

S P E C I A L R E P O R T

Best Practices
for High-Level
Disinfection and
Sterilization
of Endoscopes

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INTRODUCTION: ENDOSCOPE-RELATED ADVERSE EVENTS

Surgical instruments and endoscopes are invasive medical devices that can introduce pathogenic bacteria into the human body unless they are meticulously and properly decontaminated, cleaned, disinfected and sterilized. These devices require careful processing in specifically ordered steps, including transportation of contaminated devices from the operating or procedure room to the sterile processing department and ending with the delivery of a protected, properly reprocessed device or scope back to the surgical services department. The instruments and scopes must be protected throughout the reprocessing cycle, thus minimizing the potential for damage at all times, and the entire process must be traced and validated to ensure optimal patient safety. This report is designed to outline and review the most pertinent issues relating to the high-level disinfection and sterilization of instruments, especially endoscopes.

A number of adverse events and high-profile outbreaks over the years has triggered increasing oversight of high-level disinfection and sterilization, as we will examine later in this report. As a multi-society guidance document (Petersen, et al., 2011) notes, "The beneficial role of GI endoscopy for the prevention, diagnosis and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires reprocessing before being used on subsequent patients. The most commonly used methods for reprocessing endoscopes result in high-level disinfection. To date, all published occurrences of pathogen transmission related to GI endoscopy have been associated with 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. ... Additional outbreaks of infection related to suboptimal infection prevention practices during endoscopy or lapses in endoscope reprocessing have been well publicized. In numerous instances, risk of infection transmission has been linked to less willful, but incorrect, reprocessing as a result of unfamiliarity with endoscope channels, accessories, and the specific steps required for reprocessing of attachments. Recent on-site ambulatory surgery center surveys confirm widespread gaps in infection prevention practices."

The Pennsylvania Patient Safety Organization (2010) emphasizes that, "Much of the literature on infection prevention in endoscopy identifies failure to follow established cleaning and disinfection/sterilization processes and use of

"... Outbreaks of infection related to suboptimal infection prevention practices during endoscopy or lapses in endoscope reprocessing have been well publicized."

– Petersen, et al., 2011

"Much of the literature on infection prevention in endoscopy identifies failure to follow established cleaning and disinfection/sterilization processes and use of damaged or malfunctioning reprocessing equipment or endoscopes as the leading causes of cross contamination."

– Pennsylvania Patient Safety Organization (2010)

damaged or malfunctioning reprocessing equipment or endoscopes as the leading causes of cross contamination. Damaged equipment should be removed from service immediately or as soon as possible. If the endoscope is left in use, organic debris may enter areas of the device that are not typically exposed to disinfecting or sterilizing agents. Endoscope reprocessing typically involves a six-step protocol that includes pre-cleaning, leak testing, manual cleaning, high-level disinfecting or sterilizing, rinsing and drying, and endoscope storing. A breakdown in any one of these steps could compromise the integrity of the process leading to an endoscopy-related contamination risk. This risk can result in transmission of infectious agents (e.g., hepatitis C, HIV, mycobacterium tuberculosis) and potentially lead to patient injury or death. Often in these cases, large numbers of patients are affected and must be notified about exposure to potentially contaminated endoscopic equipment."

Across the country in the last decade, there have been reports of large-scale outbreaks related to cross-contamination. One of the largest occurred between December 2008 and April 2009 when the U.S. Department of Veteran Affairs (VA) notified approximately 10,000 patients who received endoscopic procedures at three VA facilities between April 2003 and March 2009 that they may have

been exposed to bloodborne pathogens due to improperly processed endoscopy equipment. A Department of Veteran Affairs report (2009) describes how the VA Office of Inspector General received complaints regarding the reprocessing of endoscopic equipment at several VA medical centers (VAMCs) and how VA officials assessed the extent of related problems throughout the Veterans Health Administration (VHA). The report describes the pertinent events at VAMCs where problems were reported, assesses VHA's response to the events, and provides a system-wide evaluation of current reprocessing practices. According to the VA report (2009), "Facilities have not complied with management directives to ensure compliance with reprocessing of endoscopes, resulting in a risk of infectious disease to veterans. Reprocessing of endoscopes requires a standardized, monitored approach to ensure that these instruments are safe for use in patient care. The failure of medical facilities to comply on such a large scale with repeated alerts and directives suggests fundamental defects in organizational structure."

VA officials discovered that many of the problems were related to sterile processing staff not following an established protocol. As the VA report (2009) notes, "Responsibility for reprocessing endoscopes is described in the VA Handbook, 'Supply, Processing, and Distribution (SPD) Operational Requirements.' (VA Handbook 7176, 2002) Part 6 of this document addresses decontamination and states, in part, 'All reusable medical devices used in the medical center should be processed in the SPD decontamination area. If there are other areas of the medical center where decontamination must be done, all procedures listed in this section of the handbook will apply to that area.' The handbook also states that staff reprocessing endoscopes 'should consult all manufacturers' instructions.'"

In recent years, several VHA medical facilities have been found to deviate from recommended procedures in the reprocessing of endoscopes, in some cases necessitating patient recalls.

For example, in 2003, based on problems identified at non-VA facilities, a safety alert was issued by a manufacturer that reminded customers that the auxiliary water channel must be reprocessed each time the endoscope is used. In 2004, the VA National Center for Patient Safety (NCPS) issued an alert related to an incorrect connector being used to link cleaning solution to endoscopes during reprocessing.” The alert required VHA medical facilities to provide in-service training consistent with manufacturer instructions for reprocessing specific models of GI endoscopes and incorporate knowledge of proper handling and reprocessing of GI fiberoptic endoscopes into Joint Commission competence assessment requirements for individuals tasked with this assignment. And based on a 2006 event involving the reprocessing of biopsy devices, VHA conducted a national review to assess compliance with reprocessing standards. Facilities were directed to create local policies based on manufacturers’ instructions, including requirements for demonstration of competence in performing reprocessing. (Department of Veterans Affairs, 2009)

These kinds of problems are not relegated to VA facilities; in 2004 a California hospital sent letters to more than 2,000 patients who had undergone endoscopies after a reprocessing machine was found to have malfunctioned, and in 2005 a hospital in Pennsylvania notified 200 patients when colonoscopes were discovered to have been inadequately disinfected. To further illustrate the kinds of real-world challenges being encountered in sterile processing departments, we highlight data from the Pennsylvania Patient Safety Authority (PPSA). The ECRI Institute, under contract with the Pennsylvania Patient Safety Authority, is responsible for the design, development and implementation of the statewide Pennsylvania Patient Safety Reporting System (PA-PSRS). This Web-based system is the first state reporting system in the United States to require healthcare facilities to report “near-misses” as well as actual events. The Authority requires more than 480 Pennsylvania-licensed facilities to report adverse events and near misses using PA-PSRS.

From June 2004 through 2009, the PPSA received 107 reports describing potential patient contamination due to inadequate or improper endoscope reprocessing techniques. Of the 107 reports, 62 made reference to potentially contaminated endoscopes being used on patients. In the remaining 45 reports, potentially contaminated endoscopes either reached patients, but were not used, or the reports lacked sufficient information to determine patient involvement.

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Pennsylvania Patient Safety Authority analysts established five categories of errors based on these reports:

① Not Cleaned or Deviation from Endoscope Reprocessing Protocol (65 reports)

This category describes endoscopes that either were not cleaned or were improperly cleaned during reprocessing. Reports include the following:

■ A bronchoscope that was used on a patient was not properly disinfected after use on previous patient. The room was not turned over and equipment was not changed or cleaned before the next patient was brought in. Per infection control, the first patient did not have any infectious disease that would harm the second patient, and there was no direct exchange of body fluids. The second patient will have follow-up visits to ensure no injury occurred.

② Endoscope Not Sterile (22 reports)

This category captures reports that describe endoscopes that may have been cleaned properly but not sterilized before subsequent use. Reports include the following:

- A bronchoscope was used at the beginning of a case and then washed and put in a case tray to be sterilized. The physician needed a bronchoscope immediately, and used the same scope that was used earlier. The patient was deteriorating and no other scope was immediately available.

- A case was delayed due to a scope not sterilized for a procedure.

3 Documentation/Indicator Strip Missing or Unchanged after Sterilization Process (17 reports)

This category captures reports that describe situations in which documentation or indicator test strips verifying endoscopes had been sterilized were either missing or the indicator strips did not change color (a change in color of the strip indicates that the endoscope sterilization process was successful). Reports include the following:

- A flexible ureteroscope was decontaminated, but the indicator did not change to indicate sterility. The physician opted to use scope anyway.

- Upon taking the scope to the OR, it was noted by the tech that there was no indicator in the tray.

4 Knowingly Used Unsterile Endoscope (3 reports)

While this category is not a breakdown in endoscope reprocessing, it is included to demonstrate that behavior can also contribute to the potential risk of endoscopy-related cross contamination. Reports include the following:

- Staff sent for a flexible scope as per the physician. The scope was clean but not sterile. The physician wanted the scope, and stated that the patient already had an infection, so the scope would not hurt the patient.

- A flexible cystoscope was requested from the urology clinic and the only available scope was unsterile. This was needed for the procedure and was used.

According to the Pennsylvania Patient Safety Authority, "Developing and strictly following endoscope reprocessing protocols for each specific endoscope model in a facility's inventory and for each newly purchased model can greatly reduce the likelihood of cross contamination of pathogens between patients. Reprocessing involves not only the endoscope, but also accessories (e.g., irrigation tubing) and the equipment used to clean the endoscopes (e.g., brush). Some reports to the PPSA involved the tips of cleaning brushes found inside endoscope channels after reprocessing between patients. Failure to include these items for reprocessing (as well as failure to regularly inspect and, if necessary, replace these items) also contributes to the risk of contamination. The importance of performing pre-cleaning and manual cleaning of endoscopes, including all channels (used and unused), cannot be overstated. Without effective and thorough cleaning, it would not be possible to fully high-level disinfect or sterilize the endoscope. Neither high-level disinfection nor sterilization will remove gross contamination nor will the germicidal agent (e.g., orthophthalaldehyde, ethylene oxide) used during these processes be able to penetrate surfaces beneath gross contamination to disinfect them; organic material deactivates some disinfectants. Additionally, pre-cleaning and manual cleaning are still to be performed when using an endoscope reprocessor as part of the reprocessing protocol; the endoscope reprocessor is not a substitute for manual cleaning."

As far back as 1999, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) issued a public health advisory addressing infections from

endoscopes inadequately reprocessed by an automated endoscope reprocessing system. This alert referred to several incidents in which patients developed serious infections after being examined with bronchoscopes that apparently were inadequately reprocessed in an automated endoscope reprocessor (AER). In an issue of the CDC's Morbidity and Mortality Weekly Report (MMWR 1999; 48(26); 557-560), the agency reported apparent patient-to-patient transmission of infections following bronchoscopic procedures that used bronchoscopes that were inadequately reprocessed by AERs. Investigation of the reported incidents revealed that there were inconsistencies between the reprocessing instructions provided by the manufacturer of the bronchoscope and the manufacturer of the AER; or bronchoscopes were inadequately reprocessed when inappropriate channel connectors were used with the AER. At that same time, the FDA was aware via its Medical Device Reporting (MDR) program that some users were using AERs to reprocess endoscopes that should not be processed in AERs; this practice may have resulted in damaged endoscopes and also raises questions about whether such processing results in an endoscope that is properly prepared for patient contact.

What is important to emphasize is that the FDA requires certain information in the labeling of devices such as AERs. Since 1996, the FDA has requested manufacturers of reusable medical devices to recommend at least one reprocessing method in their device labeling. The level of reprocessing should be based on the device's contact with the patient and the risk for disease transmission. Generally, endoscope manufacturers provide manual reprocessing instructions for each endoscope model. Following these instructions should result in endoscopes that are patient-ready. The FDA has also requested that the labeling of the AER include instructions for reprocessing specific models of endoscopes, and that the instructions should be based on the results of validation studies with the specific endoscope models. The 1993 FDA guidance for AER manufacturers recommended that the AER labeling: list all brands and models of endoscopes that are compatible with the AER; identify the AER's limitation to process certain brands and models of endoscopes and accessories, or identify the endoscopes and accessories that cannot be reliably reprocessed in the AER; and be compatible with the endoscope manufacturer's cleaning and disinfection instructions.

AERS have an important role to play in the high-level disinfection and sterilization process. As the ECRI Institute explains, "Endoscope reprocessors are designed to standardize and automate the preparation of a manually pre-cleaned endoscope so that it is safe for immediate reuse. Manual reprocessing is not always performed effectively or consistently due to human fallibility, the number of complicated steps involved, and the pressure to reprocess endoscopes quickly between patient procedures. Automatic reprocessors can reduce the likelihood that a crucial reprocessing step will be skipped, help ensure that reprocessing is performed consistently using a recommended protocol, and reduce personnel exposure to the irritating effects of liquid disinfectants/sterilants." We will discuss AERs more specifically in another section of this report.

