

Standardizing Endoscopic Processes to Achieve Compliance and Increase Efficiency

Lapses Highlight Urgency

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Table of Contents

Abstract	3
Reprocessing Failures Drawing Public Attention	4
Minnesota Department of Health Findings.....	4
Study Highlights Gaps in Reprocessing	5
Whistleblower Reveals Pattern of Breaches	5
Class-Action Lawsuit Cites Negligence	6
The Cost of a Reprocessing Breach.....	7
The Reprocessing Challenge	7
Preparing for The Joint Commission	8
Joint Commission Looking at Infection Control.....	9
Attaining Procedural Standardization	9
Determining the Value of Compliance	10
Conclusion: Standardization Helps Achieve Compliance.....	10

Abstract

In the past year, endoscope reprocessing has become a hot topic that is drawing ever more intense scrutiny from regulatory agencies, GI societies and the public. New reports of non-compliance, as well as additional insight into published reprocessing breaches, have highlighted the need for increased adherence to published guidelines.

More healthcare-associated outbreaks have been linked to contaminated endoscopes than to any other medical device¹, leading federal agencies and accreditation entities such as The Joint Commission to put GI endoscopy reprocessing practices under the microscope. They are demanding strict adherence to established society guidelines and scrutinizing every aspect of the high level disinfection process.

New studies reveal a disturbing lack of adherence to established protocols, and two lawsuits show new facets of legal ramifications. The first incidence of an endoscopy “whistleblower” case occurred in 2012, and recently a Pennsylvania jury found a hospital negligent in cleaning and disinfecting colonoscopes, even though none of the patients contracted a disease as a result of their exposure. Whether this is the beginning of a trend remains to be seen, but an examination of the potential cost shows that many millions of dollars are at stake.

With an emphasis on standardizing reprocessing procedures to ensure adherence and eliminate potential variables, many organizations have discovered that providing GI labs with Compliance EndoKits® delivers the right tools at the right time, thereby facilitating compliance. Compared with the cost of an infectious outbreak, 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 updated white paper summarizes the regulatory and accreditation scrutiny on endoscopic reprocessing, examines the impact of the latest breaches in reprocessing and looks at the value of standardization to achieve compliance.

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 healthcare-associated outbreaks and other pathogen transmissions during an endoscopic procedure.

Reprocessing failures for the period 2002-2006 resulted in 7,034 patient notifications. The following are recent lapses in GI reprocessing and infection control practices 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 multi-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 Nevada 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.²
- 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, which was rinsing water tubes and reservoirs used in endoscopies and colonoscopies with water, but not disinfecting.
- October 2011 – the media focuses on a clinic in Ottawa, Ontario that 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.”³

Minnesota Department of Health Findings

The Minnesota Department of Health is providing assistance when breaches occur that extends beyond standard regulatory functions. Between May 2010 and September 2011, seven endoscope reprocessing breaches were reported by five healthcare facilities, which requested assistance from the Department of Health. These incidents resulted from incorrect use of endoscopic accessories, reprocessing of single use devices, or failure to follow FDA labeling and/or manufacturer’s reprocessing instructions.

The Minnesota Department of Health is one of 10 sites across the country working with the CDC on emerging infections, says Jane Harper, BSN, MS, CIC, who works in Acute Disease Investigation and Control. "We were not contacted as part of regulatory reporting," she explains. "We were contacted by infection preventionists (IPs) for guidance and consultation. They see us as a resource, a place to receive consultation outside the regulatory area."

Harper said the Health Department works closely with the PIs on infection prevention and control, so she was not surprised to receive requests for support. "Most, if not all of the facilities thought there might be a reason to contact the FDA. We were able to do the testing for them, and also looped in the CDC, which is very experienced in these sorts of situations. Out of the seven, three resulted in FDA notifications and four involved patient notifications."

'To think these were the only breaches during this time period is very naïve.'

Without knowing the total number of procedures performed during this time period, Harper can't extrapolate the ratio of breaches to procedures, but she adds, "To think these were the only breaches during this time period is very naïve."

Study Highlights Gaps in Reprocessing

The CLEANR study (Clinical Evaluation and Assessment of Endoscope Reprocessing) examined factors affecting compliance in order to develop interventions that will improve adherence with disinfection guidelines. The study, "Factors that Contribute to Nonadherence with Endoscope Reprocessing Guidelines," evaluated reprocessing procedures and employee perceptions.⁴

Study observers documented the reprocessing of 183 endoscopes after the pre-cleaning phase and found that all steps were completed in accordance with guidelines just 47.5 percent of the time. An automated system for reprocessing yielded a 75 percent adherence rate, with the other 25 percent attributed to skipping the final wipe down. However, in cases of manual cleaning followed by automated high-level disinfection, a whopping 99 percent of reprocessed endoscopes had one or more steps skipped or performed incorrectly, although that represents a single facility out of the five studied.

