a unit from a quality perspective is a multifaceted task. Achieving and maintaining optimal quality depends highly on leadership and communication of strong support from the top of an organization. Administratively, quality improvement requires attention to external quality mandates and opportunities and provision of internal vision, advocacy, planning and oversight for the organization. For an endoscopy center, this means the owners or partners and senior on-site management should be conversant in, supportive of and

vocal about quality expectations and goals and should model desired behaviors and practices. Larger centers may place quality assurance and improvement issues in the hands of a nonphysician manager while smaller units will typically retain this activity for the managing partner. External issues pertinent to quality include mandates from regulators, payers and accrediting organizations. Guidelines from the Centers for Disease Control and the national gastroenterology societies, National Patient Safety Goals from the Joint Commission and national quality measures promulgated by several quality advocacy organizations are among the highly visible quality expectations that should be monitored for guidance. The Physicians Quality Reporting Initiative (PQRI) from the Centers for Medicare and Medicaid Services (CMS) will be discussed in more detail.

Requirements for effective, focused quality improvement efforts include:

- Recognition of current gaps in delivery of care and needs for improvement
- Motivation and leadership toward addressing the identified gaps
- Thoughtful definition of the problem and contributing factors
- Accurate and timely data
- A map or plan toward the desired endpoints
- Transparency and accountability throughout the improvement process

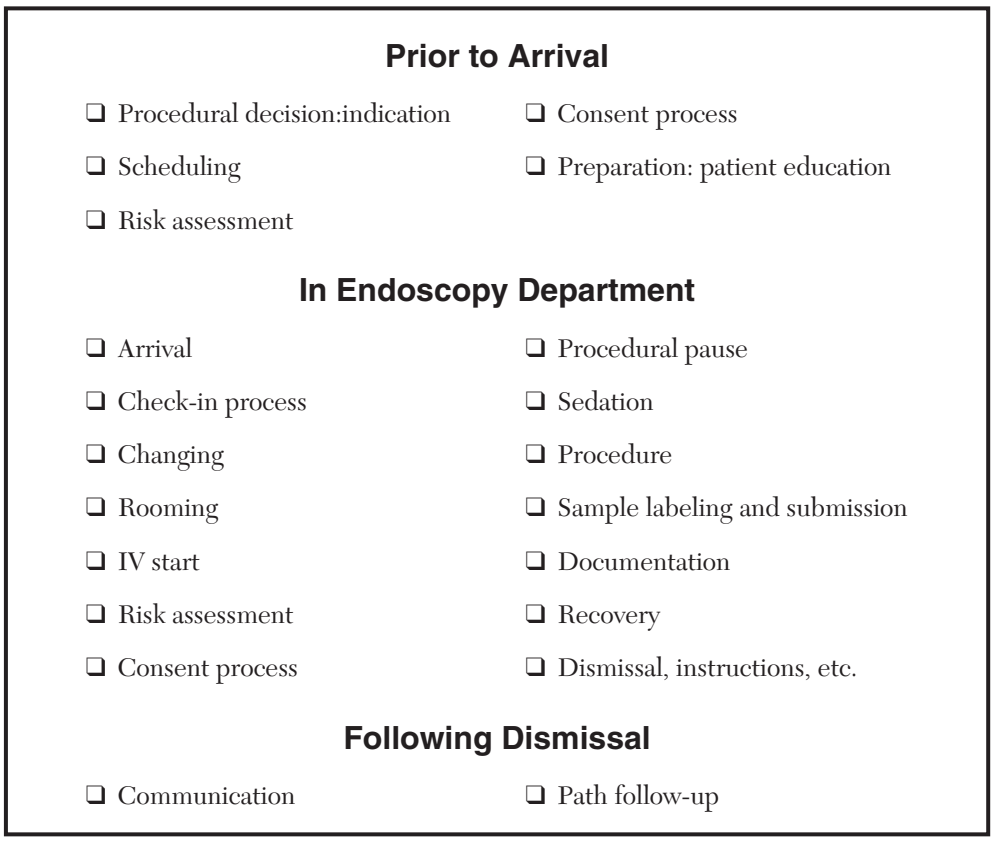
Several of these points will be discussed in greater detail throughout this chapter. The motivations to improve are multiple and may be highly altruistic or mandated and required for continued business survival. Usually, sustained business success requires public respect as a quality provider and avoidance of legal entanglements related to staff or provision of care. Transparency and equitable treatment of staff are important ways to gain insights from all perspectives, to engage all members of a workgroup and to maintain workplace morale. Lack of both individual and managerial transparency and accountability can be damaging to change efforts.