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– ECRI Institute

THE COMPLEXITIES OF MEDICAL DEVICES

At a series of workshops and at a summit held by the FDA and the Association for the Advancement of Medical Instrumentation (AAMI), stakeholders from clinical and industry discussed and debated the numerous challenges sterile processing professionals face when cleaning, decontaminating, disinfecting and sterilizing medical devices that have complex components that are difficult to disassemble, clean and reassemble properly. These events are part of the FDA's ongoing effort to address patient exposure to inadequately reprocessed reusable medical devices with the overall goal to reduce the risk of infection. It's a timely effort, judging by the continuing news of outbreaks related to improperly cleaned, disinfected and sterilized surgical instruments, as well as the aforementioned FDA's receipt of a number of reports of patient exposure to inadequately reprocessed medical devices and subsequent healthcare-associated infections (HAIs). Several reports contained evidence suggesting that inadequate reprocessing may have been a contributing factor in microbial transmission and subsequent infection. The FDA says that "A definitive causal relationship between reusable device reprocessing and any patient infection is difficult to establish, because inadequate reprocessing is not often investigated as a cause when an HAI is diagnosed. Ensuring adequate reprocessing of reusable medical devices could reduce the incidence of HAIs associated with the use of a reprocessed medical device. This will decrease the public health burden of HAIs in terms of morbidity, mortality and cost." The FDA adds that, "The adequate reprocessing of reusable medical devices is a critically important factor in protecting patient safety. Inadequate reprocessing between patients can result in the retention of blood, tissue and other biological debris (soil) in reusable medical devices. This soil can allow microbes to survive the high level disinfection or sterilization process, potentially resulting in healthcare-associated infections (HAIs) or other adverse patient outcomes."

The FDA continues to explore the nature, scope and impact of reusable medical device reprocessing problems that have been observed and the causes of these problems, as well as examine the factors which facilitate reprocessing that should be considered when designing reusable medical devices and how the design process can be improved to better incorporate "cleanability" as a design endpoint for manufacturers.

At a June 2011 FDA workshop, Michelle McMurry-Heath, associate center director for science at the FDA, explained that, "FDA has received scattered reports of improperly cleaned reprocessed medical devices. We particularly noticed difficulty in cleaning some endoscopes, arthroscopic shavers, and reusable devices with specific design features such as lumens, hinges, interior channels, and devices that cannot be easily disassembled, so we took action." McMurry-Heath explained that in 2007, these reports led to an increased concern within the FDA after news about contamination of reprocessed endoscopes in the Veterans Affairs medical system surfaced. In 2008, the FDA collaborated with the VA and CDC to try to address these concerns. In 2009, the FDA issued two safety communications on reprocessed devices, one on endoscopes and one on arthroscopic shavers, and a VA conference

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– FDA

on this topic was held. In April 2011, the FDA launched its initiative, the Reusable Medical Device Improvement Initiative, which was accompanied by new draft guidance, "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

Although some data exists as to the number of reports of outbreaks associated with medical devices, there is a paucity of information that can directly link devices to infections or reprocessing failures. Melissa Schaefer, MD, a medical officer in the Division of Healthcare Quality Promotion of the Centers for Disease Control and Prevention (CDC), addressed this issue in her presentation at the June 2011 FDA workshop. "How often are lapses in reprocessing occurring? I think the answer here is we really don't know," Schaefer said. "The reports that we hear about ... are likely the tip of the iceberg. The reason I say that is because the information we get requires facilities to actually recognize that there is an issue with



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– Melissa Schaefer, MD

reprocessing in their facility. And that requires them to proactively be monitoring the practices of the surgical techs or those that are in charge of reprocessing to make sure that they're adequately trained, and assess adherence to process measures. I don't think that that's reliably occurring in most healthcare facilities, particularly not in outpatient facilities where there's less infection control infrastructure and less oversight. Also, there's difficulty in linking outcome measures or clusters in infections to issues with reprocessing. You may see infections, but it's a number of steps to get back to the reprocessing issue, to put the links between the two. And then even if facilities see that they have an issue with reprocessing, it requires them to recognize that that issue may be a threat to their patient and to report the issues that are identified. Providers may not know what to report, where to report, or when to report. So how often do lapses in reprocessing result in infection? Again, this is a question that we really don't know the answer to, and it likely depends on a number of factors. As I have said, it's difficult to link outcome measures to issues with reprocessing."

Schaefer added, "I think the bad news is that we are continuing to hear about lapses in reprocessing of reusable medical devices, which is why we're all here today ... The good news is that these are preventable, and our sense is that the majority of the problem would be solved if the manufacturer's labels and instructions were followed, and that if people were adequately trained and educated on the importance of adequate reprocessing and the steps that need to be followed so that they don't cut these corners. The smaller proportion may require improvements to instructions or device design, but this is still a really critical component, because the issues with device design

or inadequate instructions have national or international implications, because these devices are in facilities all across the world. Again, it goes back to our knowledge of the issues relying on the reports from the providers. We can't address the problem. We can't fix the problem

if we don't know what the problem is. And so through these outbreaks, through the reports that are filed, it helps us learn from the users what the challenges are so that we can tackle them and focus our efforts."

The clarion themes that emerged from the October 2011 FDA/AAMI summit should serve as a call to action for all stakeholders with roles to play in improving patient safety in reprocessing reusable medical devices. The seven clarion themes are:

- 1 Gain consensus on "how clean is clean" and on adequate cleaning validation protocols for reprocessing reusable medical devices.
- 2 Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.
- 3 Pay early, iterative and comprehensive attention to reprocessing requirements throughout the device design process.
- 4 Make human factors and work environment factors priorities when developing reprocessing requirements.
- 5 Improve information collection and sharing to broaden the use of best practices in reprocessing.
- 6 Improve reprocessing competencies by strengthening training, education and certification.
- 7 Create a greater sense of urgency and understanding throughout the healthcare community about the consequences of inadequate reprocessing

Much of the dialogue at the June 2011 workshop and the October 2011 summit focused on what constitutes and contributes to good medical device design. Devices have become more complex and harder to clean, says Victoria Hitchins, a research microbiologist at the Office of Science and Engineering Laboratories in FDA's Center for Devices and Radiological Health, who spoke at the October 2011 summit. "Today, you can't see if the inside of the device is visibly clean due to long and/or narrow, opaque lumens and hinges."

At the June 2011 FDA workshop, the FDA's McMurry-Heath said that the agency's goals are to improve the design and innovation of design of problematic medical devices, improve reprocessing techniques and the validation of those techniques, and improve healthcare facility quality assurance processes. She said that the FDA uncovered a number of themes: "Contamination is often found in unexpected sections of the device. Sometimes following the labeling instructions did not seem to adequately clean the device, and sometimes manufacturers included unclear and confusing reprocessing instructions."

McMurry-Heath emphasized that all stakeholders needed to work together to address this issue, and explained, "For the manufacturers, this role includes device designs that actually promote disinfection, cleaning, and sterilizing. They need to provide clear and complete and easy-to-follow instructions and ways to follow those instructions very easily. They need to do adequate

"(Manufacturers) need to provide clear and complete and easy-to-follow instructions and ways to follow those instructions very easily."

– Michelle McMurry-Heath

"Successful reprocessing starts with a device that's properly designed for that purpose ... The design needs to take into account the stresses for the device, for the user and ultimately for the patient."

– Sheila Murphey

validation of their cleaning instructions so that we can be assured that they work. Meanwhile, healthcare facilities need to establish appropriate quality assurance programs for reprocessing and make sure that their employees are well trained in how to clean, disinfect and sterilize, as well as store these reusable devices. As well, we are depending upon them to report problems, both to the manufacturer and to FDA. Meanwhile, the FDA has an important role to play as well, to provide clear regulatory requirements, to promote good labeling and manufacturing, and to increase user awareness of this issue. We're working to fulfill this role with the draft guidance and this newly-launched initiative. Both are designed to increase awareness of the issue and improve labeling clarity. But we also see our role as one to promote medical device innovation to meet that challenge. And to that end, we are calling on manufacturers to study reprocessing design and improve the design of these devices."

McMurry-Heath continued, "For example, we've discovered that several features might be beneficial in making these devices easy to clean – smooth surfaces, particularly in the interior lumens area of reusable medical devices, easy disassembly, non-interchangeable connectors for critical connection points, disposable components for hard-to-clean areas – some areas, you just can't get clean – clear identification of connecting accessories, and a clear indication of which components must be discarded after each patient use and cannot be reused, and finally, designs that consider the hydrodynamic properties to prevent debris build-up. Despite these collaborative efforts, challenges remain and will remain for some time. These are complex devices and we're always going to have to take the human factors into account, no matter how clear the labeling is. And we need to be aware that there might be user error, and do what we can, particularly through the quality assurance programs, to minimize that error. And we need to make sure that even though the labeling may be detailed, that it is clear enough to follow and easy enough for a range of different types of healthcare facilities to follow."

At the June 2011 FDA workshop, Sheila Murphey, a medical officer in the Infection Control Devices Branch at the FDA's CDRH, noted the difficulties clinicians face that should be taken into consideration by medical device manufacturers: "Successful reprocessing starts with a device that's properly designed for that purpose ... The design needs to take into account the stresses for the device, for the user and ultimately for the patient. Regarding

the staff who are going to be charged with the reprocessing of the device, the institution has to make sure they've been educated properly to do what they need to do, that they receive the support and supervision to continue to do it properly. We have to commit to doing the same thing the same way on the same high level every day. People have to understand the needs of the device and the resources of the users to put it all together to do it successfully," Murphey added, "Clear and feasible instructions for use are critical to helping make sure that things are done properly. Staff have to be educated. All the tools that can be provided by industry, by professional organizations, by other interested parties, by accrediting organizations, are very useful in supporting the effort and the level of excellence that are going to be needed. We've made a very big deal about instructions

because they can be a source of salvation or a source of problems. They may not be available. They may be incomplete or confusing. They may be difficult to follow properly, tempting the user to not follow them properly. They may be outdated because a device has been updated. The user may not know whether or not they've got the relevant instructions for the relevant model. And for some devices, we've got a lot of models out there. It can be confusing both to the person at the original manufacturer's site who's trying to help the user and the user themselves. The facility can also be a source of problems. Is the space adequate? Is adequate equipment available, adequate utilities available, adequate personnel, and are the personnel given the training and the time to do the workload that they are required to do? Errors in use do happen, and everything that we can do both in terms of checking on people, checking on devices, checking on instructions can help to avoid that."

Michelle J. Alfa, PhD, FCCM, of St. Boniface Hospital, says additional attention from the FDA in matters regarding the reprocessing of medical devices will this help improve reprocessing outcomes. "In my opinion, the involvement of the FDA in scrutinizing the reprocessing of medical devices is an excellent development," Alfa says. "I believe this will provide the leverage needed within healthcare facilities to ensure that adequate processes, efficient equipment and well trained knowledgeable personnel will be made available for reprocessing of medical devices."



"In my opinion, the involvement of the FDA in scrutinizing the reprocessing of medical devices is an excellent development. I believe this will provide the leverage needed within healthcare facilities to ensure that adequate processes, efficient equipment and well trained knowledgeable personnel will be made available for reprocessing of medical devices."

– Michelle J. Alfa, PhD, FCCM

10 Things Your Organization Can Do Now to Improve Reprocessing

- 1 **The basics:** Cleaning and disinfection/sterilization of reusable devices are separate, equally important processes and must be performed before each patient use according to the device manufacturer's written instructions for use (IFU). For more information go to www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm.
- 2 **The right tools:** Have the IFU as well as all cleaning implements and equipment required by the IFU readily available in all the reprocessing areas.
- 3 **Create a multidisciplinary committee** to review the priority issues and set a plan for solving them throughout the organization. The following areas should be represented: OR, infection prevention and control, healthcare technology management (biomed), endoscopy, risk management, quality, safety, education and materials management.
- 4 **Share lessons learned:** Remind senior management and safety officers that it costs a lot less to "do it right the first time." Share lessons learned from other healthcare organizations that have had to inform patients of exposure to inadequately reprocessed reusable devices.
- 5 **Written procedures:** Establish a formal program for reprocessing, including written standardized policies and procedures that include a chain of accountability. Expert guidance can be obtained from industry experts in order to resolve conflicts between the IFU and facility policies. Written procedures should also be developed and implemented for central sterile processing reporting of inadequate instructions, equipment problems, and in-service issues to the manufacturer and, when applicable, to the FDA's MedWatch program.
- 6 **Standards matter:** Know the current standards, recommended practices and IFU.
- 7 **Purchasing:** Central sterile processing should be included in purchasing decisions for medical devices, to provide input on whether the device can be reprocessed appropriately and with the facility's existing resources.
- 8 **Separate and standardize functions and locations:** Separate central service (warehouse, stocking, etc.) from reprocessing; create standardized job descriptions and functions.
- 9 **Training:** Train, train, and retrain. Ideas include: assess staff competencies; negotiate for training budget with cost/benefit analysis to prove value; partner with vendors for education; create a list of available continuing education units (CEUs) for easy access by staff; work with human resources to create career ladders for certification and promotion; promote the importance of certification. Note: In-service for loaner or new instruments should include reprocessing in-service areas that are separate from (or in) central sterile processing.
- 10 **Assessment:** Conduct an audit of compliance with standards and regulations, using any number of available tools and resources. See References and go to: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252941.htm.

Source: AAMI; 2011 Summit Publication: Reprocessing

THE IMPERATIVES OF CLEANING, HIGH-LEVEL DISINFECTION AND STERILIZATION

Endoscopes are so problematic that they were named as No. 3 on the ECRI Institute's Top 10 Health Technology Hazards list (down from No. 1 in 2010), and as No. 4 on AAMI's list of Top 10 Medical Device Challenges for 2011 (AAMI, 2011a and 2011b). What's more, there are at least 36 types of specialized endoscopes according to the FDA's and ECRI Institute's device classification systems (AAMI, 2011b). The challenge for sterile processing personnel is to know how to effectively clean, high-level disinfect and/or sterilize these complex medical devices so that all bioburden is removed.