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Employee perceptions were examined as part of the CLEANR study. A total of 75 percent of employees felt pressure to work quickly when reprocessing endoscopes, with 37 percent noting they had observed procedure delays in the last month due to a lack of clean endoscopes. Employees were satisfied with the ease of the method used and felt it yielded good or very good results. The times for automated and manual processing were nearly identical. (It should be noted that the study was sponsored by Advanced Sterilization Products, a manufacturer of high-level disinfection systems.)

Whistleblower Reveals Pattern of Breaches

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.

In June 2012, a whistleblower lawsuit was filed against the owners of surgery centers affiliated with 1-800-GET THIN, which routinely performed upper endoscopies, alleging reprocessing failures exposed patients to hepatitis C.⁵

The plaintiff in the lawsuit also alleges that it was common practice to reuse single-use endoscopy biopsy needles and forceps used to take biopsies. The surgery centers also reused single-use brushes to clean the endoscopy scopes to save money, the plaintiff alleges.

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However, there are those in the field of infection prevention who worry that fear of retaliation will dampen reporting, including Lawrence F. Muscarella, Ph.D., Director of Research and Development at Custom Ultrasonics, Inc., and publisher (and founder) of The Q-Net Monthly. "In general, there are too many disincentives to come forward and report infractions. Our culture rarely rewards one for doing so," says Muscarella.

Following the Las Vegas breach, the Nevada Department of Health was conducted a survey among 800 nurses in the state. The researchers found that 34% of respondents were aware of a patient care condition that could have caused harm to the patient, yet had not reported it, with the most common reasons given for non-reporting being fears of workplace retaliation (44%) and a believe that nothing would come of reports that were made (38%). This helped convince Nevada to pass a law that encourages "good faith" reporting of patient safety concerns; it also supports the employer's ability to discipline nurses whose actions pose a threat to patient safety.⁶

Class-Action Lawsuit Cites Negligence

In July 2012, a Pennsylvania jury found Forbes Regional Hospital was negligent in failing to properly clean and disinfect colonoscopes used on more than 225 patients in 2004 and 2005, despite the fact that no patients contracted a disease as a result of their exposure.⁷ The ruling allows for individual jury trials to determine if damages should be awarded to patients for their "pain and suffering, inconvenience and 'loss of life's pleasures.'" The cleaning lapses occurred when the hospital bought two new colonoscopes with stand-alone auxiliary water channels and staff was not trained to clean the new channels.

This jury's verdict is notable because it's the first of its kind, according to Dr. Muscarella. "This verdict would suggest ... that a medical facility can be held liable (e.g., for pain and suffering), even if the reprocessing breach had not been necessarily shown to result in infection," he wrote in Q-Net.

Dr. Muscarella adds, "Understand that endoscope reprocessing is a discipline that bears significant responsibility, and the failure to properly reprocess a GI endoscope...can result in civil litigation and patient notification, even if the breach had not been directly linked to an instance of disease transmission."

The Cost of a Reprocessing Breach

GI facilities that fail to comply with the established society guidelines for reprocessing often blame the cost of single-use cleaning supplies. However, that could be a false economy, according to a presentation by Strategic Health Resources at the 2012 National SGNA Congress.⁸

"The Price of Avoiding a \$20 Million Loss: Operational Costs and Contamination Events in Endoscope Reprocessing" examined the risks to patients and GI facilities from inadequate cleaning and disinfection of endoscopes. The authors pointed out that several factors were converging to highlight the need for better reprocessing, including:

- The advance and availability of genetic testing of pathogens that can trace specific strains of Hep C to a specific patient
- New mandates to report infectious outbreaks to state and federal agencies
- Lapses are less tolerated by payers and patients
- Facilities face measurable risks to reputation and revenue

Summary of per incident business costs		
Business consequence	Low estimate	High estimate
1. Patient notification and testing	\$ 73,564	\$ 820,284
2. Incident investigation and reporting	\$ 25,000	\$ 75,000
3. Legal defense costs	\$ 220,833	\$ 847,750
4. Settlement or verdict costs	\$ 250,000	\$ 16,000,000
5. Loss of volume and market share	\$ 1,222,171	\$ 2,648,036
Total estimated business cost per incident	\$ 1,791,568	\$ 20,391,070

The authors made a convincing case around the cost of a breach, beginning with patient notification and testing (\$70.58 to \$76.63 per patient) to reporting the adverse event to state and federal agencies, (estimated at \$25-75,000). Add to that legal costs and settlement or verdict costs – which are not covered by malpractice insurance, plus the loss of volume and market share that results from negative publicity, and the authors total the cost per incident at \$1.8 million on the low side, rising to \$20 million for a breach with a large number of affected patients.

The Reprocessing Challenge

More healthcare-associated outbreaks have been linked to contaminated endoscopes than to any other medical device¹, according to the CDC. Perhaps that is because "endoscopes are not easy to clean," which was the conclusion of a review entitled "Transmission of Infection by Gastrointestinal Endoscopy and Bronchoscopy."⁹ Visual inspection is woefully inadequate, as it cannot detect microorganisms or bioburden left behind in an instrument's channels.¹⁰

While The Joint Commission and other accreditation organizations require that reprocessing follow manufacturers' IFUs, that can be difficult. "Some of these instructions are quite cumbersome," said

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Sue Klacik, corporate director of the International Association of Healthcare Central Service Materiel Management 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.¹¹

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 C¹², and three cases of HIV infection occurred at a VA facility in 2009.¹³

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.