Identifying Quality Improvement Needs

Every facility has process, service or outcome issues that can be improved. Indeed, accreditation organizations recognize this and typically require evidence of quality improvement mechanisms and examples of recent initiatives. Opportunities for improvement are usually apparent and can be readily identified by staff members and patients alike based upon known inefficiencies, problems with communication or recent adverse events. Other means toward their identification include the use of patient questionnaires, scrutiny of local data pertaining to the steps in delivery of endoscopic services (see Figure 18-1), or careful consideration of the measures defined by national organizations, including the published ASGE and American College of Gastroenterology (ACG) guidelines. Most facilities are limited by the number of issues that can be adequately addressed at one time. Hence, quality improvement needs and potential improvement efforts should be prioritized to identify those with greatest urgency and impact.

The particular projects to be undertaken are largely specific to the local facility; hence, it is difficult to recommend a list of improvement projects that all ambulatory endoscopy centers should undertake. Nevertheless, some projects provide universal benefit. At a minimum, all endoscopy facilities should ensure optimal performance in those matters central to their mission, such as the quality of the endoscopic procedures, and in several high risk areas, such as infection control practices, endoscope reprocessing, sedation management and

Figure 18-1
Steps in Delivery of Endoscopic Services That Warrant Oversight and Possibly Improvement Efforts



routine pre- and postprocedure management of antibiotics, anticoagulants and other medications. These elements of practice are generally easily managed if attention is paid; yet they carry significant risk to patients and the practice in the event of lapses in performance.

Quality Measures: Design and Use

Modern quality endeavors now refer to the parameters or indicators used to grade and track quality as *measures*. In single practices, the definition of most measures is straightforward; they represent an objective data-oriented expression of the problem at hand. In large populations or aggregated practices, careful formal definition helps guide subsequent data acquisition. *Quality measures* are formally defined as a numerator and a denominator; the numerator representing the frequency of a given finding (occurrence, practice or outcome) and the denominator representing the overall number of opportunities for that finding in a population of interest. Optimal quality measures are relevant, evidence-based, reliable or reproducible, valid and feasible.

Measures are often categorized as structural, process, or outcome measures. *Structural measures* are probably the easiest to assess because they define the health care environment, including facilities, equipment, staffing, expertise, written policies and procedures. They are typically scrutinized during the accreditation process. In gastrointestinal (GI) endoscopy, they could include data pertaining to credentialing and privileging records, reprocessing facilities, equipment and equipment records, availability of age appropriate resuscitative equipment

and policies for use. *Process measures* are focused on optimal performance, based upon accepted standards and evidence-based definitions of best practices. Examples of process measures in GI endoscopy include the proportions of patients who undergo screening colonoscopy at appropriate intervals following their prior procedure and the proportion of procedures for which a complete report is documented on completion, including use of a preprocedure risk assessment tool, notation of the quality of preparation, the maximal distance examined and full descriptors for pathologic findings. *Outcome measures* identify the results of care delivered from the patient perspective. These tend to be indirect measures of overall quality, and they can be altered by factors beyond the control of caregivers. Outcome measures are often evaluated in reference to overall episodes of care for a given problem over an interval of time, such as a hospitalization or an illness with a defined timeframe. Examples of outcome measures in GI endoscopy might include the proportion of patients with repeated bleeding from peptic ulcers following initial endoscopic and medical therapy or the proportion of patients with resolution of dysphagia following endoscopic dilation for a given type of esophageal stricture. While structure and process measures are more easily evaluated and altered by specific interventions, their goal is obviously improvement in patient outcomes; hence, their validity is related to their correlation to outcomes.

Many organizations monitor ongoing performance by tracking several overarching structural, process and outcome measures. When collated into timely summaries as trends on run charts or more formal control charts, these data constitute a dashboard or scorecard of current performance and trends over time. This monitoring effort may provide early identification of emerging problems before their recognition by staff or patients or before the occurrence of untoward events.

Improvements in a department's performance generally result from process improvements employed by all staff rather than altered work habits of the individual. While some measures of efficiency or quality document performance on a per individual basis, over-emphasis on an individual's parameters can hinder efforts to improve overall processes and teamwork. In addition, while useful for personal counseling, inter-individual variation is normal and should be accepted, to a point. Productivity assessments that are employed for individual or group performance appraisals should be based on measures that reflect activity directly under the personal control of the staff member or group.