The persistence of bioburden in medical devices is aided by the formation of biofilms, complex communities of microorganisms embedded in a matrix of extracellular material, formed on surfaces that come in contact with fluid, including all internal and external surfaces of endoscopes, reusable accessory equipment and automated reprocessors. According to the SGNA (2007), "Bacteria located in the biofilm has an altered phenotype and is much more resistant to chemical inactivation due to the bacteria's lowered metabolic state, slower growth rate, and exopolysaccharide production. Mechanical cleaning may be required to effectively remove established biofilms, and it is crucial to follow the cleaning protocol for endoscopes found in SGNA's Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes (2005)."

The SGNA (2007) adds that "Meticulous manual cleaning of all instruments must precede exposure to any high-level disinfectant or sterilant. Inadequate cleaning of instruments has been one factor cited in transmission of infection by flexible endoscopes. Studies demonstrate that

appropriate manual cleaning of endoscopes reduces the number of microorganisms and organic load by four to six logs or 99.9 percent. This process significantly reduces the organic and microbial challenge to the high-level disinfectant or sterilant."

"Meticulous manual cleaning of all instruments must precede exposure to any high-level disinfectant or sterilant. Inadequate cleaning of instruments has been one factor cited in transmission of infection by flexible endoscopes."
—SGNA, 2007

A focus of this report is on high-level disinfection. According to the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), high-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The FDA's definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-log₁₀ kill of an appropriate Mycobacterium species. Cleaning followed by high-level disinfection should eliminate enough pathogens to prevent transmission of infection.

Laparoscopes and arthroscopes entering sterile tissue ideally should be sterilized between patients, according to CDC guidelines, however, in the United States, this equipment sometimes undergoes only high-level disinfection between patients. As with flexible

endoscopes, these devices can be difficult to clean and high-level disinfect or sterilize because of intricate device design (such as long, narrow lumens). Meticulous cleaning must precede any high-level disinfection or sterilization process. Although sterilization is preferred, no reports have been published of outbreaks resulting from high-level disinfection of these scopes when they are properly cleaned and high-level disinfected. Newer models of these instruments can withstand steam sterilization that for critical items would be preferable to high-level disinfection.

No matter the methodology, cleanliness and sterility are the imperatives. In the operating room, the concept of a "sterile conscience" dictates aseptic technique and guides surgical services personnel in their pre-operative, perioperative and post-operative work. The same can be achieved in sterile processing says Michelle J. Alfa, PhD, FCCM, medical director of the clinical microbiology discipline, Diagnostic Services of Manitoba, St. Boniface Hospital in Winnipeg, Manitoba, Canada. "I think this is a significant issue because we want the reprocessing personnel to take ownership and pride in what they do. Often reprocessing personnel feel undervalued and underpaid. The issue of 'sterile conscience' is a subset of the bigger issue which is the individual's sense of pride and ownership of the profession. I think the necessary steps are for reprocessing personnel to acquire certification and to ensure they keep abreast of current issues through continuing education. Knowledge is power as it provides confidence that when taking a stance on inadequate approaches to reprocessing that one is acting based on knowledge to ensure the process used is one that assures best care for the patient."



"We want the reprocessing personnel to take ownership and pride in what they do. Often reprocessing personnel feel undervalued and underpaid."

– Michelle J. Alfa,
PhD, FCCM

THE MECHANICS OF SCOPE REPROCESSING AND DECONTAMINATION, DISINFECTION AND STERILIZATION

Until the day when medical devices are simpler to clean, sterile processing personnel must remain vigilant in their reprocessing tasks and understand why medical devices such as scopes can harbor bioburden and transmit dangerous pathogens. And in order to better understand high-level disinfection and the role of AERs, a review of the basics is in order, including reviewing how medical devices are classified to determine the level of decontamination, disinfection and sterilization they require.

Dr. Earle H. Spaulding of Temple University in Philadelphia developed the original Spaulding classification in a 1939 paper on the disinfection of surgical instruments in a chemical solution, later refining his classification based upon how a medical device is used. Spaulding believed the nature of disinfection could be understood readily if instruments and items for patient care were categorized as critical, semi-critical, and noncritical according to the degree of risk for infection involved in use of the items. This classification system is widely accepted and is used by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists and professional medical organizations to help determine the degree of disinfection or sterilization required for various medical devices.

Three categories of medical devices and their associated level of disinfection are recognized, according to the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities (2008):

1 ■ **Critical:** A device that enters normally sterile tissue or the vascular system. Such devices should be sterilized, defined as the destruction of all microbial life. Critical items confer a high risk for infection if they are contaminated with any microorganism; therefore, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. Examples of endoscopic instruments that require sterilization are biopsy forceps and sphincterotomes, and this category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. Most of the items in this category should be purchased as sterile or be sterilized with steam if possible. Heat-sensitive objects can be treated with EtO, hydrogen peroxide gas

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plasma; or if other methods are unsuitable, by liquid chemical sterilants. Germicides categorized as chemical sterilants include >2.4 percent glutaraldehyde-based formulations, 0.95 percent glutaraldehyde with 1.64 percent phenol/phenate, 7.5 percent stabilized hydrogen peroxide, 7.35 percent hydrogen peroxide with 0.23 percent peracetic acid, 0.2 percent peracetic acid, and 0.08 percent peracetic acid with 1.0 percent hydrogen peroxide. Liquid chemical sterilants reliably produce sterility only if cleaning precedes treatment and if proper guidelines are followed regarding concentration, contact time, temperature, and pH.

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■ **Semi-critical:** A device that comes in contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices (such as endoscopes) should receive at least high-level disinfection, defined as the destruction of all vegetative microorganisms, mycobacteria, small or non-lipid viruses, medium or lipid viruses, fungal spores, and some, but not all, bacterial spores. Semi-critical items contact mucous membranes or non-intact skin. This category includes respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, cystoscopes, anorectal manometry catheters and diaphragm fitting rings. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible. Intact mucous membranes, such as those of the lungs and the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria and viruses. Semi-critical items minimally require high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde and peracetic acid with hydrogen peroxide are cleared by the FDA and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met. When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered.

3

■ **Noncritical:** Devices that do not ordinarily touch the patient or touch only intact skin, such as stethoscopes. These items may be cleaned by low-level disinfection. Some items that may come in contact with non-intact skin for a brief period of time (such as hydrotherapy tanks or bed side rails) are usually considered noncritical surfaces and are disinfected with intermediate-level disinfectants (such as phenolic, iodophor, alcohol or chlorine).

The CDC considers flexible endoscopes to be classified as semi-critical devices because they come in contact with mucous membranes but do not normally enter sterile tissue; therefore, the CDC recommends that flexible endoscopes receive at least high-level disinfection. Sterilization inactivates all microbes, including bacterial endospores, whereas high-level disinfection will inactivate all vegetative bacteria, mycobacteria, fungi, and viruses, but not necessarily all bacterial endospores. According to ECRI Institute's "Healthcare Product Comparison System: Flexible Endoscope Reprocessors, Automatic": "Because endoscopes are used repeatedly during the course of a day, they must be reprocessed quickly between procedures. Therefore, neither ethylene oxide (EtO) sterilization, which can take up to 36 hours, nor glutaraldehyde cold sterilization, which can take up to 10 hours and possibly damage endoscopes, is practical. In addition, very few flexible endoscopes can withstand steam sterilization without deterioration. The high cost of these instruments makes simply adding additional inventory to

accommodate the long processing time impractical. Therefore, most hospitals usually choose either HLD or liquid sterilization in lieu of conventional sterilization methods. (At present, there is no conclusive evidence indicating that one method is safer than the other.) Most hospitals use either an activated 2 percent glutaraldehyde solution or ortho-phthalaldehyde (OPA) for HLD or hydrogen peroxide or peracetic acid for sterilization. Peracetic acid is also increasingly being used for HLD.”

The ECRI Institute (2009) explains that flexible endoscopes can cause nosocomial infection in two ways: the endoscope can auto-inoculate a patient with his or her own microbes (referred to as an endogenous infection), or a contaminated endoscope can act as a carrier, transmitting a variety of microorganisms to the patient from either a previous patient or the environment. The ECRI Institute (2009) states, “There have been reports of reprocessors becoming contaminated and subsequently passing contamination to scopes that were processed in them. The microorganisms often found in tap water can proliferate to significant levels in endoscopes, their accessories, and ancillary equipment during improper storage or as a result of improper maintenance of a reprocessor. However, if correct reprocessing and equipment maintenance protocols are followed, infection risk is relatively low. Bacteria filters are intended to remove microbial pathogens from the water used to rinse disinfectant/sterilant off the newly reprocessed endoscopes; however, filters must be changed regularly to remain functional and there is no guarantee the water will be totally free from contaminants. Although requirements vary by country, periodic testing for pathogenic microorganisms in the rinse water would help to reduce the risk of infection. Hospital personnel must ensure that all internal endoscope channels are free from residual water droplets. Failure to evacuate rinse water from the endoscope’s internal channels with 70 percent alcohol and/or forced air has been linked to infections caused by waterborne pathogens, such as *Pseudomonas aeruginosa*, which thrive in moist environments. This precaution is especially important if the endoscope will be in storage for a significant amount of time since a lull in use would provide pathogens with the opportunity to colonize and proliferate in large quantities.”

Rutala (2004) observes that infections have been traced to deficient practices relating to the reprocessing of scopes including inadequate cleaning (especially of all channels); inappropriate/ineffective disinfection (attention must be paid to time exposure, perfuse channels, test concentration, ineffective disinfectant, inappropriate disinfectant); failure to follow recommended disinfection practices; and flaws in the design of the endoscopes or the AERs.

The American Society for Gastrointestinal Endoscopy (ASGE) emphasizes the key steps in endoscope reprocessing, especially:

- Bedside cleaning and aspiration of enzymatic detergent through the suction channel
- Manual washing and brushing of accessible channels
- Subsequent disinfection via immersion for an appropriate duration in a liquid chemical germicide of appropriate concentration
- A water rinse, alcohol flush and air drying of all channels.

The SGNA (2007) outlines steps to clean and perform high-level disinfection of gastrointestinal endoscopes, emphasizing that “endoscope manufacturers’ instructions should always be consulted for design features unique to a particular instrument, which may require specific

reprocessing detail.” While the following protocol specifically addresses gastrointestinal endoscopes, its steps may be applied to reprocessing other types of flexible endoscopes.

Proper endoscope reprocessing must include the following steps:

- 1 pre-cleaning
- 2 leak testing
- 3 cleaning
- 4 rinsing
- 5 disinfection
- 6 rinsing
- 7 drying
- 8 storage

Let’s review each step in more detail.

1 Pre-cleaning

According to the SGNA (2009), the reprocessing protocol begins immediately following the procedure, when the insertion tube is wiped with a wet cloth or sponge soaked in freshly prepared detergent solution. This cloth/sponge should be disposed of, sterilized or high-level disinfected between cases, according to Rutala and Weber (2004). The distal end of the endoscope should be placed into the detergent solution. The solution should be suctioned through the biopsy/suction channel, alternate suctioning detergent solution and air several times until the solution is visibly clean. Finish by suctioning air, noting that alternate suctioning of fluid and air is more effective than suctioning fluid alone in the removal of debris from internal lumens, and that immediate flushing of the biopsy/suction and air/water channels precludes drying of organic and inorganic debris on lumen surfaces and may remove large numbers of microorganisms. The manufacturer’s instructions should be followed when flushing or blowing out air and water channels. Flush the auxiliary water channel as well. Detach the endoscope from the light source and suction pump and transport the endoscope to the reprocessing area in an enclosed container which will prevent contamination during transport. These steps help to moisten and soften debris in preparation for the subsequent, more vigorous manual cleaning step and the reprocessing steps that should occur in an area separate from the procedure room.

2 Leak testing

This step is performed in the processing room after pre-cleaning but before manual cleaning begins. This test consists of pressurizing the endoscope with air and submerging it in water to check for damage such as leaks. If damage exists, air bubbles should be visible while the endoscope is submerged. If damage is evident, the endoscope is removed from service and repaired. If no damage is evident, the endoscope continues to the manual cleaning stage.

The SGNA (2009) advises that the leak test be performed before immersion of the endoscope in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure. The leak test should also be conducted according to the endoscope manufacturer’s instructions.

Manual cleaning of endoscopes is necessary immediately after removing the endoscope from the patient and prior to automated or manual disinfection; this is the first and most important step in removing the microbial burden from an endoscope.
– SGNA, 2009

For manual leak testing, the SGNA (2009) indicates that the endoscope must be completely disassembled so that all surfaces may be reached for thorough cleaning. Remove suction valves, air water valves and biopsy valves; discard those parts that are designated as disposable. Attach the leak tester and pressurize the scope before submerging it in water. Refer to specific manufacturer's instructions to determine if it is necessary to remove other detachable parts before leak testing. With the pressurized insertion tube completely submerged, flex the distal portion of the scope in all directions, observing for bubbles. Submerge the entire endoscope and, observing the control head of the scope, depress the freeze and release buttons. Check the insertion tube and distal bending section as well as the universal cord for bubbles coming from the interior of the scope.

For computerized leak testing, the SGNA (2009) advises the following steps: Remove suction valves, air water valves, and biopsy valves. Attach the leak tester to the computer. Input data including scope ID and user. Move knobs and depress the freeze and release buttons when indicated. Reprocess when test is complete. Follow the endoscope manufacturer's instructions if a leak or high humidity is detected or if the endoscope appears damaged.

3 Cleaning

The endoscope is first immersed in an enzymatic detergent solution, and then debris is wiped and/or brushed from the endoscope's exterior surfaces. All the channels—even those not used during the endoscopic procedure—are brushed, aspirated, and flushed with the detergent. All the endoscope's removable parts are cleaned separately.