Preparing for The Joint Commission

Jonathan Buscaglia, MD doesn’t believe there is such a thing as being too prepared. Buscaglia, the Director of Advanced Endoscopy at Stony Brook University in Long Island, New York, recently passed a Joint Commission visit with “flying colors,” he says.

“We self-audit so frequently that when the actual inspection takes place, it isn’t as big a deal,” he explained. “We regularly mimic a Joint Commission visit and take someone through step-by-step. We constantly analyze and scrutinize society guidelines and keep up our logs and tests.” By following these practices year around, the hospital is prepared at the time of the actual visit.

Buscaglia said that while the Joint Commission inspectors examined a number of best practices, infection control was the primary focus. “They spent a significant period of time on the disinfection process; high level disinfection was still their main concern.”

‘Let’s face it, reprocessing is not a job people keep for decades. EndoKits help ensure we do it the same way every single time.’

Stony Brook uses Compliance EndoKits to help achieve compliance among the people who are at the bottom of the pay rung at the hospital. “Standardization is of paramount importance when it comes to scope reprocessing,” Buscaglia said. “We have several people doing reprocessing, and they tend to rotate frequently. Let’s face it, reprocessing is not a job people keep for decades. EndoKits help ensure we do it the same way every single time.”

The monitoring and self-examination at Stony Brook is key to achieving good results, confirms Muscarella, although he would like to see more audits conducted by external agencies. “I believe auditing should be more frequent, more robust and include more accountability,” he says. “Recommendations are worth nothing if you are not monitoring the staff to ensure they are following them.”

Muscarella adds that because there is a human element in reprocessing, there is going to be some variability. “Even the guidelines vary,” he says. “Someone has to monitor the procedure to ensure you don’t have deviation or drift from the original training and guidelines. You’re always going to have inherent variability; we just want to minimize that by standardizing the cleaning process.”

Joint Commission Looking at Infection Control

The GI unit at Kaiser Baldwin Park received an excellent rating during its 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 in Central California, oversees three GI centers. She says that inspections can be a nerve-racking 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.”

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 set society guidelines. 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

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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.”

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.”

Buscaglia said while Stony Brook Hospital has adopted the EndoKit, not every facility has addressed the transportation of a soiled endoscope. “Truth is, a lot of people are still just bringing scopes into the reprocessing room with stool dropping on the floor. They have two options: one, they can go with the (EndoChoice) CinchPad, which is a new option, or two, they can get a cart for each room and wheel it into the next room.”

Carts were not an option for Stony Brook, which already has an issue with keeping halls free of clutter. “Going the cart route can be expensive and you get into space issues,” he said. “We truly believe that EndoKits have been a net gain in terms of finances for us.”

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.

Conclusion: Standardization Helps Achieve Compliance

While it may seem that reprocessing guidelines 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 or have an accident. 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.

‘Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.’

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.” GI societies are responding by discussing the creation of a standardized safe surgery checklist

for endoscopic procedures 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.

¹ http://www.cdc.gov/hicpac/Disinfection_Sterilization/3_0disinfectEquipment.html

² <http://www.southernnevadahealthdistrict.org/download/outbreaks/final-hepc-investigation-report.pdf>

³ <http://www.va.gov/oig/54/reports/VAOIG-09-01784-146.pdf>

⁴ http://www.aspj.com/us/sites/default/files/pdf/AD-100159-01-US_CLEANR_Endoscope-Nonadherence-Study.pdf

⁵ <http://documents.latimes.com/whistleblower-lawsuit-vs-1-800-get-thin/>

⁶ “Tragedy into Policy: A Hepatitis C Outbreak and a Study of Nevada RNs Lead to New Protections for Whistleblowers”, American Journal of Nursing blog, June 7, 2011

⁷ <http://www.post-gazette.com/stories/local/neighborhoods-east/forbes-hospital-found-negligent-645685/?p=2>

⁸ 2012 SGNA 29th Annual Course Syllabus

⁹ Kimmey MB, Burnett DA, Carr-Locke DL, et al. Transmission of infection by gastrointestinal endoscopy. *Gastrointest Endosc* 1993; 36:885-8.)

¹⁰ HHS Action Plan to Prevent Healthcare-Associated Infections: Incentives and Oversight;

<http://www.hhs.gov/ash/initiatives/hai/incentives.html>

¹¹ <http://www.infectioncontrolday.com/news/2011/10/summit-shines-spotlight-on-reprocessing-challenges.aspx>

¹² <http://www.va.gov/oig/54/reports/VAOIG-09-01784-146.pdf>

¹³ <http://www.infectioncontrolday.com/news/2009/04/hepatitis-hiv-cases-confirmed-at-va-hospital.aspx>