Data Collection and Use

Central to any quality improvement effort is the availability of accurate and timely data. The sequential and repetitive nature of most (GI) endoscopy makes it amenable to data collection and action on findings. The selection of data points to track and the design of data acquisition forms should follow the identification of quality improvement goals and the definition of specific measures. Manual data collection with clipboards and checklists are adequate for ad hoc quality projects and for routine documentation of simple chores not requiring aggregated analysis (e.g., daily temperatures on a refrigerator). Most simple data collection, even of a manual sort, can be incorporated into the workflow of the frontline nursing and office staff. However, manual aggregation and analysis of daily data elements over the long term or of elements buried in patient care records can be particularly burdensome. As with most health care organizations, computerized databases are now almost mandatory tools for optimal clinical documentation, communication, business management and quality improvement in the endoscopy unit. Fortunately, modern endoscopic databases and reporting systems can now aggregate most data elements incorporated in quality measures. For

larger practices, it is useful to employ an individual with a good understanding of both clinical and managerial issues as well as database queries and capabilities. If available, skills in basic statistics and process control charting are also useful.

Implementing Quality Improvement Projects

The process of addressing an individual improvement need is often referred to as *undertaking a quality improvement project*. This phrase implies focused attention on a problem. Using established techniques, a well-defined sequence of activities and a target timeline, the process is facilitated by use of a transparent and well-defined plan. Although steps to initiating a quality improvement project can vary, the essential steps include the following:

1. Identify potential improvement opportunity.
2. Gather information about optimal practices.
3. Gather information about current local practices.
4. Identify gaps and reasons for gaps between local and optimal practice.
5. Develop and improve strategy.
6. Assess effectiveness and cost-effectiveness of proposed strategy.
7. Assess further improvements in proposed strategy and whether it should be implemented.

Once an issue is identified, current practices are fully explored and understood, performance gaps are identified in comparison to optimal practices and strategies for improvement are developed and assessed for clinical effectiveness and cost-effectiveness. Mapping of the current state using flow charts, cause-and-effect diagrams, histograms and other relationship tools can be helpful in identifying gaps in care, points of risk and waste.

Several major methodologies or combinations of methodologies are usually employed in health care quality improvement projects. They overlap significantly, yet each emphasizes slightly different principles and end goals. All emphasize pilot testing of potential improvements with reassessment and redesign followed by further testing.

The *Plan-Do-Study-Act (PDSA) method* involves cycles of planning (*P*), small scale pilot testing (*D*), analysis of test results and lessons learned (*S*), followed by incorporation and maintenance of new processes into practice (*A*) versus repeated *PDSA* cycles. This method is useful when resources and time are limited and rapid, stepwise improvement is desired.

The so-called *Lean method*, as popularized in writings about methods of the Toyota Corporation, seeks to increase efficiency and reduce waste by excluding all processes, steps or inputs that fail to contribute value to the end product. This approach is useful when existing practices are deemed to be inefficient and cumbersome with bottlenecks and excessive rework. It employs collaborative team input and careful process revision through value stream mapping.

The *Six Sigma method* is an intensively data-driven approach to minimizing variation and, thereby, reducing defects or errors to improve quality. This method also uses a cyclic approach referred to as the *Define-Measure-Analyze-Improve-Control (DMAIC) method*, similar to the PDSA improvement cycles. Six Sigma methods are especially appropriate for repetitive, high frequency processes because they employ more rigorous analytical tools and process control charting under the guidance of local black belt or green belt experts.

Selected Quality Improvement Techniques and Tools

A number of techniques are commonly used for assessment of clinical practice and outcomes of care.

Credentialing and Privileging

Credentialing and privileging are both mandated by the accreditation process. Reprivileging is required every two years; however, in some facilities it is accomplished in a pro forma fashion without legitimate consideration of performance and outcomes. Given that the process of granting privileges engenders some liability to the organization, the process is both a critical responsibility as well as an opportunity for organizations to assess and reassess the quality of their providers, particularly those for whom concerns have been raised.