The SGNA (2009) advises that a cleaning solution should have a broad spectrum of effectiveness against various contaminants and not harm the device being cleaned. It notes that the ideal solution would combine the benefits of water and organic solvents and also be able to penetrate and lift soil from the instrument suspending it in solution. Enzymatic cleaning solutions use surfactants to break down and digest bioburden. They are specifically selected to have a negligible effect on surface tension while still suspending soil particles. This feature provides easy rinsibility. Specific product labeling will define the time required for this enzyme activity to take place and must be incorporated into the cleaning process.

Manual cleaning of endoscopes is necessary immediately after removing the endoscope from the patient and prior to automated or manual disinfection; this is the first and most important step in removing the microbial burden from an endoscope, according to the SGNA (2009). Retained debris may inactivate or interfere with the capability of the active ingredient of the chemical solution to effectively kill and/or inactivate microorganisms.

The SGNA (2009) recommends the following steps for manual cleaning: Fill a sink or basin with freshly-made solution of water and a medical grade, low-foaming, neutral pH detergent formulated for endoscopes that may or may not contain enzymes. Dilute and use according to the detergent manufacturer's instructions, noting that freshly prepared detergent

solution should be used for each endoscope to prevent cross-contamination, and that low-foaming detergents are recommended such that the device can be clearly visualized during the cleaning process, preventing personnel injury and allowing for complete cleaning of lumen surfaces. Excessive foaming can inhibit good fluid contact with the device surfaces. Immerse the endoscope. Wash all debris from the exterior of the endoscope by brushing and wiping the instrument while submerged in the detergent solution. Whenever practical, leave the endoscope submerged in the detergent solution when performing all subsequent cleaning steps. Note that the instrument should be left under water during the cleaning process to prevent splashing of contaminated fluid and aerosolization of bioburden. Use a small, soft brush to clean all removable parts, including inside and under the suction valve, air/water valve, and biopsy port cover and openings. Use non-abrasive and lint-free cleaning tools to prevent damage to the endoscope. Brush all accessible endoscope channels including the body, insertion tube and the umbilicus of the endoscope. Use a brush size compatible with each channel. After each passage, rinse the brush in the detergent solution, removing any visible debris before retracting and reinserting it. Continue brushing until there is no debris visible on the brush. Clean and high-level disinfect reusable brushes between cases. Attach the endoscope manufacturer's cleaning adapters for suction, biopsy, air, and water channels. Note: Automated pumps are available for this step that eliminate the manual flush. Refer to manufacturer's guidelines for the use of these devices. Attach the manufacturer's cleaning adapters for special endoscope channels (e.g., elevator channel, auxiliary channel and double-channel scopes). To achieve adequate flow through all lumens, various adapters or channel restrictors may be required. Refer to the manufacturer's instructions. Flush all channels with the detergent solution to remove debris. Soak the endoscope and its internal channels for the period of time specified by the label, if using an enzymatic detergent.

"While proper mechanical cleaning (stage 1) and high-level disinfection (stage 2) are crucial to the prevention of disease transmission during GI endoscopy, the success of an endoscope reprocessing procedure also depends on the adequacy of the drying step and the microbial quality of the water used to remove the residual liquid chemical germicide from the endoscope after disinfection."

– Nelson and Muscarella, 2006

4 Rinsing

The endoscope is then rinsed with water. Rinsing may also include using forced air to remove excess water from the endoscope before disinfection or sterilization. According to the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), rinsing endoscopes and flushing channels with sterile water, filtered water or tap water will prevent adverse effects associated with disinfectant retained in the endoscope (e.g., disinfectant-induced colitis). Items can be rinsed and flushed using sterile water after high-level disinfection

to prevent contamination with organisms in tap water, such as nontuberculous mycobacteria, Legionella or Gram-negative bacilli such as Pseudomonas. Alternatively, a tap water or filtered water (0.2m filter) rinse should be followed by an alcohol rinse and forced air drying. SGNA (2007): All high-level disinfectants or sterilants used to reprocess flexible endoscopes have the potential to injure mucous membranes if not thoroughly rinsed from the endoscope. In addition, rinse water may contaminate the endoscope following chemical exposure. After high-level disinfection, the endoscope must be rinsed and the channels flushed with sterile, filtered or tap water to remove the disinfectant/sterilant.

Nelson and Muscarella (2006) emphasize that, "While proper mechanical cleaning (stage 1) and high-level disinfection (stage 2) are crucial to the prevention of disease transmission during GI endoscopy, the success of an endoscope reprocessing procedure also depends on the adequacy of the drying step and the microbial quality of the water used to remove the residual liquid chemical germicide from the endoscope after disinfection. In general, three types of water are used to rinse endoscopes after chemical immersion: tap water, bacteria-free water, and "sterile" or "sterile filtered" water. Despite their label claim, however, all of these water types, including "sterile" water, have been linked to bacterial contamination and nosocomial infection following endoscopy. Because the water used to rinse the endoscope after chemical immersion is not generally microbiologically monitored (i.e., periodically cultured), its microbial quality is almost always unknown. The rinse water contacts the endoscope after high-level disinfection (or "liquid sterilization"), whether achieved manually or using an automated endoscope reprocessor (AER), and in many cases just prior to clinical use (if not exposed to a drying cycle). Thus any contamination of the rinse water will inevitably lead to contamination of the endoscope regardless of the potency, strength, or effectiveness of the preceding cleaning process or of the LCG, AER or automated processing system."

Nelson and Muscarella (2006) add that, "The importance of microbiological monitoring of the rinse water used during the reprocessing of GI endoscopes is controversial. Whereas some countries encourage this practice, others (including the United States) do not, having concluded that the relationship between the presence of bacteria in the rinse water and nosocomial infection has not been adequately defined. As discussed previously, contamination of endoscopes with waterborne, Gram-negative bacteria has been linked to adverse patient outcomes. Unless the rinse water is monitored to evaluate its microbial quality and content, the potential exists for the rinse water to contain pathogenic microorganisms capable of re-contaminating the endoscope during terminal water rinsing, compromising the effectiveness of the reprocessing procedure, invalidating the disinfection (or "liquid sterilization") claim, and posing a risk of nosocomial infection. Periodic sampling of the rinse water used during endoscope reprocessing also provides independent verification that the bacterial filter, which is used to improve the microbial quality of the rinse water used by virtually all AERs, is working properly and producing "bacteria-free" or "sterile" water as labeled. Bacterial filters have

"The importance of microbiological monitoring of the rinse water used during the reprocessing of GI endoscopes is controversial."

– Nelson and Muscarella, 2006

a limited life-span and have been reported to fail, allowing bacteria to pass, resulting in true and pseudo outbreaks. It is for these and other reasons that some reports recommend microbiological monitoring of the rinse water, to preempt re-contamination of the endoscope. The importance and necessity of this practice, and the recommendation that the rinse water be bacteria-free or sterile, is minimized, however, by thoroughly drying the endoscope after completion of every reprocessing cycle (i.e., between patient procedures and before storage) to prevent the transmission of waterborne microorganisms that may reside in the rinse water. Professional organizations and governmental agencies are encouraged to develop standards that establish permissible levels of waterborne bacteria (and endotoxins) for the rinse water, to ensure its microbial quality does not pose an infection risk during endoscopy.”

5 High-level disinfection/sterilization

The endoscope is either high-level disinfected or sterilized. Sterilization inactivates all microbes, including bacterial endospores, while high-level disinfection inactivates all vegetative bacteria, mycobacteria, fungi and viruses, but not necessarily all bacterial endospores. This step can be performed manually or by using an endoscope reprocessor. The decision to disinfect or sterilize an endoscope is typically based on the aforementioned Spaulding classification system.

To use high-level disinfectants and sterilants, the SGNA (2009) recommends the following steps: Prepare the product according to disinfectant/sterilant manufacturer’s label instructions.

Test the product for the MEC according to the label on the test strip container, noting that the reuse life of a reusable high-level disinfectant/sterilant is related to several factors including, but not limited to, dilution, time/temperature, and number of uses. It is essential that the level of active ingredient be at or above that required to kill and/or inactivate the desired microorganisms. (In each facility, a quality study is recommended to assist in determining guidelines for your particular circumstances.) The MEC may never be used to extend the reuse life claim of the product, and the MEC may never be used beyond the date specified on activation. Use a product-specific test strip, and keep a log of the test results.

For manual disinfection, the SGNA (2009) advises the following process: Completely immerse the endoscope and all removable parts in a basin of high-level disinfectant/sterilant. (The basin must be of a size to accommodate the endoscope without undue coiling, and must have a tight-fitting lid to contain the chemical vapors. To prevent damage to the endoscope, the endoscope should not be soaked with other sharp instruments that could potentially damage the endoscope.) Inject disinfectant into all channels of the endoscope until it can be seen exiting the opposite end of each channel. Take care that all channels are filled with the chemical, and that no air pockets remain within the channels. Cover the soaking basin with

"Professional organizations and governmental agencies are encouraged to develop standards that establish permissible levels of waterborne bacteria (and endotoxins) for the rinse water, to ensure its microbial quality does not pose an infection risk during endoscopy." – Nelson and Muscarella, 2006

a tight-fitting lid to minimize chemical vapor exposure. Soak the endoscope in the high-level disinfectant/sterilant for the time/temperature required to achieve HLD. Use a timer to verify soaking time. Purge all channels completely with air before removing the endoscope from the high-level disinfectant/sterilant. Purging the channels preserves the concentration and volume of the chemical, and prevents exposure from dripping and spilling.

For automated high-level disinfection, the SGNA (2009) emphasizes that, "It is necessary to follow all steps for the manual cleaning of the endoscope prior to using an automated reprocessor. No independent confirmatory data are currently available to show that automated reprocessors are able to provide cleaning of endoscopes that is comparable to that of manual washing and brushing (ASGE, 2007)."

The SGNA (2007) says that an automated endoscope reprocessor should have the following features:

- The machine should circulate fluids through all endoscope channels at an equal pressure without trapping air. Channel flow sensors provide an added measure of compliance.
- The detergent and disinfectant cycles should be followed by thorough rinse cycles and forced air to remove all used solutions.
- The disinfectant should not be diluted with any fluids.
- The machine should be self-disinfecting.
- No residual water should remain in hoses and reservoirs.
- Cycles for alcohol flushing and forced air drying are desirable.
- The machine should also feature a self-contained or external water filtration system.
- A method to automatically store or print data verification of cycle completion is desirable.

To use an automated reprocessor, the SGNA (2009) recommends the following process: Follow steps for manual cleaning of the endoscope. Prepare the endoscope reprocessor according to manufacturer's guidelines. Place the endoscope in the reprocessor and attach all channel adapters according to manufacturer's instructions (users should check with their endoscope manufacturer for model-specific information). Place valves and other removable parts into the soaking basin of the reprocessor. Unless the reprocessor has a dedicated space for accessories, reprocess these items separately. If the machine has a cycle that uses enzymatic detergent, it should be a product that is compatible with the reprocessor and the endoscope. Note that improper amounts and dilution of the enzymatic detergent may allow detergent residue to remain on the internal and external surfaces of the endoscope, and/or on the sink surfaces of the reprocessor. Enzymatic detergent residue may interfere with the action of the high-level disinfectant or sterilant. Set the machine for the appropriate time and temperature depending on the chemical used. Start the machine and allow it to complete all cycles/phases. Note that if cycles/phases are interrupted, HLD cannot be ensured and full cycle must be repeated. If a final alcohol rinse cycle is not included in the automated reprocessor cycle, this step should be done manually followed by purging all the channels with air until dry. Drying and storage procedures are the same as described in the aforementioned manual disinfection process.

No discussion of high-level disinfection and sterilization is complete without examining best practices related to the chemicals used in these processes. As Rutala and Weber (1999)

observe, “The characteristics of an ideal chemical sterilant used as a high-level disinfectant should include broad antimicrobial spectrum, rapid activity, material compatibility, lack of toxicity to humans and the environment, odorless, non-staining, unrestricted disposal, prolonged reuse life and shelf life, easy to use, resistant to organic material, ability to be monitored for concentration and cost effective.”

One of the most important considerations relating to HLD chemicals is determining the minimum effective concentration (MEC) of reusable chemicals such as glutaraldehyde, 7.5 percent hydrogen peroxide, 0.08 percent peracetic acid/1 percent hydrogen peroxide and 0.55 percent ortho-phthalaldehyde are reusable products (FDA, 2005). A gradual reduction in the effectiveness of high-level disinfectants/sterilants can be triggered by the presence of microbes and organic matter, dilution by rinse water and age of the chemical solution. As the SGNA (2007) explains, “Reusable high-level disinfectant/sterilants must be changed whenever the MEC fails or the reuse life expires, whichever comes first. If additional chemical solution is added to an automated endoscope reprocessor (AER) or basin (if manually disinfected) the reuse life should be determined by the first use/activation of the original solution. The practice of “topping off” of the chemical does not extend the reuse life. The appropriate number of reuses of each of these products must be determined by testing that the solution is at or above its MEC. Use product-specific test strips. MEC should be monitored according to the manufacturer’s instructions (AAMI, 2005) and a log of test results should be maintained.”

6 Rinsing

Following manual disinfection, the SGNA (2009) recommends thoroughly rinsing all surfaces and removable parts, and flushing all channels of the endoscope and its removable parts with clean water according to disinfectant and endoscope manufacturer’s recommendations. Rinsing prevents exposure and potential injury of skin and mucous membranes from chemical residue. Fresh clean water should be used for each rinse of the endoscope.

