Standardizing Endoscopic Processes to Achieve Compliance and Increase Efficiency

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EndoChoice Inc. funded this important research in support of the GI community.
Abstract

The rising number of Healthcare Acquired Infections (HAIs) – or at least the higher level of attention – has placed a spotlight on all aspects of infection control. Federal agencies and accreditation entities such as the Joint Commission are now putting GI endoscopy reprocessing procedures under the microscope, demanding strict adherence to established society guidelines and scrutinizing every aspect of the disinfection process.

With an emphasis on standardizing reprocessing procedures to ensure adherence and eliminate potential variables, many organizations have discovered that providing nurses with GI compliance kits delivers the right tools at the right time, thereby facilitating compliance. Compared with the cost of treating an HAI (which is non-reimbursable) or paying overtime for skilled medical staff to manage supplies and turn rooms over, GI compliance kits are not only cost effective, but are rapidly becoming the clinical gold standard for endoscopy procedures.

This paper examines the regulatory requirements and society guidelines for reprocessing, the advantages offered by compliance kits and the value of standardization to achieve compliance.

The Threat of Infections

The Centers for Disease Control and Prevention (CDC) estimates that one out of 20 hospitalized patients will acquire an infection while receiving health care treatment for other conditions.¹ HAIs kill nearly 100,000 Americans a year according to the CDC, with two million patients needing treatment that costs over $25 billion a year.

The cost to hospitals of treating an HAI directly affects their bottom line, as Medicare and Medicaid can deny reimbursement for hospital readmissions within 30 days of discharge. It is anticipated that commercial insurers and accountable care organizations might follow.

In 2009, the Centers for Medicare and Medicaid Services (CMS) declared it would no longer cover the costs of “preventable” conditions, mistakes and infections resulting from a hospital stay. Tied in with this is a reward system for “whistleblowers” who report medical errors that are hidden or inappropriately reported. The industry can expect to see more cases emerge with this intensified spotlight on HAIs.

There are relatively few reported cases of Hospital Acquired Infections (HAIs) resulting from endoscopic examinations, which are thought to be one of the safest procedures performed in a hospital. Of the more than 20 million GI endoscopic procedures performed annually in the U.S.,² the number of cases involving pathogen transmission are relatively small – approximately 1 in 1.8 million procedures.³

The largest review of pathogen transmissions included 265 scientific articles published between 1966 and 1992.⁴ That review found 281 instances of pathogen transmission that were attributable to GI endoscopy. In every instance, pathogen transmission was associated with one of the following issues:

- A breach in currently accepted cleaning and disinfection guidelines
- Use of an unacceptable liquid chemical germicide for disinfection
The number of pathogen infections is probably grossly underestimated.... Heightened awareness, more stringent inspections and reporting incentives are likely to change that.

Reprocessing Failures Drawing Public Attention

One means of tracking lapses in reprocessing procedures is through patient notifications, and these are receiving more news coverage as the general public becomes aware of the potential for HAIs and other pathogen transmissions during an endoscopic procedure.

Reprocessing failures for the period 2002-2006 resulted in 7,034 patient notifications. Following are a few recent events which have raised public awareness:

- February 2008 – a hepatitis C outbreak in Las Vegas is traced to an endoscopy center, prompting **tests of 50,000 patients, physicians and staff** for hepatitis and HIV. While re-use of syringes and single-dose vials of sedation drugs were blamed for the outbreak, further investigation showed significant reprocessing lapses as well. Flagrant violations of reprocessing procedures and thousands of incidents of re-use of single-use products were uncovered by investigators, who audited procedure logs against purchasing records. For example, in 2007 the clinic purchased approximately 2,000 bite blocks but performed 5,800 EGDs.\(^5\)

- December 2008 – at the VA Hospital in Murfreesboro, TN, the use of an incorrect connector results in **widespread patient notifications and MSNBC coverage**.

- April 2009 – **one patient tested positive for HIV and seven others for hepatitis C** after colonoscopies at a VA facility in Miami.

- October 2011 – it’s widely reported that a clinic in Ottawa, Ontario has been improperly reprocessing upper and lower GI endoscopes for almost a decade, requiring the **notification of 6,800 patients**.

When the Department of Veterans Affairs (VA) conducted an inspection in 2009 into the use and reprocessing of endoscopes at VA medical facilities, they discovered that facilities were not complying with management directives for reprocessing, resulting in a risk of infection for veterans. The report concluded that: “Reprocessing of endoscopes requires a standardized, monitored approach to ensure that these instruments are safe for use in patient care.”\(^6\)
2011 – The Year of New Guidelines

CMS, working with the Joint Commission and other accrediting bodies, is using a variety of tools—including regulatory oversight and financial incentives—to address the problem of HAIs. The assessment used in the agency’s infection control analysis begins with the question of whether the facility has an explicit infection control program, followed by, “Does the infection control program follow nationally recognized infection control guidelines?”

Specifically, CMS and the Joint Commission want to see adherence to specialty-specific guidelines, such as those adopted by industry and specialty society organizations. The “Multisociety Guideline on Reprocessing Flexible GI Endoscopes” adopted on May 2, 2011 by the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Healthcare Epidemiology of America (SHEA), is one example of these guidelines.