Physician Peer Review

Physician peer review is a method to monitor the appropriateness of the quality and quantity of routine care provided by individual clinicians. Reviews may be periodic and routine or episodic and related to concerns raised about a provider's practice. Typically, samples of patient encounters are reviewed by one or more noncompeting clinicians from the same discipline, employing standardized review criteria to assess quality issues. If questions are raised by the physician-reviewer, the physician whose care is being questioned is asked to comment on the specific quality issue in a fair hearing process. Peer review information is confidential and protected from legal discovery in most states. A peer review process may be incorporated in the biannual reprivileging process.

Audit-Feedback Methods

Audit-feedback methods provide comparative summary statistics to providers pertaining to any useful indicator of their practice, such as procedure volumes, average medication dosing, patient comfort data, completion rates, withdrawal times, adenoma detection rates, etc. When provided together with anonymous data of other practitioners, this functions as an internal or local benchmarking system, allowing physicians to recognize if their practice patterns or results are outside of the norm. Such information typically drives performance improvement without further specific counseling though lower thresholds might be employed as warning systems for potential need for remedial intervention.

Tissue Log Review

Tissue log review is a process intended to ensure consistency between the documented procedure indications, the procedure performed and tissue acquired and to prevent lapses in response to significant pathology. This routine process varies among organizations but typically involves review of all malignant pathology for adequate follow up and a subset of other pathology for consistency in practice. Discrepancies are reviewed in detail and practice modifications are instituted to preclude repetition of missed diagnoses or incorrect pathology sampling or submission practices.

Adverse Events, Incidents and Complaints

Adverse events, incidents and complaints should be reviewed for all undesirable outcomes that meet a predetermined threshold of severity or risk. This should include, at a minimum, all sentinel events, serious adverse events, and significant grievances or complaints from patients or employees. Definitions and nomenclature for adverse events related to (GI) endoscopy have recently been proposed. Adverse reactions should be tracked on an ongoing basis to allow identification of trends requiring unit wide or individual intervention.

Benchmarking

Benchmarking is a method of self-comparison against the highest performers among a group of like practitioners or institutions. To be useful, benchmark results should be risk adjusted or must include comparable groups relative to the population served and services delivered. Adequate numbers of cases must be submitted to provide representative data, and measures must be quantifiable and attainable. Benchmarking can be done internally among all members of a group, facility or hospital staff or externally against multiple groups or against aggregate data from many groups. When used locally for individual practitioners, benchmarking is similar to an audit-feedback program.

Well-known examples of national benchmarking programs include the University HealthSystem Consortium, involving 90 percent of the nation's nonprofit academic medical centers, and the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP). Some benchmarking programs, such as the ACS-NSQIP, are highly detailed and resource intensive, requiring significant investment of personnel time for chart abstracting and data submission. For endoscopic procedures, most benchmark measures of interest can be abstracted in automated fashion from an electronic medical record. National and regional pilot projects have demonstrated the utility of benchmarking GI procedural practices for both colonoscopy (Irving Pike, MD, at Sentara Healthcare) and ERCP (Peter Cotton, MD, at Olympus). Both projects are now maturing into broader national initiatives. One result is the newly established nonprofit benchmarking group GI Quality Improvement Consortium (GIQuIC) that is wholly-owned by the ASGE and the ACG together. This program formally established relationships with a database-benchmarking vendor in late 2009 with anticipated enrollment of participating endoscopy centers and professional groups beginning gradually in 2010 and beyond. It is expected the program and data links will facilitate future use of submitted data for participation in various pay-for-performance measures and programs, such as PQRI and others.

Endoscopy Unit Recognition Program

The Endoscopy Unit Recognition Program of the ASGE was established to promulgate best practices, particularly in regard to infection control, and to provide a means for endoscopy facilities to distinguish themselves from lesser-quality services offered in various other environments. Certification in the program requires concurrent three-year accreditation by a national accrediting body (the Accreditation Association for Ambulatory Health Care, the Joint Commission and the American Association for Accreditation of Ambulatory Surgery Facilities, Inc.); institution of specific ASGE guidelines pertaining to infection control practices, endoscope reprocessing and credentialing of staff; attendance by a physician or administrator at

the ASGE course on unit quality and safety; and membership of at least 50 percent of the practicing endoscopists of the center in the ASGE. The major benefits of the program are the guidance and training provided regarding quality assurance and infection control and receipt of the Endoscopy Unit Recognition Award, which allows use of the logo in printed and electronic media and marketing. While any unit can be subject to an ad hoc error in practice, certification should reassure patients that they are not likely to be subjected to systemic errors within a given facility.