7 Drying

According to the CDC’s Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), forced-air drying markedly reduces bacterial contamination of stored endoscopes, most likely by removing the wet environment favorable for bacterial growth. After rinsing, items should be dried and stored (e.g., packaged) in a manner that protects them from recontamination.

According to the SGNA (2007), “Irrespective of the quality of the water used to rinse flexible endoscopes during manual or automated reprocessing, the entire endoscope must be dried, with each of its internal channels being flushed with 70 percent alcohol, followed by forced-air drying, both between patient and prior to storage. This step greatly reduces the possibility of recontamination of the endoscope by waterborne microorganisms and it also facilitates drying the instrument. Nelson and Muscarella (2006) concur, and emphasize that drying the endoscope during post-processing (stage 3) is necessary to prevent potential re-contamination of the endoscope with waterborne microorganisms during terminal water rinsing. Nelson and Muscarella (2006) point to surveys indicating that not all GI endoscopy

units dry the endoscope after water rinsing and prior to reuse or storage and emphasize that rinse water that is not removed during drying and remains in the endoscope's narrow internal channels between patient procedures or during storage can provide the ideal environment for waterborne microorganisms to colonize and multiply. Cases of nosocomial infection due to the transmission of microorganisms that have colonized and proliferated in the moist internal channels of inadequately dried and improperly stored endoscopes to the patients undergoing GI endoscopy have been reported, resulting in patient injury and death.

The SGNA (2009) advises sterile processing personnel to purge all channels with air until dry, but avoid the use of excessively high air pressure which can damage the internal channels of flexible endoscopes. Flush all channels, including accessory channels, with alcohol until the alcohol can be seen exiting the opposite end of each channel (70 percent isopropyl alcohol is used to assist in drying the interior channel surfaces). Purge all channels with air, noting that alcohol mixes with the remaining water on the channel surfaces and acts to encourage evaporation of the residual water as air flows through the channel. Remove all channel adapters. Dry the exterior of the endoscope with a soft, clean lint-free towel. Thoroughly rinse and dry all removable parts. Do not attach removable parts (e.g., valves, etc.) to the endoscope during storage. Note that storage of endoscopes with the removable parts detached lowers the risk of trapping liquid inside the instrument and facilitates continued drying of the channels and channel openings.

8 Storage

The SGNA (2007) says that storage of the endoscope in a dry and well-ventilated environment in accordance with the endoscope manufacturer's instructions is important to prevent the colonization of bacteria and subsequent patient infection. The endoscopes must hang vertically with its control valves and biopsy inlet cap removed to facilitate air movement (SGNA, 2005).

The SGNA (2009) recommends the following steps: Hang the endoscope vertically with the distal tip hanging freely in a clean, well-ventilated, dust-free area. A storage area with good ventilation will encourage continued air drying of the surfaces, and prevent undue moisture build-up, thus discouraging any microbial contamination. Correct storage of the GI endoscope will prevent damage to the exterior of the instrument by protecting it from physical impact. Padding the lower portion of the storage area with non-porous material may prevent damage to the distal end of the scope.

Nelson and Muscarella (2006) note that, "Provided the endoscope is properly reprocessed and dried prior to storage, reprocessing the endoscope immediately before its first use of the day does not appear to be necessary. There are few data that provide insight into the number of days a specific type of GI endoscope may remain in storage without posing an infection risk and requiring reprocessing before its reuse. Two studies, however, suggest that properly reprocessed and dried endoscopes may remain in storage for five to seven days without requiring reprocessing before reuse. The type of endoscope, its frequency of reuse, and the effectiveness of the reprocessing and drying protocols may all be factors that influence and affect the number of days a GI endoscope can remain safely in storage without posing a risk of bacterial colonization and nosocomial infection. Research to determine storage intervals is encouraged." This issue is "unresolved" according to a new multi-society guideline (2011) discussed later in this report.

UPDATED GUIDANCE FOR SCOPE REPROCESSING

Flexible GI endoscopes should first be completely cleaned and then subjected to at least high-level disinfection – a recommendation made by the FDA and the CDC, as well as professional organizations such as ASGE, the American College of Gastroenterology, the American Gastroenterology Association, the Society of Gastroenterology Nurses and Associates (SGNA), the Association of periOperative Registered Nurses (AORN), and the Association for Professionals in Infection Control and Epidemiology (APIC). The recommended practices from these federal agencies and professional organizations are widely available, yet compliance with these guidelines is lacking. As an example, in 1991, Gorse and Messner surveyed more than 2,000 members of SGNA and found that compliance with various aspects of existing guidelines ranged from 67 percent to 93 percent. That same year, a collaborative study by the FDA and several state health departments investigating endoscope reprocessing at more than 25 healthcare facilities reported that 24 percent of patient-ready endoscopes (GI endoscopes and bronchoscopes) were culture positive, and these were associated with “a number of fundamental errors in the disinfection process.” In 1997, Jackson and Ball surveyed 19 family practice and internal medicine offices performing flexible sigmoidoscopy and found that all were deficient in following reprocessing guidelines in at least one area. Although subsequent studies suggested that compliance with reprocessing guidelines had improved, a minority of endoscopy centers still did not conform completely to accepted guidelines. In a 2004 survey of SGNA members at centers in the mid-Atlantic states, compliance with published standards was inconsistent, with a wide variation in adherence to

both global principles and specific steps of manual cleaning, high-level disinfection, drying and quality monitoring. In 2009, the CDC piloted an infection control audit tool during inspection of 68 ambulatory surgical centers in four states to assess adherence to recommended practices. Adherence to recommendations for reprocessing of endoscopic equipment was not uniform in 28.4 percent of 67 ambulatory surgery centers.

In June 2011, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Healthcare Epidemiology of America (SHEA) updated existing guidelines from 2003. The two organizations collaborated with multiple physician and nursing organizations, infection prevention and control organizations, federal and state agencies, and industry leaders to develop and update these evidence-based guidelines for reprocessing GI endoscopes. This updated guidance document includes discussion of new and/or evolving reprocessing issues and updated literature citations. Specific additions or changes include review of expanded details related to critical reprocessing steps (including cleaning and drying), reprocessing issues for various endoscope attachments such as flushing catheters, discussion of risks related to selected peri-procedural practices including medication administration,

The recommended practices from federal agencies and professional organizations are widely available, yet compliance with these guidelines is lacking.

and mention of newly recognized issues for which there are incomplete data with which to guide practice. They include endoscope shelf life or “hang time” (the interval of storage after which endoscopes should be reprocessed before use), the role of microbiological surveillance testing of endoscopes after reprocessing, and questions regarding endoscope durability and longevity from the standpoint of infection prevention.

The multi-society guideline makes the following recommendations:

- 1 All healthcare personnel in the endoscopy suite should be trained in and adhere to standard infection prevention and control recommendations (e.g., standard precautions), including those to protect both patients and healthcare workers.
- 2 Pre-cleaning should be performed at the point of use, before bioburden has an opportunity to dry and before complete decontamination. Point-of-use pre-cleaning should remove visible debris by wiping the exterior of the endoscope with appropriate detergent solution and aspiration of a large volume of detergent solution through the air/water and biopsy channels.
- 3 After point-of-use pre-cleaning, transport the soiled endoscope to the reprocessing area for subsequent steps in high-level decontamination before remaining soil dries. During transportation, soiled endoscopes should be contained in a manner that prevents exposure of staff, patients, or the environment to the potentially infectious organisms. An open container can suffice for transport to immediately adjacent reprocessing rooms, but fully enclosed and labeled containers or bags should be used for transportation to distant reprocessing areas.
- 4 Perform pressure/leak testing after each use and before formal reprocessing, according to manufacturer guidelines.
- 5 Before manual or automated high-level disinfection, meticulously clean the entire endoscope, including valves, channels, connectors, and all detachable parts. Disconnect and disassemble endoscope components (e.g., air/water and suction valves) as far as possible and completely immerse the endoscope and components in an appropriate detergent that is compatible with the endoscope, according to the manufacturer’s instructions. Flush and brush all accessible channels to remove all organic (e.g., blood, tissue) and other residues. Repeatedly actuate the valves during cleaning to facilitate access to all surfaces. Clean the external surfaces and components of the endoscope by using a soft cloth, sponge, or brushes.
- 6 Use brushes appropriate for the size of the endoscope channel, parts, connectors, and orifices (e.g., bristles should contact all surfaces) for cleaning. Cleaning items should be disposable or thoroughly cleaned and disinfected/sterilized between uses.
- 7 Discard enzymatic detergents after each use because these products are not microbicidal and will not retard microbial growth.
- 8 Reusable endoscopic accessories (e.g., biopsy forceps, other cutting instruments) that break the mucosal barrier should be mechanically cleaned as described previously and then sterilized between each patient use (high-level disinfection is not appropriate).
- 9 Ultrasonic cleaning of reusable endoscopic accessories and endoscope components may be used to remove soil and organic material from hard-to-clean areas.

10 Endoscopes (and accessories) that come in contact with mucous membranes are classified as semi-critical items and should receive at least high-level disinfection after each patient use.

11 There are new high-level disinfectants and agent-specific machines on the market. Information regarding these technologies should be obtained from the FDA Web site and independent peer-reviewed publications. Use a high-level disinfectant cleared by the FDA for high-level disinfection (www.fda.gov/cdrh/ode/germlab.html).

12 The exposure time and temperature for disinfecting semi-critical patient care equipment vary among the FDA-cleared high-level disinfectants. Follow the FDA-cleared label claim for high-level disinfection unless several well-designed experimental scientific studies, endorsed by professional societies, demonstrate that an alternative exposure time is effective for disinfecting semi-critical items. The FDA label claim for high-level disinfection with greater than 2 percent glutaraldehyde at 25 degrees C ranges from 20 to 90 minutes depending on the product. Multiple scientific studies and professional organizations support the efficacy of greater than 2 percent glutaraldehyde for 20 minutes at 20 degrees C. -

13 Select a liquid disinfectant or sterilization technology that is compatible with the endoscope. The use of specific high-level disinfectants or sterilization technologies on an endoscope should be avoided if the endoscope manufacturer warns against their use because of functional damage (with or without cosmetic damage).

14 The selection and use of disinfectants in the healthcare field is dynamic, and products may become available that were not in existence when this guideline was written. As newer disinfectants become available, persons or committees responsible for selecting disinfectants for GI endoscope reprocessing should be guided by FDA clearance of these products and by information in the scientific literature.

15 Completely immerse the endoscope and its components in the high-level disinfectant solution and ensure that all channels are perfused. Non-immersible GI endoscopes should not be used.

16 If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components can be effectively reprocessed with the AER (e.g., the elevator wire channel of duodenoscopes is not effectively disinfected by most AERs and this step should be performed manually). Users should obtain and review model-specific reprocessing protocols from both the endoscope and the AER manufacturers and check for compatibility.

17 If an AER is used, place the endoscope and endoscope components in the reprocessor and attach all channel connectors according to the AER and endoscope manufacturers' instructions to ensure exposure of all internal surfaces with the high-level disinfectant solution.

18 If an AER cycle is interrupted, high-level disinfection or sterilization cannot be ensured; therefore, the cycle should be repeated.

19 Because design flaws have compromised the effectiveness of AERs and can also involve endoscopes, the infection prevention staff should routinely review FDA advisories, manufacturer alerts, and the scientific literature for reports of endoscope and AER deficiencies that may lead to infection.

20 After high-level disinfection, rinse the endoscope and flush the channels with sterile, filtered, or tap water to remove the disinfectant solution. Discard the rinse water after each use/cycle. Flush the channels with 70% to 90% ethyl or isopropyl alcohol and dry by

using forced air. The final drying steps greatly reduce the risk of remaining pathogens, as well as the possibility of recontamination of the endoscope by waterborne microorganisms.

21 Visually inspect both endoscopes and reusable accessories frequently in the course of their use and reprocessing, including before, during, and after use, as well after cleaning and before high-level disinfection. Damaged endoscopes and accessories should be removed from use for repair or disposal.

22 When storing the endoscope, hang it in a vertical position to facilitate drying (with caps, valves, and other detachable components removed, per manufacturer's instructions).

23 Endoscopes should be stored in a manner that will protect them from contamination.

24 Although reuse of endoscopes within 10 to 14 days of high-level disinfection appears to be safe, the data are insufficient to provide a maximal duration for use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes. This interval remains poorly defined and warrants further study. As noted in the previous discussion, several organizations advise shorter intervals.

25 High-level disinfect or sterilize the water bottle (used for cleaning the lens and irrigation during the procedure) and its connecting tube at least daily. As noted in the previous discussion, some organizations espouse more frequent exchange of water bottles and tubing. Sterile water should be used to fill the water bottle.

26 Maintain a log for each procedure indicating the patient's name and medical record number (if available), the procedure, and the serial number or other identifier of the endoscope (and AER, if used) to assist in an outbreak investigation.

27 Perform routine testing of the liquid high-level disinfectant to ensure at least the minimum effective concentration of the active ingredient. Check the solution at the beginning of each day of use (or more frequently) and document the results. If the chemical indicator shows that the concentration is less than the minimal effective concentration, the solution should be discarded.

28 Discard the liquid high-level disinfectant at the end of its reuse life (which may be a single use), regardless of the minimal effective concentration. If additional liquid high-level disinfectant is added to an AER (or basin, if manually disinfected), the reuse life should be determined by the first use/activation of the original solution (i.e., the practice of "topping off" of a liquid high-level disinfectant pool does not extend its reuse life).

