PROBING THE CHALLENGES OF Endoscopes

Martha Vockley

In the final episode of the second season of the TNT drama, *Men of a Certain Age*, lead character Terry decides to mark his 50th birthday by getting a colonoscopy. He persuades his same-aged friends Joe and Owen to join him—and they make a golf-and-gambling weekend out of it at a Palm Springs resort.

The trio of pals might have been less sanguine about their colonoscopies had they known that, about the same time the episode aired last fall, a “John Doe” had a similar endoscopic procedure that resulted in a class-action lawsuit. The lawsuit, filed in February against Tulane Medical Center in New Orleans, alleges negligent exposure to infectious diseases—namely, hepatitis B, C, and HIV—due to improper disinfection of endoscopes used to perform colonoscopies, sigmoidoscopies, and upper endoscopies of the stomach, according to the *The Times-Picayune*.

In a letter to 360 affected patients, the medical center’s CEO, Dr. Robert Lynch, admitted that, from Oct. 7 to Dec. 1, 2010, the device was not disinfected at the proper temperature recommended by the device manufacturer. While the medical center immediately corrected its five-step disinfection process, reported the lapse to public health officials, and consulted experts who say the infectious disease risk is “minimal to nonexistent,” all affected patients were offered free disease testing. Similarly, the Vancouver Island Health Authority in 2010 notified about 500 patients who had endoscopy procedures at Victoria General Hospital that they might have been exposed to viruses during their tests.

In addition, the Veterans Administration (VA) is facing lawsuits over endoscopic cross-contamination, including one filed in February by one of 11,000 veterans who had colonoscopies in Miami, Tennessee, and Georgia between 2004 and 2009 with equipment the VA acknowledged to be improperly cleaned, according to the *The Miami Herald*. The Miami veteran alleges that he contracted HIV from a contaminated colonoscope.

The television dramatization and the real-life incidents—just a sampling of a number of reported disinfection or sterilization incidents—illustrate some of the opportunities and challenges with endoscopes facing the healthcare industry and biomedical technology professionals.
Market and Healthcare Opportunities

On the opportunity side, market forces are rapidly driving up the use of endoscopes, and particularly flexible endoscopes, in healthcare. Endoscopic procedures are increasingly popular, due to rising health issues of an aging population; growing patient preference for minimally invasive surgery; and cost savings from reduced patient stays, anesthesia, clinical care, and monitoring compared to more invasive procedures. When a prime-time television show builds an episode around colonoscopies, that’s an indicator of how common, accepted, and routine these procedures have become.

Moreover, changes in healthcare legislation—especially greater coverage for colorectal cancer screening—is expected to boost already very high procedure volumes, fueling market growth.

Advances in technology, meanwhile, continue to increase the sophistication and capabilities of endoscopes. Indeed, there are at least 36 different types of specialized endoscopes, according to the device classification systems of the U.S. Food and Drug Administration (FDA) and ECRI Institute, a nonprofit organization specializing in scientific research for healthcare.

‘Everything Snowballed’

As the market for endoscopes grows, so do the challenges surrounding these devices for healthcare institutions and biomedical technology professionals. Chief among these challenges are reprocessing, or proper high-level disinfection or sterilization of devices after they’ve been used for clinical procedures, and inventory and maintenance.

FDA, in a 2009 joint communication with the Centers for Disease Control and the VA, warned healthcare facilities, including hospitals, ambulatory care facilities, and private practices, that “flexible endoscopes are fundamentally difficult to clean and disinfect or sterilize.” With improper cleaning of endoscopes or endoscopic accessories, “patients can be exposed to body fluids and tissue contaminants from prior patients, which can result in the transmission of pathogens that affect large numbers of people.”

ECRI Institute put cross-contamination from flexible endoscopes in third place on its 2011 Top 10 Health Technology Hazards list. That’s down from first place in 2010—but it’s a sign that cross-contamination remains a significant concern.