The ASGE Quality Assurance in Endoscopy Committee explained that, “All published occurrences of pathogen transmission related to GI endoscopy have been associated with the failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Despite the strong published data regarding the safety of endoscope reprocessing, concern over the potential for pathogen transmission during endoscopy has raised questions about the best methods for disinfection or sterilization of these devices between patient uses.”

The Society for Gastroenterology Nurses and Associates (SGNA) maintains separate guidelines for reprocessing gastrointestinal endoscopes. While there are slight differences between the ASGE and SGNA guidelines, in essence both agree that with appropriate reprocessing there is virtually no risk of transmission of patient-borne or environmental microorganisms.

Turning the Spotlight on Reprocessing

The Joint Commission has been taking a close look at endoscopy reprocessing and high-level disinfection (HLD), urging accredited organizations to review their sterilization and HLD processes in detail. In the July 20, 2011 issue of Joint Commission Online, the Joint Commission noted that surveyors are expected to receive in-depth training on endoscopy reprocessing, signaling this is an area of intensified focus for the commission. Additionally, reports began surfacing in early 2012 that the Joint Commission has issued Requirements for Improvement (RFIs) in California, Nevada and New Jersey over their lack of adherence to reprocessing procedures.
ASCs can expect similar, heightened scrutiny for their infection control processes, according to the CDC. Those centers cited for deficient practices are required to correct them; ASCs that fail to correct serious deficiencies risk termination of their participation in Medicare. Equipment reprocessing is one of the five areas targeted by CMS and CDC, which has provided in-depth infection control training for inspection surveyors.11

The U.S. Food and Drug Administration (FDA) is also focusing on compliance with reprocessing guidelines, issuing a consumer alert12 in late 2011 and creating a website13 with both industry and consumer information. The FDA Consumer Update quotes Frank Nemec, MD, a Las Vegas gastroenterologist and patient advocate, who advises his patients to ask this question: “What precautions are in place to ensure that the procedure will be done safely?”

The FDA joined with the Association for the Advancement of Medical Instrumentation (AAMI) to sponsor an October 2011 summit on reprocessing. At the two-day summit, nearly 250 experts debated how to improve the reprocessing of reusable medical devices, with solutions such as better device design, clearer instructions, more training and better pay for sterile processing technicians.14

The ECRI Institute included cross-contamination from flexible endoscopes in its listing of “Top 10 Technology Hazards for 2012.”15 After warning that cross-contamination from improper reprocessing can lead to life-threatening infections, the authors write: “Flexible endoscope reprocessing requires consistent adherence to a multistep procedure. Failure to properly perform any step, including some necessary manual tasks, could compromise the integrity of the process.”

The fact that facilities stray from procedures was confirmed in 2009, when the CDC piloted an infection control audit tool during inspection of 68 ambulatory surgical centers in four states to assess adherence to recommended practices. The audit tool found that infection control lapses are common; of 68 ASCs assessed, two-thirds had at least one lapse in infection control, and at 28.4% of the ASCs adherence to recommendations for reprocessing of endoscopic equipment was not uniform.16

The Reprocessing Challenge

“Endoscopes are not easy to clean” is the conclusion of a review entitled “Transmission of Infection by Gastrointestinal Endoscopy and Bronchoscopy.”4 Visual inspection is woefully inadequate, as it cannot detect microorganisms or bioburden left behind in an instrument’s channels.7

While the Joint Commission and other accreditation organizations require that reprocessing follow the manufacturer’s IFU, that can be difficult. "Some of these instructions are quite cumbersome," said Sue Klacik, corporate director of the International Association of Healthcare Central Service Materiel Management and manager of central services at St. Elizabeth Health Center in Youngstown, Ohio, at the October FDA/AAMI summit. Speakers said that most IFUs are more than 75 pages long, and sometimes give conflicting or confusing instructions.14
The VA states that reprocessing has a narrow margin of safety, warning that “any deviation from the recommended processing protocol can lead to the survival of microorganisms and an increased risk of infection.” The report identifies the three viruses that are of the most concern – hepatitis B, hepatitis C and the human immunodeficiency virus (HIV) – which can take months or years to become apparent. There are proven cases of transmission through endoscopy for hepatitis B and hepatitis C, and three cases of HIV infection occurred at a VA facility in 2009.17

Complicating the adherence to standards are human and procedural factors, including training, use of compliant supplies, variances in protocols, differing room setups and facility preferences, and differences between facilities. Despite the existence of societal guidelines – which also have minor deviations – these deterrents set the stage for potential problems.

For decades, surgical packs or kits have been used in the operating room to facilitate procedure preparation and support adherence to best practices. Each kit contains the items needed to perform a specific procedure, ensuring that all items are readily available and eliminating the need to search for a missing item or skip a critical step. GI practitioners are adopting the practice, using compliance kits such as the Compliance EndoKit® by EndoChoice® Inc. to help standardize endoscopy reprocessing and ensure compliance with society guidelines.