29 Facilities where endoscopes are used and disinfected should be designed to provide a safe environment for health care workers and patients. Air exchange equipment (e.g., ventilation system and exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapors (e.g., glutaraldehyde). The vapor concentration of the chemical disinfectant used should not exceed allowable limits (e.g., those of the American Conference of Governmental Industrial Hygienists and the Occupational Safety and Health Administration). Although organic vapor respirators appropriate for chemical exposures can provide respiratory protection (e.g., in the event of spills), they are not intended for routine use and are not a substitute for adequate ventilation, vapor recovery systems, and work practice controls.

30 Personnel assigned to reprocess endoscopes should receive device-specific reprocessing instructions (i.e., endoscope and/or AER manufacturer, as needed) to ensure proper cleaning and high-level disinfection or sterilization. Competency testing of personnel that reprocess endoscopes should be performed and documented on a regular basis (e.g., at the start of use, annually). Temporary personnel should not be allowed to reprocess endoscopes until competency has been established.

31 All personnel using chemicals should be educated about the biological and chemical hazards present while performing procedures that use disinfectants.

32 Personal protective equipment (e.g., gloves, gowns, eyewear, respiratory protection devices) should be readily available and should be used, as appropriate, to protect workers from exposure to chemicals, blood, or other potentially infectious material.

33 Healthcare facilities should ensure that users can readily identify whether and when an endoscope has been reprocessed. Category II

34 The use of routine environmental microbiological testing of endoscopes for quality assurance has not been established but warrants further study.

35 If environmental microbiological testing is performed, standard microbiological techniques should be used.

36 Reprocessing of non-endoscopic devices, accessories and attachments should adhere to manufacturers' recommendations.

37 Standard infection prevention practices for aseptic administration of medications, including injectable agents and sedation and analgesia, should be used.

38 In the event of an outbreak caused by a suspected infectious or chemical etiology, the environmental sampling should be performed according to standard outbreak investigation.

39 Endoscopy-related infections should be reported to all of the following: (a) persons responsible for infection control at the institution; (b) the appropriate public health agency (state or local health department as required by state law or regulation); (c) the FDA (www.fda.gov/medwatch); (d) the manufacturer(s) of the endoscope, disinfectant/sterilant, and AER (if used).

The multi-society guideline (2011) acknowledge that "A variety of issues pertinent to reprocessing of flexible endoscopes remain unresolved based on currently available data. Some have received little comment in the existing literature and standards, whereas others have generated considerable discussion or even formal position statements. All warrant further study to clarify optimal practices." These unresolved issues include:

- The interval of storage after which endoscopes should be reprocessed before use, sometimes termed hang time or shelf life, has been the subject of limited investigations. The available data suggest that contamination during appropriate storage for intervals of seven to 14 days is negligible, is not associated with duration, occurs only on the exterior of instruments, and involves only common skin organisms rather than significant pathogens. One study demonstrated limited contamination, predominantly by environmental nonpathogenic organisms, within 24 hours of reprocessing. In a similar study, limited contamination by

nonpathogenic organisms was noted on exterior surfaces and valve ports of endoscopes, but none from fluid flushed through the biopsy channels after five days of storage.⁴⁰ A subsequent study sampled endoscopes serially during clean storage for 14 days. Positive cultures were identified during the first five days of sampling, but not thereafter. In a duplicate second phase, no surveillance cultures were positive, and in a third phase of testing after seven days of storage, only a single culture was positive for *Staphylococcus epidermidis*, a low virulence skin organism. Hence, although reuse within 10 to 14 days appears to be safe, the data are insufficient to provide a maximal duration for use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes. In the absence of full data, however, reprocessing during this interval before use may be advisable, particularly for (a) instruments used infrequently because of low volumes or specialty applications, (b) instruments used in patients at high-risk of infection such as those whose immune systems are suppressed by medications or disease, and (c) instruments used in procedures with anticipated entry to otherwise sterile regions such as the biliary tree, pancreas, and peritoneal space. In the interest of utmost caution, AORN and the Association for Professionals in Infection Control and Epidemiology espouse maximal storage intervals without reprocessing of 530 and 731 days, respectively.

- The optimal frequencies for replacement of clean water bottles and tubing for insufflation of air and lens wash water and waste vacuum canisters and suction tubing have not been determined. In one instance, concern relates to the potential for backflow from a soiled endoscope against the direction of forced fluid and air passage into the clean air/water source and, in the other, from contaminated tubing and collection chamber against a vacuum into clean instruments used for subsequent patients. No data exist pertaining to the safety or potential risk of per-procedure versus per-day exchange of these attachments, and most guidelines do not address these issues. In the interest of utmost caution, AORN espouses changing the clean air/water bottle and tubing for each patient, and some accreditation organizations survey for exchange of waste vacuum canisters and tubing for each procedure. Both issues warrant study.

- Microbiological surveillance testing of endoscopes after reprocessing, during storage, or before use has not been advised in current American standards. However, this quality assurance measure is advised in reprocessing guidelines of several international organizations, including the Gastroenterological Society of Australia and the guideline of the combined European Society of Gastrointestinal Endoscopy and the European Society of Gastroenterology

"Although reuse within 10 to 14 days appears to be safe, the data are insufficient to provide a maximal duration for use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes."

– Petersen, et al., 2011

and Endoscopy Nurses and Associates committee. Available data suggest that detection of non-environmental pathogens common to the GI tract in reprocessed instruments should serve as an indicator of contaminated or faulty reprocessing equipment, inadequate solutions, or failed human processes. The use of surveillance cultures is confounded by the delay in feedback when using standard microbiological culture techniques and the frequent isolation of nonpathogenic organisms caused by environmental contamination. Alternative indicators of adequate reprocessing have been proposed, but they remain investigational and have not been widely applied in clinical practice. The Gastroenterological Society of Australia standards provide guidance for interpretation of varied culture results. Nevertheless, uniform standards and guidance for sampling and culture technique or for use of alternate indicators of adequate cleaning are lacking. Further research on the methodology and utility of surveillance cultures or sampling is encouraged.

- Relatively new technologies for high-level disinfection are now available, including one cleared by the FDA for automated washing without brushing before high-level disinfection (EvoTech from Advanced Sterilization Products). The demonstration of efficacy and FDA clearance was based on laboratory testing and limited clinical use supported by sophisticated research techniques. Recent independent company-sponsored studies also demonstrate significant clearance of protein and other bioburden. Another reprocessor and disinfectant combination was recently cleared with labeling for high-level disinfection after attenuated washing and brushing (OER-Pro from Olympus America). These technologies and those still to come warrant further well-designed, peer-reviewed studies by using commercially available machines in clinical settings.

- Endoscope durability and longevity are incompletely understood. Data from high-volume units suggest common intervals between major and minor repairs, but there are no published data regarding material durability and the potential for reduced function or reduced ability to attain high-level disinfection after a certain number of years or procedures. Because instruments from low-volume endoscopy units may be retained for many years and those from busy departments are often sold on secondary markets, where they remain in use both in the United States and in other regions of the world, the manufacturers and resellers are encouraged to study and communicate data on these issues to guide the health care industry.

The multi-society guideline (2011) emphasizes that “When evidence is lacking, expert opinion, independent guidelines or standards for accreditation may differ, as cited in the previous discussion and in some of the specific recommendations. Users should always refer to FDA labeling and manufacturers’ instructions for device-specific reprocessing guidance. Accrediting bodies will typically survey for performance in accord with this guidance. In rare cases, FDA labeling claims and/or manufacturers’ guidance may lag behind evolving data or rely on extreme assumptions or thresholds of safety that are not pertinent to safe, yet efficient, healthcare. If alternative practices are demonstrated to be optimal by several well-designed scientific studies and are endorsed by multiple professional societies, they can be considered for use by an organization.”

"Users should always refer to FDA labeling and manufacturers' instructions for device-specific reprocessing guidance."

– Petersen, et al., 2011

AUTOMATED ENDOSCOPE REPROCESSORS (AERS)

The ASGE says that national consensus standards dictate that the manual washing and brushing of all accessible channels has always been a critical step prior to performing high-level disinfection, and that automated endoscope reprocessors (AERs) represent a break from this consensus standard. Automated endoscope reprocessors are FDA cleared for high-level disinfection of flexible endoscopes when used according to manufacturer's recommendations. All currently available systems are labeled for high-level disinfection following manual washing, as outlined by the Society for Gastrointestinal Nurses and Associates (SGNA).

While the introduction of automated, brushless washing of endoscope channels represents a potentially significant advancement, the Technology Committee of the ASGE emphasizes the existing multi-society guidelines and other international standards, all of which highlight the importance of manual washing and brushing for the overall efficacy of high-level disinfection. The redundancy achieved by adding an automated washing step following manual washing can undoubtedly provide an extra level of safety. The ASGE cautions about dispensing with manual washing and brushing steps before the capabilities of AERs are confirmed in independent studies and in clinical practice.

AERs are cleared by the Food and Drug Administration (FDA) for high-level disinfection of flexible endoscopes when used according to manufacturer's recommendations. Most are labeled for high-level disinfection after manual cleaning, as outlined by the SGNA, and there is one AER that has received labeling clearance for use after bedside pre-cleaning only, without prior manual cleaning and channel brushing, according to the ECRI Institute (2009).

ECRI Institute's "Healthcare Product Comparison System: Flexible Endoscope Reprocessors, Automatic" notes, "Endoscope reprocessors are designed to standardize and automate the preparation of a manually pre-cleaned endoscope so that it is safe for immediate reuse. Manual reprocessing is not always performed effectively or consistently due to human fallibility, the number of complicated steps involved, and the pressure to reprocess endoscopes quickly between patient procedures. Automatic reprocessors can reduce the likelihood that a crucial reprocessing step will be skipped, help ensure that reprocessing is performed consistently using a recommended protocol, and reduce personnel exposure to the irritating effects of liquid disinfectants/sterilants."

Advantages of AERs include automated channel flushing and the reduction of manual steps that can also reduce labor costs. AERs also are designed to improve consistency, efficiency and compliance. According to the ECRI Institute, "Endoscope reprocessors are designed to either disinfect or sterilize using an automatic system to soak the endoscope and purge its channels. All reprocessors have a disinfect/sterilize and rinse cycle; some units allow the cycling times

"Automatic reprocessors can reduce the likelihood that a crucial reprocessing step will be skipped, help ensure that reprocessing is performed consistently using a recommended protocol..."

– ECRI Institute

to be set by the operator. Some models also offer wash or pre-disinfection, multiple rinse (including alcohol), and air-purging cycles.”

An automatic reprocessor connects to the facility’s water supply and typically consists of the following components:

- A basin (with a lid) in which the endoscope is reprocessed
- Channel tubing with adapters to irrigate most, but not necessarily all, of the endoscope’s channels
- A timing mechanism to control the time of the reprocessing phases
- Liquid and air pumps
- A reservoir for the disinfectant/sterilant

The ECRI Institute outlines how AERs work: Using the connectors of the endoscopic reprocessor, the operator attaches the reprocessor to the endoscope’s channels, places the endoscope in the unit, and starts the reprocessing procedure. (Some units can reprocess several scopes at a time.) The disinfectant/sterilant is transferred from a reservoir into the basin containing the endoscope. Several processor models use a prepackaged, single-use sterilant container; the container is automatically opened, and the sterilant is aspirated into the basin and mixed with sterile, filtered water. Some models contain a heater to raise the temperature of the disinfectant/sterilant, allowing a wider variety of germicides to be used.

Most reproprocessors provide documentation of the disinfection/sterilization cycle, either in the system’s memory or as a hard-copy printout. The documentation should indicate either that all the necessary parameters have been met or that the cycle has been automatically canceled or aborted by the user and the reason why. Many new models include a leak test function, either standard or as an option; some models test for leaks before and after the cycle.

Once the final rinse cycle is complete, the endoscope is ready for reuse. If the endoscope is going into storage, it may be necessary to purge its channels with forced air to ensure thorough drying, preventing the proliferation of bacteria. Sometimes an alcohol rinse is performed to facilitate the drying process. To reduce the possibility of contaminating an endoscope during reprocessing, the reprocessor itself should be regularly disinfected or sterilized according to the manufacturer’s recommendations; some units have programmed cycles that perform this function.

The ECRI Institute notes that, “There have been reports of reproprocessors becoming contaminated and subsequently passing contamination to scopes that were processed in them. The microorganisms often found in tap water can proliferate to significant levels in endoscopes, their accessories, and ancillary equipment during improper storage or as a result of improper

“There have been reports of reproprocessors becoming contaminated and subsequently passing contamination to scopes that were processed in them ... However, if correct reprocessing and equipment maintenance protocols are followed, infection risk is relatively low.”

– ECRI Institute

maintenance of a reprocessor. However, if correct reprocessing and equipment maintenance protocols are followed, infection risk is relatively low.”

To help avoid potential problems, the ECRI Institute (2009) makes the following points:

- Bacteria filters are intended to remove microbial pathogens from the water used to rinse disinfectant/sterilant off the newly reprocessed endoscopes; however, filters must be changed regularly to remain functional and there is no guarantee the water will be totally free from contaminants. One reprocessor model sounds an alarm when filters need to be replaced. Although requirements vary by country, periodic testing for pathogenic microorganisms in the rinse water would help to reduce the risk of infection.

- 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. Hospital personnel must ensure that all internal endoscope channels are free from residual water droplets. Failure to flush rinse water from the endoscope’s internal channels with 70 percent alcohol and/or forced air has been linked to infections caused by waterborne pathogens, such as *Pseudomonas aeruginosa*, which thrive in moist environments. This precaution is especially important if the endoscope will be in storage for a significant amount of time since a lull in use would provide pathogens with the opportunity to colonize and proliferate in large quantities.