In 2009, FDA issued a notice that conveyed agency concerns about unapproved changes to the STERIS System 1 Processor, a tabletop liquid chemical system used in many healthcare facilities to sterilize endoscopes and other medical devices. FDA advised healthcare administrators to find alternative processors, which sent them scrambling to transition to “legally marketed alternative devices” within three to six months—and raised endoscope reprocessing to a risk management and C-Suite concern. This challenge proved so daunting, logistically and financially, that FDA in February 2010 extended the transition period to 18 months, and in April 2011 issued another six-month extension. Healthcare facilities now

Endoscopies aren’t just for older people—and they’re not for gastrointestinal procedures only. Pregnant women, for example, may undergo endoscopic chorionic villus sampling (CVS) of the placenta during early pregnancy to screen the baby for genetic defects or an amnioscopy to monitor fetal condition. Pediatricians use otoscopes in routine examinations to diagnose children’s ear infections. Children who swallow something that lodges in their air passages might have a bronchoscopy to remove it. Athletes—pro and amateur—and couch potatoes alike prefer minimally invasive arthroscopic surgery to examine and repair joint damage.

Endoscopes aren’t just for people, either. Veterinary endoscopy is increasingly common as well. There are, in fact, specialized endoscopes for domestic and exotic creatures, including dogs, cats, birds, rodents, reptiles, horses, cows, large zoo animals, and fish.
have until Feb. 2, 2012, to make the transition.

As William Carroll, manager of clinical engineering at Aurora Health Care in Wisconsin puts it: "Ensuring compliance with the STERIS System 1 recall" is the main endoscope-related challenge his institution faces.

In 2010, The Joint Commission required flexible and rigid endoscopes to be included in the medical equipment inventory of clinical engineering departments—even though only flexible endoscopes had been identified in the cross-contamination warning. Under this new requirement, endoscopes are considered diagnostic equipment and, as such, must be included in the medical equipment inventory and maintained, either in-house or by an outside organization.

"Endoscopes are now probably the most politically charged devices within an organization."
David Francoeur, CREST Services

"Everything snowballed about 18 to 24 months ago," sums up David Francoeur, vice president of operations of CREST Services, a medical equipment service provider in the Dallas–Fort Worth area, and vice-chair of AAMI’s Technology Management Council (TMC). “Endoscopes are now probably the most politically charged devices within an organization.”

Despite the alarms sounded over the past few years, FDA says that endoscope cross-contamination “may be an underreported area. As we raise awareness of this issue, we expect an increase in the number of reports—followed by a decrease after the initial awareness uptick.”

**Delicate Devices, Hard Use**

Part of the challenge of keeping endoscopes clean and in good working order, according to Francoeur and other TMC members, is that they are fragile devices, put to the test day in and day out.

“Endoscopes are fairly delicate pieces of equipment,” Francoeur says. Their small scopes and narrow tubes are inserted and extracted, enduring huge ranges of motion, bending and twisting through body cavities, taking on body fluids and liquids. And that’s just in normal clinical use. Endoscopes also are moved to and from, up, down, and around healthcare and
service provider facilities, and left hanging up to dry after the high-level disinfection or sterilization process. “They get damaged pretty easily,” Francoeur says.

Improper handling during clinical use, transit, high-level disinfection, sterilization, servicing, and storage is an issue that even the best quality systems, processes, and equipment can’t override. For this, healthcare providers are stepping up to provide education and training on proper care of endoscopes—either on their own or in partnership with service providers contracted to perform high-level disinfection, sterilization, or maintenance—to everyone who comes into contact with them.

Both FDA and Joint Commission actions to reduce the risk of cross-contamination from endoscopes, and particularly flexible endoscopes, are putting high-level disinfection and sterilization processes in the spotlight.

“The issue with flexible endoscopes, like any lumened device, is that the internal channels are not visible for inspection after cleaning,” says Ralph Basile, vice president with Healthmark Industries Company, Inc., an infection control products manufacturer in the Detroit, MI, area. “Thus, if improperly reprocessed, gross organic debris can remain and provide a source of contamination. Further, while automated devices are more widely used, manual procedures remain key to cleaning, including bedside cleaning. Failure to adequately flush the device immediately after use, and extended time between use and reprocessing, greatly increases the chance the device will not be effectively reprocessed. Even use of automated devices has not been a guarantee of success, as recent news headlines have demonstrated. Improper use of these devices has resulted in compromised instruments.”

In addition, original equipment manufacturers (OEMs) often guarantee endoscope performance only if the devices are repaired by the OEM.