**Joint Commission Looking at Infection Control**

The GI unit at Kaiser Baldwin Park received an excellent rating during a March 2012 Joint Commission visit with the inspector visiting the department particularly interested in how they transport the endoscope, according to Sergio Rivas, lead nurse in charge of gastroenterology and pulmonary at the hospital.

“[The Joint Commission inspector] asked one of the LVNs about transferring the scope in a covered container to the cleaning room, and really liked the way we use the EndoKits to achieve compliance,” Rivas said. “They asked questions and spent a lot of time in the disinfecting room. In particular they wanted to look at our high level disinfecting, ensure we were using test strips, and see if we were performing QC on the strips.”

At Maine Medical Center in Portland, nurse manager Bonnie Boivin, RN, BSN, explains, “Using EndoKits has made for a very standard way of doing things, and that is always good when the Joint Commission comes. We went through a visit recently, and they liked that we had achieved a standard approach to our cleaning process by using the kits in all of our areas of service, including bronchoscopy, ERCP and endoscopy.”

Katrina Holmes, Surgery Center Administrator for Sutter Gould Medical Center, oversees three GI centers. She says that inspections can be a nerve-wracking time. “I know they’re coming and that they are looking for an infection control issue, and I don’t want to give them one.”

Her facility recently underwent an inspection and she said that rather than just looking at policies and procedures, “This time they spent at least 30 to 45 minutes in the processing room, following every step of the scope processing. The inspectors want to see that we’re doing it the same way every single time.
That’s where a product like the EndoKit comes in. It allows me to standardize, and it allows me to know that we’ll pass inspection.”

**Attaining Procedural Standardization**

Using compliance kits can help facilities to establish a consistent quality of care for patients by reducing human variables in both case preparation and reprocessing. Each patient is going to receive the same standard of care by having the same procedural supplies and adherence to infection control regulations. Standardization can also be viewed as a means of risk management by demonstrating compliance with regulations.

Variables between facilities – and even procedure rooms – can also result in different approaches to reprocessing. These variables include the training and tenure of endoscopy staff as well as limitations and differences in the physical work areas of different facilities. The use of compliance kits help ensure that everyone follows established best practices to achieve a greater level of standardization.

For Holmes, with three GI centers, “My staff can walk into another center and take over without any hesitation or training because we do it exactly the same at every center.”

During off-peak hours such as nights and weekends, staff from other departments may often be called to help perform endoscopy procedures. Supplying staff with preconfigured compliance kits gives them the appropriate tools to meet cleaning guidelines and provide a consistent level of care.

**Determining the Value of Compliance**

Like most providers, Maine Medical Center is watching their supply costs very carefully. Their purchasing department questioned nurse manager, Bonnie Boivin, when she decided to add compliance packs to her inventory. According to Boivin, the benefits were easy to quantify: “We needed to be compliant with transporting the scopes in a contained manner. Once that was explained, everyone quickly understood the value offered by EndoKits.”

Other facilities highlighted a number of additional benefits which make compliance kits valuable from both a regulatory standpoint and cost effectiveness, including reducing inventory management costs, reducing waste, and improving procedural efficiencies.

An efficiency study conducted at Erie County Medical Center (ECMC) in Buffalo, NY found that the use of endoscopy kits reduced set-up and clean-up times by more than 50%. The center actually saved 2.5 hours per week in clinical staff time in set-up/clean-up times based on 75 procedures per week. This valuable time can be devoted to:
- Reducing clinical staff overtime costs
- Providing higher levels of patient care
- Proactive preventative scope maintenance
- Reallocation of staff to other tasks

ECMC also found that the kits contributed to a higher level of employee satisfaction. “Kits help our employee morale by lowering the stress of our nurses by ensuring that they have all the supplies needed for each procedure,” said Lynn Hart, RN, nurse manager at ECMC. “They can focus on doing their jobs instead of worrying if they picked all of the correct supplies.”
Conclusion: Standardization Helps Achieve Compliance

While it may seem that industry standards exist solely to add stress and additional work, in reality they have been crafted – and accepted – to ensure the safety of patients and treatment staff. In the relatively rare instances when contamination has occurred, it has been uniformly traced to a lack of adherence to guidelines.

Skirting the regulations or being lax in procedural compliance is like speeding – sooner or later the odds are that you will get ticketed. In the case of endoscopy reprocessing, the penalties are much more severe, extending beyond Joint Commission and CMS censure to the endangerment of those in your facility. With the spread of drug-resistant diseases, the risk of noncompliance grows even more serious as a matter of patient safety.

At the joint FDA/AAMI meeting, one of the “clarion themes” was a call to “Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.” Industry societies are responding by discussing the creation of a standardized safety checklist for endoscope reprocessing which would provide facilities with clear instructions and repeatable steps to reduce misinterpretation and increase comprehension by staff.

Compliance kits streamline the cleaning process and make it easier and more convenient to meet guidelines and achieve standardization in a single room or throughout a multi-location organization. Their rapid adoption across the country is establishing a new standard of care in endoscopy.

“Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.”

15. www.ecri.org/2012_Top_10_Hazards
16. Ibid.