- Another common cause of nosocomial infections is improper application of endoscope connectors, resulting in inadequate irrigation with the disinfectant/sterilant in the endoscope’s internal channels. Additionally, a technician may not notice model differences such as extra channels, and should be trained to recognize and follow unique model requirements. Currently, no reprocessors eliminate the need for connectors entirely, but one model allows an endoscope to be loaded with fewer connectors for the channels, simplifying the manual aspects of the reprocessing procedure and thus, helping to obviate user error. This model has a pressurized compartment that encases the endoscope’s control handle and forces solution through all channels that connect to the control handle.

- Glutaraldehyde residues are toxic and can have deleterious effects on a patient’s mucous membranes when not adequately removed from the endoscope during rinsing. Endoscopy staff must be aware of possible disinfectant or sterilant exposure, even with an automated system. Exposure to any reprocessing agent can result in user injury. Use of any subpotent agents in automatic reprocessors or failure to follow proper procedures can lead to both failed reprocessing and contamination.

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.

■ Not all endoscopes are compatible with every endoscope reprocessor. Discrepancies have been noted between the claims made by automatic endoscope reprocessor manufacturers and by endoscope manufacturers. Reprocessor manufacturers may claim that endoscopes are compatible with their products, but endoscope manufacturers may disagree. Additionally, processing an endoscope in an unapproved unit may void warranties or raise service contract costs. Compatibility must be guaranteed by both parties for safe reprocessing.

The ECRI Institute has issued recommendations for minimum performance requirements for endoscope reprocessors; recommended specifications have been categorized into one group including all automated disinfecting and sterilizing reprocessors for flexible endoscopes:

① Endoscope reprocessors should have an auto-disinfection cycle to optimize efficiency and to reduce the risk of the reprocessor becoming contaminated.

Reprocessors should also produce documentation of cycle times and results for review if an incident or infections occur due to an unsafely shortened cycle. Audible and visual alarms should alert technicians in the event of a problem or device failure.

② Not all endoscopes are compatible with every endoscope reprocessor. ECRI Institute recommends that, to avoid having to purchase new endoscopes and to prevent damage to existing endoscopes, facilities ensure that both the reprocessor manufacturer and the endoscope manufacturer approve compatibility claims.

③ Despite technological advancements that have decreased the risk of infection, there are still many potential sources of disease related to endoscope reprocessing. ECRI Institute recommends obtaining training with purchase; proper training should include instructing hospital personnel how to mitigate the more common, preventable sources of infection.

Before purchasing an endoscope reprocessor, hospitals should assess their current endoscope-reprocessing protocol. Hospital staff may want to consider an automatic reprocessor if they are experiencing the following problems: (1) disinfectant or sterilant exposure complaints, (2) reprocessing inconsistency, and/or (3) inability to handle the volume of endoscopes that need reprocessing.

The ECRI Institute says that other considerations when evaluating an AER include:

- Whether to choose HLD or sterilization
- Whether the reprocessor will fit into the hospital's current workflow; and if not, whether the workflow can be changed to accommodate the reprocessor

ECRI Institute recommends that, to avoid having to purchase new endoscopes and to prevent damage to existing endoscopes, facilities ensure that both the reprocessor manufacturer and the endoscope manufacturer approve compatibility claims.

"Future technological developments will most likely aim to address the shortcomings of endoscope reprocessing, such as by reducing cycle times, lowering costs, and limiting contact with harmful chemicals."

– ECRI Institute

- The expected level of disinfectant/sterilant exposure and whether extra ventilation may be required by the manufacturer
- Whether the endoscopes are compatible with the reprocessor; compatibility statements should be requested before purchase
- Whether endoscope models intended to be reprocessed have all been validated with the reprocessor under consideration
- Whether the reprocessor requires the endoscopes to be modified by the manufacturer to fit into the unit
- The combination of safeguards that the unit offers to prevent system and user errors (i.e., alarms, progress suspension)
- The ability to abort/skip a cycle without warning the operator
- The number of scopes a unit can process simultaneously
- The time per cycle; length of the rinse and forced-air cycles
- The ease of use regarding the connectors and adapters
- Reports of reprocessor contamination
- Whether the reprocessor is equipped with a water-filtration system and the life expectancy and replacement costs of its filters; also, whether the unit automatically alerts users to the need to replace filters
- The type of disinfectant/sterilant the unit can accommodate and its cost per cycle
- Whether the liquid chemical germicide (LCG) is proprietary and only available from a single source. For reusable LCG, how is minimum effective concentration (MEC) measured
- The space required for the unit (i.e., whether it is a tabletop or floor model)
- Special temperature and pressure requirements for the water supply
- The processor's ability to circulate liquids through channels without producing air pockets
- The processor's capacity to self-disinfect/self-sterilize

As for the future of automated reprocessing, the ECRI Institute (2009) notes, "Future technological developments will most likely aim to address the shortcomings of endoscope reprocessing, such as by reducing cycle times, lowering costs, and limiting contact with harmful chemicals. Trends will most likely be toward a more automated endoscope-cleaning process to eliminate the need for manual pre-cleaning. Another trend is integrating a radio-frequency identification (RFID) tracker or bar-code scanner to facilitate documentation. More units may incorporate an alcohol rinse, along with higher air pressures to facilitate drying. Manufacturers will also investigate new ways of reprocessing endoscopes, including the use of chlorine dioxide and ozone, as well as disposable endoscopes and sheaths."

MANUAL VS. AUTOMATIC HIGH-LEVEL DISINFECTION

In the presentation, “Flexible Endoscope Reprocessing: Problems that Have Occurred and How to Prevent Them,” Michelle J. Alfa, PhD, FCCM, of St. Boniface Hospital, points out the pitfalls associated with manual cleaning of medical devices such as endoscopes, and cautions that AERs must also be used correctly. Alfa explains that improper manual cleaning encompasses not cleaning channels or not cleaning accessory devices such as channel brushes, as well as suboptimal cleaning such as lack of immersion or inadequate brushing. Alfa advises personnel to review reprocessing protocols, make sure that staff understand these processes, and assess their competencies regularly. It is also advised that infection preventionists conduct routine audits to observe actual practices. Although AERs are designed to automate and standardize a process that has inherent variables, Alfa cautions that sterile processing personnel should ensure that all connections from the scope to the AER are double-checked so flow of the liquid chemical germicide is optimal (protocols should be reviewed regularly and staff’s competencies should be assessed). Technicians should also ensure that the correct LCG is delivered (a double signature is achieved whenever a new bottle is connected), and that the MEC is tested every day that it is used, ensuring that the process is foolproof.

As Alfa, et al. (2010) note, “The manual cleaning phase is a critical part of the reprocessing protocol and is prone to errors. These human errors may include; failing to clean channels because staff were not aware of them, failing to properly assess if channels are blocked or leaking, or not flushing adequate fluid volumes through all channels ... The greatest concern when errors are made is that high-level-disinfection (HLD) may be inadequate thereby allowing infectious organisms to survive and be transmitted to the next patient that the endoscope is used on. Infection transmission and chemical colitis associated with improper reprocessing of flexible endoscopes still is a concern. Despite the advent of automated endoscope reprocessors that have ‘wash cycles’ as part of the whole process, there are a number of studies that question the cleaning efficacy of such cycles.”

Alfa, et al. (2010) sought to perform simulated-use testing as well as a clinical study to assess the efficacy of an AER’s cleaning performance for flexible colonoscopes, duodenoscopes, gastroscopes and bronchoscopes. The main aim was to determine if the cleaning achieved using the AER was at least equivalent to that achieved using optimal manual cleaning.

Simulated-use testing consisted of inoculating all scope channels and two surface sites with Artificial Test Soil (ATS) containing 108 cfu/mL of *Enterococcus faecalis*, *Pseudomonas aeruginosa* and *Candida albicans*. Duodenoscopes, colonoscopes, and bronchoscopes (all Olympus endoscopes) were included

“The manual cleaning phase is a critical part of the reprocessing protocol and is prone to errors. These human errors may include; failing to clean channels because staff were not aware of them, failing to properly assess if channels are blocked or leaking, or not flushing adequate fluid volumes through all channels.”

– Michelle J. Alfa, PhD, CFFM

in the simulated use testing. Each endoscope type was tested in triplicate and all channels and two surface sites were sampled for each scope. The clinical study evaluated patient-used duodenoscopes, bronchoscopes, colonoscopes, and gastroscopes (scopes used for emergency procedures were excluded) that had only a bedside flush prior to being processed in the AER (i.e., no manual cleaning). There were 10 to 15 endoscopes evaluated post-cleaning and to ensure the entire AER cycle was effective, five endoscopes were evaluated post-cleaning and post-high level disinfection. All channels and two external surface locations were sampled to

evaluate the residual organic and microbial load. Effective cleaning of endoscope surfaces and channels was deemed to have been achieved if there was < 6.4 µg/cm² of residual protein, < 1.8 µg/cm² of residual hemoglobin and < 4 Log₁₀ viable bacteria/cm². Published data indicate that routine manual cleaning can achieve these endpoints so the AER cleaning efficacy must meet or exceed these to establish that the ECR cleaning cycle could replace manual cleaning.

In the clinical study 75 patient-used scopes were evaluated post cleaning and 98.8 percent of surfaces and 99.7 percent of lumens met or surpassed the cleaning endpoints set for protein, hemoglobin and bioburden residuals. In the simulated-use study 100 percent of the colonoscopes, duodenoscopes and bronchoscopes evaluated met or surpassed the cleaning endpoints set for protein, and bioburden residuals (hemoglobin was not evaluated).

The researchers concluded that the AER's cleaning cycle provides an effective automated approach that ensures surfaces and channels of flexible endoscopes are adequately cleaned after having only a bedside flush but no manual cleaning. They emphasize that endoscopes used for emergency procedures or where reprocessing is delayed for more than one hour must still be manually cleaned prior to placing them in the AER.

As we have seen earlier in this report, the SGNA (2009) has stated, "It is necessary to follow all steps for the manual cleaning of the endoscope prior to using an automated reprocessor. No independent confirmatory data are currently available to show that automated reprocessors are able to provide cleaning of endoscopes that is comparable to that of manual washing and brushing." In the clinical use study and simulated-use study by Alfa, et al. (2010) it was shown that the cleaning process used by an AER provided excellent removal of both organic material (protein and hemoglobin) and bioburden from all flexible endoscopes evaluated.

This is significant because despite the overall low rates of infection associated with flexible endoscopy procedures, flexible endoscopes are still the most common cause of healthcare device-associated outbreaks, and studies suggest that "in healthcare there is widespread difficulty in achieving the endoscope manufacturers recommended manual cleaning and that great variability exists in the manual cleaning currently being performed," according to Alfa,

"In healthcare there is widespread difficulty in achieving the endoscope manufacturers' recommended manual cleaning and that great variability exists in the manual cleaning currently being performed."

—Alfa, et al., 2010

et al. (2010) who add, "The value of AERs with validated cleaning combined with efficient HLD and final rinsing cannot be overemphasized. However, not all AER cleaning cycles are equivalent as many of the 'cleaning' cycles in commercially available AERs do not have FDA-cleared cleaning claims and therefore still require manual cleaning prior to processing in the AER ... Our data suggest that because of the efficacy of the ECR cleaning cycle and the fact that the cycle cannot be "shortened" by the user, the potential for build-up biofilm would likely be reduced compared to manual cleaning where short-cuts in cleaning are common."

The impact of human factors comes into play in any discussion of reprocessing compliance. Ofstead, et al. (2010) note that the main cause of endoscopy-associated infections is failure to adhere to reprocessing guidelines. The researchers say that more information about factors impacting compliance is needed to support the development of effective interventions. The purpose of their multisite, observational study was to evaluate reprocessing practices, employee perceptions and occupational health issues. Data were collected utilizing interviews, surveys and direct observation. Written reprocessing policies and procedures were in place at all five sites, and employees affirmed the importance of most recommended steps. Nevertheless, observers documented guideline adherence, with only 1.4 percent of endoscopes reprocessed using manual cleaning methods with automated high-level disinfection versus 75.4 percent of those reprocessed using an automated endoscope cleaner and reprocessor. The majority reported health problems (i.e., pain, decreased flexibility, numbness or tingling). Physical discomfort was associated with time spent reprocessing. Discomfort diminished after installation of automated endoscope cleaners and reprocessors. The researchers report that enhanced training and accountability, combined with increased automation, may ensure guideline adherence and patient safety while improving employee satisfaction and health.

It cannot be emphasized enough that proper manual cleaning of scopes and other medical devices is essential, with or without the use of AERs. "In my opinion, machines are only as good as the driver!" Alfa emphasizes. "So a poorly maintained automated machine may provide worse results than a manual process performed by a well-trained person. That said, I do believe that automating the cleaning process has advantages as it ensures a reproducible process every single time. I want to emphasize that even with an AER that has an automated cleaning cycle that the bedside flush/wipe-down is still required. In terms of AERs that have manual cleaning cycles, I think it is critical that users ensure the cycle has been validated and FDA cleared, thereby ensuring that it will provide efficient cleaning without requiring full manual cleaning. If the AER cleaning cycle is not validated and FDA cleared, then the site should ensure there is manual cleaning prior to the AER cleaning cycle. Even for validated cleaning cycles there are limitations that the AER manufacturer will specify. For instance, one AER manufacturer requires that manual cleaning is still performed prior to the automated cleaning if the endoscope was delayed more than one hour before it was placed into the AER (this is especially important for emergency procedures performed after hours where there may be significant delays before the endoscope is reprocessed)."