Storage is a related issue that remains a potential problem. For devices that are used frequently—daily or more often—storing properly reprocessed scopes is not an issue, Basile says. However, “extended storage of scopes can lead to problems, particularly if the

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To see a full list of the different types of endoscopes, visit www.aami.org/publications/BIT.
channels are not effectively dried after reprocessing with an alcohol flush and forced-air drying," he says.

“The good news is that there are now tools available to test flexible endoscopes for cleanliness,” he adds. Healthmark, for example, offers tests for organic soils and also for microbial contamination after extended storage. “These tests are easy to use, with easy-to-interpret results. They also provide rapid results—all key features in busy endoscopy centers.”

Huntington Memorial Hospital in Pasadena, CA, has not had any cross-contamination incidents from endoscopes. But the hospital takes the possibility very seriously. “It can certainly be a huge issue and thus hospitals need to ensure proper controls are in place,” says Huntington's Izabella Gieras, director of clinical technology. “We have tapped into our service maintenance vendor for additional education, in-services, and refreshers to ensure our central sterile staff and endoscopy department staff stay up to date with any new and current policies and procedures for proper scope sterilization.”

**Inventory and Maintenance**

Many healthcare providers and biomedical technology professionals seem to be still working through the inventory and maintenance requirements established by The Joint Commission in 2010.

The inventory requirement is tricky for a couple of reasons. First, the sheer number and diversity of scopes in use make tracking, documenting, and storing all the tubes and cameras a logistical challenge. Second, when endoscopes are serviced, parts can be switched out for maintenance, repair, or replacement, which is raising the question of whether the parts need to be tracked separately. At some point, each part may need an electronic tag or

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**FDA’s Perspective**

The federal agency cites four challenges it faces with endoscopes from a regulatory perspective:

1. Reprocessing validation studies are not always adequate. For example, validation studies do not always use clinically relevant test soils or consider internal device components.
2. User instructions for reprocessing may be insufficient or unclear.
3. User instructions have not been validated in terms of supporting the user in performing the necessary tasks.
4. New technologies often present challenges. Understanding how the technologies work, their indications for use, and their safety and effectiveness must be combined with design and disinfection abilities, which influence their reuse.

FDA says that manufacturers, healthcare facilities, and the user community all have roles to play to address these challenges.

The agency encourages manufacturers to:

- Improve labeling and cleaning practices
- Conduct rigorous validation of the reprocessing instructions
- Consider design features that facilitate cleaning
- Improve endoscope safety through better designs and manufacturing

FDA encourages healthcare facilities to implement strong quality assurance programs that include:

- Training employees to set up, clean, disinfect or sterilize, and store reusable devices
- Following manufacturers’ instructions and providing easy access to those instructions
- Periodic retraining and assessment of competence

“As always, we also encourage healthcare facilities to report problems to the manufacturer and the FDA,” FDA says. “Ineffective or incomplete reprocessing of reusable medical devices, such as endoscopes, can present significant risks to public health.”

The agency and AAMI are holding a Medical Device Reprocessing Summit Oct. 11–12 in Silver Spring, MD. The summit will follow a public workshop on reprocessing that FDA had scheduled for early June.

The agency says the user community has a role to play, as well, including the power to:

- Demand better, more reliable, and more durable endoscopes that come with more effective instructions for use
- Request that manufacturers demonstrate that their validation of designs and labeling are appropriate and effective
**Endoscopes—and the Endoscope Market**

Most endoscopes consist of a long, thin tube, which is either flexible or rigid, attached to a light and video camera. These medical devices capture images inside organs or tissues. The images and devices can be used to confirm a diagnosis, take a biopsy and, if fitted with surgical instruments, perform surgery, such as removal of organs, tumors, or foreign objects. Endoscopic ultrasound devices use high-frequency sound waves to produce images.

Newer capsule endoscopes are wireless cameras, ingested in vitamin-sized pills, which transmit images of the digestive tract to a recorder worn on a belt or around the waist. Virtual endoscopy uses computed tomography (CT) or magnetic resonance imaging (MRI) scans to generate 3D diagnostic images in real time. Both capsule and virtual endoscopy are expected to increase in coming years.