Physicians Quality Reporting Initiative

So-called pay-for-performance (P4P) programs have been touted as useful means of inducing optimal practices by individual practitioners and groups alike. Conceptually, P4P programs offer incentive payments to providers for meeting predetermined goals in the provision of care. Numerous pilot programs have been established by both governmental and private payers. The PQRI is a CMS initiative that offers incentive payments to eligible professionals who satisfactorily report data on quality measures for covered professional services furnished to Medicare beneficiaries. PQRI was originally established in the 2006 Tax Relief and Health Care Act, but it has evolved annually and is subject to ongoing legislative and rulemaking revisions. For 2010, individual physicians may employ claims-based reporting on PQRI quality measures or measures groups on their Medicare Part B claims, or they may report via a qualified PQRI registry or via a qualified electronic health record product. Those who meet the criteria for satisfactory submission of PQRI quality measures during the 2010 PQRI reporting period will earn an incentive payment equal to two percent of their total estimated Medicare Part B allowed charges for covered professional services furnished during the same interval. A group practice reporting option is also available.

To date, few measures specific to (GI) endoscopy have been incorporated into the PQRI program. Participation in the PQRI program requires attention to somewhat arcane billing detail. This should become gradually easier with the evolution of electronic record systems and of non–claims-based measures. Benchmarking databases may serve as PQRI qualified registries in the future, greatly enhancing the attraction to participation in both programs. Details regarding the evolving status of GI- and endoscopy-specific measures available for reporting and submission processes are available on the ASGE and CMS Web sites.

Summary

Practitioners and administrators should all gain familiarity with the major principles of quality assurance and quality improvement because they are now integral to the practice of medicine. Board certification, accreditation and payer reimbursement all require active coherent quality improvement experience or programs. Organizations should employ individuals responsible for more complete understanding and guidance of local improvement efforts. Ultimately, such efforts benefit both patients and professional endeavors.

Suggested Further Reading

1. 2010 National Patient Safety Goals page. The Joint Commission Web site. Available at: http://www.jointcommission.org/patientsafety/nationalpatientsafetygoals. Accessed November 25, 2009.
2. About UHC resource page. University HealthSystem Consortium Web site. Available at: https://www.uhc.edu/12443.htm. Accessed November 26, 2009.

3. About ASC NSQIP resource page. American College of Surgeons National Surgical Quality Improvement Program Web site. Available at: https://acsnsqip.org/main/about_overview.asp. Accessed November 26, 2009.
4. ASGE Practice Guideline. Measuring the quality of endoscopy. *Gastrointest Endosc.* 2006;58:S1-S38.
5. Bolsin S, Colson M. Making the case for personal performance monitoring in healthcare. *Int J Qual Health Care.* 2003;15:1-2.
6. Brief History of Project resource page. GI Qualty Improvement Consortium Web site. Available at: http://www.giquic.org. Accessed November 26, 2009.
7. Chassin MR, Galvin RX. The urgent need to improve health care quality. *JAMA.* 1998;280(11):1000-1005.
8. Committee on Quality of Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: National Academies Press; 2001.
9. Gustafson DH, Hundt AS. Findings of innovation research applied to quality management principles for health care. *Health Care Manage Rev.* 1995;20(2):16-33.
10. Harrington L, Pigman H. Quality measurement. In: Varkey P, ed. *Medical Quality Management: Theory and Practice.* Sudbury, MA: Jones and Bartlett Publishers; 2010.
11. Johansson JF. Continuous quality improvement in the ambulatory endoscopy center. *Gastrointest Endosc Clin N Am.* 2002;12:351-365.
12. Johansson JF, Schmitt C, Deas TM, et al. Quality and outcomes assessment in gastrointestinal endoscopy. *Gastrointest Endosc.* 2000;52:827-830.
13. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System.* Washington, DC: National Academies Press; 2000.
14. Langley GJ, Nolan KM, Nolan TW, et al. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance.* San Francisco, CA: Jossey-Bass; 1996.
15. Lim T. Statistical process control tools for monitoring clinical performance. *Int J Qual Health Care.* 2003;15:3-4.
16. Matchar DB, Samsa GP. The role of evidence reports in evidence-based medicine: a mechanism for linking scientific evidence and practice improvement. *Jt Comm J Qual Improv.* 1999;25(10):522-528.
17. Petersen BT. Advances in endoscopy: ASGE's Endoscopy Unit Recognition Program. *Gastroenterol Hepatol.* 2009;11(5):756-757.
18. Physician Quality Reporting Initiative overview page. Centers for Medicare and Medicaid Services Web site. Available at: http://www.cms.hhs.gov/PQRI. Accessed November 25, 2009.
19. Rex DK, Bond JH, Winawer S, et al. Quality in the technical performance of colonoscopy and the continuous quality improvement process for colonoscopy: recommendations of the US Multi-Society Task Force on colorectal cancer. *Am J Gastroenterol.* 2002;97:1296-1308.
20. Sanaka MR, Super DM, Feldman ES, et al. Improving compliance with postpolypectomy surveillance guidelines: an interventional study using a continuous quality improvement initiative. *Gastrointest Endosc.* 2006;63:97-103.
21. Sentinel Event page. The Joint Commission Web site. Available at: http://www.jointcommission.org/SentinelEvents. Accessed November 25, 2009.
22. Womack J, Jones D. *Lean Thinking: Banish Waste and Create Wealth in Your Corporation.* New York, NY: Simon and Schuster; 1996.