Another endoscopic procedure, natural orifice transluminal endoscopic surgery (NOTES), is an experimental technique that could one day make surgery safer, more precise, and less painful—and eliminate incisions and scars, according to the Center for Integration of Medicine & Innovative Technology in Boston.

Market statistics and projections by GBI Research highlight the prevalence of endoscopes in the healthcare industry:

- The global endoscope market is projected to reach $6.5 billion by 2016, with a compounded annual growth rate of 4 percent from 2009 to 2016.
- The current value of the U.S. market for endoscopy devices is $2.3 billion and is forecast to reach $3.1 billion by 2016.
- Capsule endoscopy systems are projected to be the fastest growing category of endoscopic devices. However, flexible endoscopes currently continue to be the largest category of endoscopic devices in the global market, with a market share of 48 percent. This category is forecast to surge to 59 percent by 2016.

Source: GBI Research. *Endoscopy Devices Market to 2016—Need For Therapeutic Endoscopy and Advances in HD Endoscopy to Drive Flexible Endoscopes.* November 2010
The profile of endoscopes has been so magnified and the cross-contamination fears so elevated that healthcare facilities are looking for longer-term solutions.

To meet the maintenance requirements, clinical engineering departments don’t necessarily have to maintain the endoscopes. Other departments, or outside service providers, can do the maintenance—as long as it is documented.

Huntington Memorial Hospital is drawing on internal and external relationships to meet inventory and maintenance requirements. “Since the requirements came out last year, we have proactively worked with our service maintenance vendor on the preventive maintenance (PM) program and inventory management,” Gieras says. “We have the flexible and rigid scopes on a quarterly PM program and have all the relevant documentation available within the clinical technology department.

“We are fortunate to have very collaborative departments in surgery, endoscopy, and central sterile, which work with us to gain access to all the scopes for PMs on a quarterly basis, as well as any other time a service need arises,” she adds.

The Pasadena hospital is seeing some strategic benefits from its stronger inventory and maintenance processes. “With the proactive and regular preventive maintenance schedules and ongoing assessment of our scopes by clinical technology and our service maintenance vendors,” Gieras says, “we have certainly enhanced our quality assurance program for our rigid and flexible scopes. The regular maintenance helps us stay on top of our inventory and assists us with strategic scope replacement when it comes to budget planning.”

**Potential Solutions**

The profile of endoscopes has been so magnified and the cross-contamination fears so elevated that healthcare facilities are looking for longer-term solutions.

“We do see a number of requests for improvement related to endoscope sterilization and high-level disinfection,” adds The Joint Commission’s Louise Kuhny. “This is a key patient safety issue. Organizations should make sure all their documents are aligned with the guidelines and aligned with practices within the organization.”
The biggest problem is that we can’t see inside these scopes. To put it bluntly, we’re just taking a shot in the dark with reprocessing.”

Nancy Chobin, RN, certified sterile processing and distribution manager (CSPDM), and educator at St. Barnabas Health Care System in Livingston, NJ. Chobin also serves as executive director of the non-profit Certification Board for Sterile Processing & Distribution, Inc., a member of AAMI’s sterilization standards committee, and a consultant to more than 200 hospitals, healthcare systems, and surgery centers in the United States and Canada.

From these vantage points, she offers a grim assessment of the state of practice today. “The biggest problem is that we can’t see inside these scopes,” she says. “To put it bluntly, we’re just taking a shot in the dark with reprocessing. It’s important to verify the effectiveness of the cleaning process at least weekly, as recommended in ANSI/AAMI ST79.”

Many healthcare facilities Chobin works with are not performing this verification, which contributes to “breeches in infectious disease control.”

“As a consultant, over the past two years I have been involved in at least four major breeches that were not reported in the media,” she says. “It’s a significant problem.”

The sheer volume of endoscopies, coupled with inadequate training and staff capacity, contribute to the risk as well. “These services are just exploding in terms of volume,” she says. “People are not aware of how time-consuming it is to reprocess these scopes. Every manufacturer has different nuances, different cleaning processes. It can take 34 steps to reprocess a scope. None can be overlooked. You can’t rush disinfection and sterilization.”

One part of the process should be rushed, however—the initial cleaning after a clinical procedure. For many scopes, this should occur within an hour of use, but sometimes does not—particularly with endoscopes on rolling carts deployed in most healthcare facilities, Chobin says. This can result in dried, caked-on matter that makes it difficult to disinfect or sterilize the instruments.

In addition, many healthcare facilities are short on adequately trained endoscope reprocessing staff. “You can’t just show somebody how to do this once and then walk away and say they’ve been trained. These scopes and the reprocessing are so sophisticated that people have to be thoroughly trained,” she says, and retrained continually. Chobin also believes that the low-wage salaries typically paid to reprocessing staff are “woefully inadequate.”

As an informed champion, Chobin believes that a collaborative, industry-wide initiative is in order to standardize and implement improved endoscope design and reprocessing practices. “I would love to have the FDA take the lead on this,” she says. “We look to them to protect our patients’ safety.” In fact, as of press time, FDA was planning a June 8–9 public workshop on reprocessing. Additionally, AAMI and FDA are set to hold a summit on medical device reprocessing Oct. 11–12 in Silver Spring, MD. The agency is also working with AAMI and other standards-setting groups to develop standards and other guidance on cleaning reusable devices.

In 2004, Chobin’s home state of New Jersey became the first state to require all sterile processors to be certified. Several other states, including Arizona, California, Colorado, Maryland, New York, Pennsylvania, Ohio, Oregon, and Washington, have similar legislation in the works. The International Association of Healthcare Central Service Materiel Management (IAHCSMM) advocates legislation to require certification and offers certification and recertification programs for technicians, instrument specialists, and healthcare leaders.

The New Jersey-based Certification Board for Sterile Processing & Distribution also offers training and certification for six roles in scope reprocessing and management: technician, GI scope processor, surgical instrument processor, ambulatory surgery technician, manager, and supervisor.

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Nancy Chobin, St. Barnabas Health Care System
A surgeon prepares a patient for laparoscopic surgery.

CREST Services, one of scores of endoscope service companies, provides in-house services to clinical engineering and biomedical departments nationwide. The company is finding that many healthcare systems do not have the capacity to manage the endoscope requirements on their own. “As an organization, we’ve recognized the need as being so great that we’ve decided that we will have a dedicated resource, in part or in whole, to manage the scopes completely,” Francoeur says. “They do nothing but make sure the scopes are clean, inventoried, and maintained.”

He anticipates that “scope managers” and “scope specialists” will become a new career specialty, just as some biomedical technology professionals specialize in magnetic resonance imaging (MRI), computed tomography (CT), or wireless devices.

Third-party providers are working to help healthcare providers meet their endoscope cleaning, inventory, and maintenance requirements—and finding that their services are much more valuable than they were a year or two ago.

Priority One, a Dallas–Fort Worth area service provider that repairs endoscopes, illustrates this closer relationship with its customers. Priority One provides no-cost preventive maintenance inspections (PMIs) on endoscopes, recommended at least every six months—and more frequently if requested. The company provides the make, model, serial number, and condition of each item, which helps with inventorying.

“A dedicated technical representative will perform the inspection,” says Ed Adams, vice president of operations with Priority One. “An assessment will be performed on each scope. The results will be reviewed with the staff or manager, so they are aware of and understand the need for any immediate or future service or handling issues for each endoscope. A copy of the detailed inspection report will be given to the department at this time. A PMI summary report will be forwarded to the facility showing the results of the inspection as well as any recommended work that may be needed.” The company also offers equipment handling and care advice to help extend the life of endoscopes and prevent unnecessary repairs.

Priority One has offered PMIs and customized service reporting for years, using a longstanding quality management system that includes standard operating procedures for quality assurance and safety. Now, though, these services—and the staff education—are increasingly valued.

“What we are changing is the way these value-added services are perceived,” Adams says. “Now the services we offered our customers are required. We view this as a positive by helping reduce unnecessary repairs.”

In addition, Priority One is paying closer attention to its customers’ reprocessing programs and practices to check whether they interpret, implement, and adhere to OEM-recommended procedures. “By having greater access to reprocessing personnel, this
allows us to assist in identifying and correcting non-standard reprocessing practices,” Adams says.