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INFECTION CONTROL IN ENDOSCOPY

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Ambulatory endoscopy centers (AECs) provide an efficient and comfortable environment for the delivery of endoscopic services. Ensuring a safe procedure for both patients and staff is central to a quality care experience, and maintenance of effective infection control processes throughout an endoscopy center is a key component of safety. Moreover, proper reprocessing of endoscopic equipment is a critical element of infection control. Endoscope reprocessing must be done correctly each and every time; a breach of protocol leading to transmission of infection has the potential to discredit the field of gastrointestinal (GI) endoscopy. Physicians and associates working in AECs must be vigilant about strict adherence to all infection control and reprocessing guidelines.

General Infection Control Principles

Recommended practices for the prevention of transmission of infection in health care settings have been promulgated and widely disseminated as guidelines. The latest Centers for Disease Control (CDC) guidelines published in 2007 and should be part of the standard operating practices for any AEC.

Personal protective equipment, such as gowns, gloves, eye protection and respiratory protective devices, should be easily available and used appropriately to protect AEC personnel from exposure to blood, body fluids, chemicals and other potentially hazardous materials.

Both the CDC and the Occupational Safety and Health Administration (OSHA) require the use of gloves when touching blood or other potentially infectious materials (e.g., during procedures and when transporting soiled instruments). The CDC also recommends the use of masks and eye protection (or a face shield) during patient care activities that are "likely to generate splashes or sprays of blood, body fluids, secretions and excretions." OSHA recommends the use of such equipment whenever "splashes, spray, splatter or droplets of other infectious materials may be generated and eye, nose or mouth contamination can be reasonably anticipated." Thus, recommendations for the use of eye protection and a mask (or a face shield) allow some discretion and may be subject to interpretation. Both CDC and OSHA recommend the use of protective aprons or gowns "when appropriate."

Hand washing should occur after contact with any potentially infectious or contaminated items. CDC recommends that hands be washed immediately after gloves are removed, between patients and, in some situations, during examination of the same patient to prevent cross contamination of different sites.

Safe Injection Practices

Safe injection practices are part of high quality medical care in all settings, including the AEC. Outbreaks of the hepatitis C virus infection have originated in endoscopy centers and have been traced to improper injection practices. Improper use of single and multidose anesthetic vials, reuse of needles and syringes and improper use of intravenous tubing and connectors have all been implicated. A widely publicized incident in Las Vegas in 2008 resulted in at least six people developing acute hepatitis C. Cross contamination between patients occurred after syringes that were reused to draw additional doses of sedatives or analgesics from single-use vials were subsequently used for other patients undergoing endoscopy. CDC guidelines relevant to safe injection practices in an AEC include the following:

- Use an aseptic technique.
- Do not administer medications from a syringe to multiple patients, even if the needle or the cannula on the syringe is changed.
- Use fluid infusion sets for one patient only.
- Use single-dose vials whenever possible.
- Do not administer medications from single-dose vials to multiple patients.
- If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile.
- Do not keep multidose vials in immediate patient treatment areas.

Endoscope Reprocessing

Transmission of infection via GI endoscopy is exceedingly rare. A comprehensive review was published in 1993 detailing transmission of infection in endoscopy from 1966 through 1992. Because guidelines for cleaning and reprocessing endoscopes were not widely disseminated until the late 1980s, this review separated infections occurring before and after 1988. Twenty-eight reported infections occurred between 1988 and 1992, while 40 million procedures were estimated to have been done, yielding an approximate rate of one in 1.8 million. Based on more current estimates, the pathogen transmission rate may be lower yet and, indeed, may be as rare as one in six to 10 million. Heightened awareness of possible cross contamination via GI endoscopy is evident given recent media attention to breaches in protocols in various parts of North America.

Every patient must be considered a potential source of infection and all endoscopes must be reprocessed in a standardized fashion. All recent cases of pathogen transmission related to endoscopy have been the result of a breach in following such accepted protocols. Reprocessing standards are published, updated and widely available and include the Multisociety Guidelines (2003) as well as individual guidelines from the American Society for Gastrointestinal Endoscopy (2008), Society for Gastrointestinal Nurses and Associates Inc. (2008), European Society for Gastrointestinal Endoscopy (2008), Association of Perioperative Registered Nurses (2002) and the British Society of Gastroenterology (1998).

Procedure for Reprocessing Endoscopes

Critical steps in endoscope reprocessing include cleaning, rinsing, disinfection, rinsing, drying and storage. Manual cleaning is the most important step in endoscope reprocessing, reducing the bioburden on an endoscope by several logs (more than 99.99 percent) and thereby dramatically reducing the load of organisms and debris. Manual cleaning alone may well eradicate Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV); these are among the easiest organisms to eradicate. Still, manual cleaning alone is not sufficient; liquid chemical disinfection must follow.

Cleaning should be performed before any bioburden has a chance to dry. The entire endoscope, including valves, channels and connectors, should be meticulously cleaned immediately after a procedure using a compatible enzymatic cleaner. Additionally, all removable parts should also be disassembled and placed in detergent. All accessible channels and surfaces should be flushed before and after brushing to remove all organic matter and debris. Valves should be actuated during the cleaning process to ensure access to all surfaces. The external surfaces of the endoscope may be cleaned with a soft cloth, sponges or brushes.

Endoscopes should receive high level disinfection after each patient use. *High level disinfection* is defined as the absence of all microbial life, including vegetative microorganisms, mycobacteria, viruses, fungi and some, but not all, bacterial spores. This is an appropriate level of reprocessing for use of an endoscope in a subsequent patient. Sterilization of an endoscope is possible with the use of ethylene oxide gas and may sometimes be indicated when an endoscope will be used within a sterile operating field. However, sterilization of an endoscope is associated with a 24-hour turnaround time, making this generally impractical in routine practice.

A high level disinfectant should be used that is cleared by the US Food and Drug Administration (FDA) for such a purpose and is compatible with the endoscope. Many agents are available and the choice and proper use of disinfectants for reprocessing GI endoscopes is continuously changing with development of newer agents. The exposure time and temperature for disinfecting endoscopes varies among the FDA-approved high level disinfectants. Some of the newer agents allow shorter reprocessing cycles and are not associated with the toxic fumes that are found with gluteraldehyde use. Users should be guided by FDA clearance information and manufacturer's instructions when using such substances for reprocessing endoscopes.

High level disinfection may be done in a basin or, more commonly, in an automated endoscope reprocessor (AER). Automated machines are not a substitute for manual cleaning and should not be referred to as *washing machines*. Endoscopes and their components must be fully immersed in the high level disinfectant or sterilant and all channels must be fully perfused. The disinfection process must be allowed to proceed for the entire recommended time. If the automated cycle is interrupted and the recommended time for reprocessing not completed, high level disinfection cannot be ensured.

The final step in endoscope reprocessing involves rinsing the endoscope and flushing the channels with sterile or filtered water to remove the disinfectant. Rinse water should be discarded after each use. Following rinsing, channels should be flushed with 70-percent to 90-percent ethyl or isopropyl alcohol and dried with forced air. This greatly reduces the possibility of recontamination of the endoscope with waterborne organisms. The endoscope should be stored vertically (not coiled in a case) to facilitate drying, and storage should be in a clean area. Caps, valves and other detachable components should be removed for storage per the manufacturer's instructions and replaced prior to the next use.

Related Issues in Reprocessing

Several other reprocessing issues are also relevant to endoscopy centers. Water bottles have been implicated as the source of pathogen outbreaks (especially pseudomonas). They should receive a high level disinfection or sterilization at least daily and sterile water should be used to fill the bottle.