Putting It in Perspective

While the current challenges with endoscopes are testing healthcare providers and biomedical technology professionals, it may be comforting to know that the situation could be worse. “About 12 years ago, I wrote an article on video endoscopes and I have followed their care and maintenance ever since,” says Tom O’Dea, owner of Tom O’Dea Health Care Engineering in Minnesota and a hospital and healthcare consultant. “It seems to me that three of the big problems touched on in those days have largely been solved.” He cites these improvements:

1. The processing of “long,” flexible endoscopes has been automated so that the process can be safer for patients and for processors, who now experience no ill effects from breathing fumes of hazardous substances.
2. An objective tool for evaluating image quality is now available.
3. Third-party maintenance providers help keep costs in bounds.

Advice from
The Joint Commission

The Joint Commission, which has received complaints about endoscope reprocessing from patients, patient family members, and employees of healthcare facilities, offers several pieces of advice:

Consider endoscope reprocessing in risk assessments. The Joint Commission requires accredited organizations to go through a four-step process to develop their infection control programs:

• Assess risks
• Set goals to minimize the possibility of prioritized risks
• Implement planned interventions
• Evaluate the effectiveness of the plan and interventions

“As we know from the very public media reports, endoscope reprocessing is something that most organizations should consider in step one of the four-step process,” says Louise Kuhny, clinical educator with Accreditation and Certification Operations at The Joint Commission. “We allow organizations to prioritize their risks. We know that large-size hospitals will come up with a large number of risks, and they cannot work on everything at once. But this should be a consideration. It’s not a requirement.” Kuhny referenced Infection Control (IC) Standard 01.03.01, which describes the risk management process.

Follow relevant scientific guidelines. Healthcare organizations that do decide to improve endoscope reprocessing should use “evidence-based national guidelines or, in the absence of such guidelines, expert consensus” when they formulate interventions (IC 01.05.01) and cleaning, disinfection, and sterilization processes (IC 02.02.01).

“Joint Commission surveyors go to all areas in accredited organizations where sedation or anesthesia occurs,” Kuhny says. “This would include endoscopy units. We compare the process for the reprocessing of endoscopes with the relevant scientific guidelines.” The primary document organizations should rely on is the Center for Disease Control’s Healthcare Infection Control Practices Advisory Committee (HICPAC) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. AAMI/ANSI and Association of periOperative Registered Nurses (AORN) guidelines are relevant as well, Kuhny says.

Err on the side of caution. Joint Commission surveyors compare their observations in the processing of scopes with the organizations’ stated policies, procedures, and practices, and with the manufacturers’ indications for use (IFU). IFUs sometimes go beyond the HICPAC guidelines, Kuhny says. “We expect compliance with the more stringent guidelines,” she says. “Err on the side of caution. Take the more stringent approach.”
AAMI’s Leadership Role

AAMI has been spearheading efforts to improve patient safety during endoscopic procedures for the past year.

Last fall, AAMI convened an issue forum of stakeholders to examine the state of practice on reprocessing flexible endoscopes. This issue forum was a formal follow-up to a new work item proposal for a recommended practice from sterilization expert Nancy Chobin and an ad hoc meeting held in the spring of 2010 at AAMI’s sterilization standards committee meetings. The issue forum included participation from key user stakeholder groups and regulatory agencies:

- American Society for Gastrointestinal Endoscopy (ASGE)
- Association of periOperative Registered Nurses (AORN)
- Centers for Disease Control (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Certification Board for Sterile Processing and Distribution, Inc. (CBSPD)
- International Association of Healthcare Central Service Materiel Management (IAHCSMM)
- Society of Gastroenterology Nurses and Associates (SGNA)
- Society for Healthcare Epidemiology of America (SHEA)
- U.S. Food and Drug Administration (FDA)

This group, which also included several service providers, noted that guidance and significant literature on reprocessing flexible scopes exists. However, there is a need to update and consolidate this information into a clear document of current best practices that would carry more weight in the field. To that end, AAMI is collaborating with stakeholders on two products that could help the healthcare community:

- A technical information report on reprocessing, Human factors engineering—cleaning instructions for reusable medical devices
- A standard or technical information report on device design, with recommendations for manufacturers on designing endoscopes that are easier to clean.

References


“So I think the situation for flexible video endoscopes has vastly improved,” O’Dea says. ■

Resources