Disinfectant solutions must be tested for potency on a regular basis since they become diluted with repeated use. Regular monitoring of these solutions is mandatory to ensure that the concentration of the active ingredient remains above the minimum effective concentration for germicidal activity. Chemical indicators such as test strips are typically used for this purpose. Moreover, disinfectants have a shelf or reuse life and must be discarded at the end of this time period regardless of the minimal effective concentration. If additional disinfectant solution is added to an AER or manual disinfection basin, the reuse life should be determined by the first use of the original solution; topping off does not extend the reuse life of the disinfectant.

Finally, while everyone involved in endoscopy should be familiar with the basics of endoscope reprocessing, this task should be the domain of dedicated staff specifically trained to perform this function. These individuals should receive device-specific training, along with regular competency testing to ensure maintenance of skills. Reprocessing should not be assigned to temporary personnel unfamiliar with the equipment and procedures.

Documentation and Quality Assurance

AECs must meet standards of accrediting organizations; in general, infection control policies and procedures must be specified, regularly reviewed and updated as necessary. A method of tracking each procedure and the endoscope that was used should be in place to assist in the event of an outbreak investigation. Quality assurance programs should be in place to verify the effectiveness of all infection control procedures. A more detailed discussion of benchmarking is provided in Chapter 20.

Summary

Appropriate infection control measures are essential for the safe care of patients undergoing endoscopic procedures. Such measures include meticulous implementation and use of accepted infection control standards and careful attention to endoscope reprocessing guidelines. Future efforts in this area will continue to focus on improved adherence to guidelines, standardization of reprocessing equipment to make the process easier and less prone to variation and development of improved endoscope and reprocessor design to minimize the potential for errors.

Suggested Further Reading

1. Alvarado CJ, Reichelderfer M. APIC guidelines for infection prevention and control in flexible endoscopy. *Am J Infect Control.* 2000;28:138-155.
2. American Society for Gastrointestinal Endoscopy. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointest Endosc.* 2003;58:1-8.
3. American Society for Testing and Materials. *Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera.* West Conshohocken, PA: American Society for Testing and Materials; 2000.
4. Association of Perioperative Registered Nurses. *Recommended Practices for Use and Care of Endoscopes: 2002 Standards, Recommended Practices, and Guidelines.* Denver, CO: Association of Perioperative Registered Nurses; 2002:229-232.
5. Banerjee S, Shen B, Nelson DB, et al. Infection control during GI endoscopy. *Gastrointest Endosc.* 2008;67:781-790.
6. Beilenhoff U, Neumann CS, Rey JF, et al. ESGE-ESGENA guideline: cleaning and disinfection in gastrointestinal endoscopy. *Endoscopy.* 2008;40:939-957.
7. Beilenhoff U, Neumann CS, Rey JF, et al. ESGE-ESGENA guideline for quality assurance in reprocessing: microbiological surveillance testing in endoscopy. *Endoscopy.* 2007;39: 175-181.
8. Cleaning and disinfection of equipment for gastrointestinal endoscopy: report of a working party of the British Society of Gastroenterology Endoscopy Committee. *Gut.* 1998;42:585-593.
9. Garner JS. Guideline for isolation precautions in hospitals. *Infect Control Hosp Epidemiol.* 1996;17:53-80.
10. Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings 2007. Centers for Disease Control Web site. Available at: http://www.cdc.gov/ncidod/dhqp/gl_isolation.html. Accessed December 15, 2009.
11. Universal Precautions. Bloodborne Pathogens resource page. Occupational Safety and Health Administration Web site. Available at: http://www.osha.gov/SLTC/etools/hospital/hazards/bbp/bbp.html#Uprecautions. Accessed December 15, 2009.
12. Society of Gastroenterology Nurses and Associates, Inc. Standards of infection control in reprocessing of flexible gastrointestinal endoscopes. *Gastroenterol Nurs.* 2000;23:172–87.
13. Society of Gastroenterology Nurses and Associates, Inc., Practice Committee. Reprocessing of water bottles used during endoscopy. *Gastroenterol Nurs.* 2006;29:396-397.
14. Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med.* 1993;118:117-128.
15. Standards of infection control in reprocessing of flexible gastrointestinal endoscopes, 2008. Society of Gastroenterology Nurses and Associates, Inc., Web site. Available at: http://www.sgna.org/Resources/3_stdofinfectionFINAL1208_2.pdf. Accessed December 15, 2009.