"I believe that automating the cleaning process has advantages as it ensures a reproducible process every single time."

– Michelle J. Alfa,
PhD, FCCM

SCOPE REPROCESSING CHALLENGES: A Q&A WITH CHRIS LAVANCHY



Chris Lavanchy, engineering director of the Health Devices Group at ECRI Institute, has extensive experience working with sterile processing departments and provides his insights regarding the imperatives of proper medical device reprocessing

Q: What are some of the common problems posed by endoscopes?

A: In the reprocessing arena, endoscopes are problematic. One of the things we have seen over the years is that it is critical to ensure that sterile processing personnel have the appropriate instructions for cleaning that specific endoscope. Endoscopes vary tremendously in their design and it is especially important if you are using an automated endoscope reprocessor, to have the appropriate adapters for that endoscope. One of the key messages for technicians is that they need device-specific reprocessing instructions. Reprocessing protocols should be documented somewhere and they should be something that is accessible to the person performing the reprocessing tasks.

Q: What are some of the specific problems you are seeing?

A: With regard to endoscope reprocessing, we continue to hear about horrible situations where many patients may have been affected by improper reprocessing. It's such a recurrent problem that this topic continues to land on our top 10 technology hazards list. Through our accident investigation services we often gain unique insight into the root cause of such reprocessing failures. Sometimes it's because there has been a change to the process without the appropriate oversight. These incidents tend to create high-visibility situations where hundreds, thousands or tens of thousands of patients are notified that they may have been exposed to contaminated instruments. For example, a facility switched to a different liquid chemical germicide for use in their automated endoscope reprocessor but failed to adjust the unit's settings for the new indicated operating temperature. In another incident, repairs were made to AERs and the facilities failed to verify that the fluids going into the system are maintained at the required temperature. These things are particularly important because you can buy the best endoscope reprocessor, you can have the best technician handling the scopes, but if the oversight isn't there, if you don't have the appropriate processes, checks and balances in place, then it's very easy to run into serious problems.

Q: What can infection preventionists do to assist sterile processing departments?

A: Infection preventionists can help by periodically checking with sterile processing technicians to make sure that they are aware that the manufacturers' instructions exist, that they know how to find them, and are in fact using those instructions and applying them to the process correctly. It's a bit burdensome, perhaps, but it's probably the only way they can ensure that things are being done properly -- especially with staff turnover being so high in healthcare facilities.

Q: What do you believe to be manufacturers' responsibility?

A: For at least the last 10 years, the FDA has specifically emphasized the need for medical device manufacturers to provide at least one viable method for reprocessing a reusable medical device. They can specify a high-level disinfection or sterilization method, or whatever is applicable, but the reality is, the more options that the vendor provides for reprocessing, the better it is for the hospital. In some cases, what they're asking the hospital to do may not be practical. What we advise hospitals to do when they are buying medical instruments and equipment, is to review the reprocessing information that is available from the manufacturer and consider that in their purchasing decisions. I've been to some hospitals where the reprocessing technicians first became aware that they were being given a new instrument to reprocess when it was presented to them dirty from the OR. That is just not the way to do things. Ideally, the central sterile department should be involved in the overall purchasing decision so that these personnel would understand what the requirements are for reprocessing that new device being considering for purchase.

I think the awareness of device-related reprocessing issues is definitely being raised, and the FDA workshops and the AAMI/FDA summit have been helpful in getting the word out that there are instruments whose cleanability was a secondary consideration in their design. For example, at the FDA/AAMI summit someone showed a suction probe that had been cut open and how it would be virtually impossible to remove the debris. Fortunately I think it is a relatively rare thing today for an instrument to be designed like that, but the more that this concern is publicized, the more likely it is that manufacturers will ensure there is very diligent consideration of proper design for cleanability as products are being developed that would allow for greater cleanability.

Q: The participants at last year's FDA/AAMI Summit on Reprocessed Medical Devices were stumped on how to define "clean" and "cleanability" – what does it tell you about the processes to which personnel ascribe?

A: Anyone in the central sterile field knows that there's a fundamental tenet – if you can't clean something you can't sterilize it – that's a well accepted understanding. But the general concept of what's clean has never been really fully defined or standardized. Most facilities I have spoken with look at the instruments during the cleaning stage of reprocessing and if they look clean then they are considered clean. Well, many instruments have crevices and surfaces that are not easily visible to the eye for inspection so how do you make that judgment? For instruments with lumens they may flush the lumens with water or saline and if nothing is coming out, they may assume that it is clean – but is that really an accurate indication of whether all of the internal surfaces are clean? I was very happy to see that the FDA and AAMI were emphasizing the concern about cleanability and pursuing ways to define what is an acceptable level of cleanliness in a reprocessed instrument. There are some interesting technologies being considered to quantify clean out there – whether they will be practical for day-to-day cleaning I don't know. However, there are people who are researching this

and I think what will trickle down from that research we should be able to get will be some very good ideas about how to design instruments better to avoid debris build-up and how to validate that designs are effective at enabling cleanability. The research will also hopefully lead to better ways to know how to better verify that these instruments have been cleaned before they go into an automated endoscope reprocessor.

Q: How to you address the dichotomy that exists between automation versus manual cleaning?

A: Certainly there are arguments on both sides of the automation versus manual cleaning debate. I think ECRI Institute's general perspective is that automated cleaning is probably the preferred way to go. The reasoning is that a manual process is unfortunately subject to human failures; it's also subject to the technician being pressured by the OR staff to turn an instrument around faster. Manual processes also are subject to variances in how consistently can a person do a particular activity task from day to day and as well as variances between people. from person to person – does that cleaning and pre-reprocessing in preparation differ tremendously? With an automated system you can eliminate a lot of that variability. But of course automated systems can fail as well. It's important that if you have an automated system you ensure that it is reliable, that it is properly maintained, and that it can't be easily circumvented at the operator's discretion. When the central sterile staff are being pressured to turn devices and equipment around faster, if the automated system allows you to short-cut the process, the situation can be as much of a concern as the variability in manual reprocessing. We generally advise hospitals to go with automated systems if they have the choice. Automated endoscope reprocessors have been shown to be effective and I know there are some machines today that actually include automated washing, which has been demonstrated through testing to FDA's satisfaction to be equivalent to or even possibly better than a manual process.

Q: What about the potential for technicians to eventually work around an automated system?

A: When the ECRI Institute performs comparative studies of automatic endoscope reprocessors, for

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– Chris Lavanchy, ECRI
Institute

example, we look very closely at human factors design, we examine how easy is it to work around the intended approach and that factors into our judgment about the product. If we find that it is easy to bypass the safety features or alter process times that an AER designer included, we will down-rate the unit for that because we know this is a significant concern among users. We are very familiar with the reprocessing environment and know how much pressure there is, how noisy it is, how fatiguing it can be for the technician working there. If you give reprocessing technicians the opportunity, deliberate or not, to modify the process that an automated system provides, then there's not as much real benefit to using the automatic system in the first place.

Q: Whose responsibility is it to provide oversight?

A: We are familiar with problems that sometimes arise from poor interaction between central sterile teams and OR personnel. I've seen facilities where an adversarial relationship exists between these teams. What we often find is that if both departments report to a common executive, these problems disappear or are at least effectively managed. I think turf wars can arise when you have operational teams that need to collaborate but the operational managers or vice presidents have widely different areas of responsibility. While the leaders may share the common institutional mission, they also have their own more immediate agendas related to their areas of responsibility and budgets. So having everyone following the same reporting channel can be helpful in developing cohesion between the different groups. In the instance I mentioned where the OR reported to one executive and the central sterile department reported to a different executive, we found that there was a lot of blame-placing going on and that the particular hospital was really struggling to figure out how they could make things work better. The situation fostered a sense of competition rather than collaboration. I know it sounds obvious, but when you are there and you hear the arguments coming from these folks you quickly realize that the sense of institutional mission has been lost.

Q: How critical is proper education and training? And when there are breaches in reprocessing practice, are they due to knowledge gaps or implementation gaps, or both?

A: Education is important in ensuring effective reprocessing at a couple of levels. In the case of the contentious central sterile and OR departments I mentioned previously, it was apparent that neither department understood the work that the other group was doing and what is involved in doing that work. I think that lack of understanding fostered a lot of the resentment and contention that arose – they wanted to know why the other group was being so unreasonable, yet they didn't understand each other's situation. So just helping them better understand what is being required of the staff in each department can go a long way. It has also been my experience in talking with central sterile departments that at one time the level of education of the technicians varies considerably. I believe that is changing today – there is more pressure on hospitals and the department managers to ensure that their

people have the appropriate credentials and ongoing training. They must ensure that their technicians are using equipment properly and understand the impact of failing to carry their responsibilities out properly.

Q: How can the ECRI Institute help?

A: There are a number of avenues through which the ECRI Institute can assist. In addition to providing consulting services we also invite hospitals to report to us problems they have with technology for investigation. We also are a patient safety organization (PSO) for a number of states or regions that allow hospitals to report adverse events they might have experienced with medical devices. It allows them to participate in a non-punitive process that encourages reporting of adverse events without fear of litigation. to a centralized agency that pools and analyzes the data so that it can be used for ongoing quality improvement processes. Through the PSO program we can help hospitals share wisdom gained from looking across many facilities and facilitate the development of best practices. The PSO concept came about because it was recognized that having hospitals report problems to manufacturers and FDA has not proven to be an effective way to track and identify causes of adverse events. Congress created PSOs to provide a forum free from legal discoverability to encourage free exchange of what is often considered sensitive information.

Hospitals and managers must ensure that their technicians are using equipment properly and understand the impact of failing to carry their responsibilities out properly.

Q: What do you believe is critical to keep in mind for the future?

A: It is important to keep the concern of inadequate instrument reprocessing on hospital executive's radar because they are dealing with a lot of complex issues, at a time when resources are in short supply. If you don't, the other challenges they are facing will quickly divert their attention. Providing reminders of the important need for this ongoing vigilance is key. The more hospital departments are vocal about the problems they are encountering with reprocessing, the better the chances are that device manufacturers, and agencies such as FDA and AAMI and ECRI Institute will be aware of what needs to change. Unfortunately because the topic may be viewed as dirty laundry hospitals may be deterred from talking candidly. However, unless the problem is addressed and really confronted publicly by all involved, I believe these issues will persist.

Preventing Cross-Contamination in Endoscope Processing

In November 2009, the FDA, CDC, and Veterans Affairs issued a safety alert cautioning healthcare facilities about the risks to patients if flexible scopes are not cleaned, disinfected and/or sterilized according to established guidelines. The alert pointed out, "If flexible endoscopes or endoscopic accessories are not properly processed, patients can be exposed to body fluids and tissue contaminants from prior patients, which can result in the transmission of pathogens and affect large numbers of people. Recent reports to FDA of processing errors with flexible endoscopes have highlighted the continuing importance of this issue. Reported errors included the use of improper accessories for endoscopy irrigation set-ups, improper reprocessing intervals for reusable endoscopy accessories, failure to discard single use accessories, and failure to follow the manufacturer's instructions for endoscope reprocessing. Flexible endoscopes are fundamentally difficult to clean and disinfect or sterilize. Because of this, it is essential that facilities establish a quality system program that covers all aspects of endoscopy procedure management. Adequate patient protection can only be achieved by vigorous compliance with such a program."

The alert issued the following general recommendations for healthcare facilities:

- Establish an institutional program for endoscope processing, along with written procedures for monitoring adherence to the program and a chain of accountability. Ensure that those responsible for endoscope processing understand the importance of this job and that they maintain proficiency in performing it for each type of endoscope they handle.

- Train employees to set up, clean, disinfect or sterilize, and store endoscopy equipment properly. Periodically retrain and assess competence. Endoscopy is a constantly evolving technology, so it is essential to stay up to date with the specifics of each device your institution uses.

- Instruct staff to read and follow the endoscope manufacturer's instructions for use. Personnel responsible for reprocessing endoscopes must have the manufacturer's instructions available for each endoscope and its accessories, because various endoscopes and their accessories often must be processed differently (e.g., most flexible endoscopic equipment cannot tolerate steam sterilization).

- Ensure sterile processing staff members understand that the cleaning and disinfecting of endoscopes are two separate processes. Thorough cleaning of the endoscope must be done first, in order to remove gross contamination and debris. Without this step, the endoscope cannot be effectively disinfected or sterilized. Cleaning should begin immediately after use by thoroughly flushing the channels and rinsing/wiping the outside of the endoscope. This must be followed by a very thorough cleaning with brushes, concentrating especially on the channels. Only then is the endoscope ready for high level disinfection, which can be done manually or in an automatic endoscope reprocessor (AER). During disinfection, the high level disinfectant must contact every contaminated surface/channel for the time recommended by the disinfectant manufacturer.

- Ensure that the AER or sterilizer is compatible with the endoscope. Before using an AER, confirm that it properly fits the endoscope. Adhere to the AER or sterilizer instructions that

specify which endoscope makes and models it can process. And be sure that the instructions for endoscopes, AERs and germicides do not contradict one another. If you become aware that instructions are contradictory, inform the endoscope and AER manufacturers as well as FDA.

- Ensure that endoscopes or accessories that contact sterile tissue are sterilized before each use, and that endoscopes that contact intact mucous membranes undergo at least high-level disinfection before each use.

The alert issued the following general recommendations for manufacturers:

- Ensure that the instructions for processing your flexible endoscopes and accessories are easily accessible to users, that they are complete and easy to understand, and that the steps follow in logical sequence.

- Ensure that updated versions of reprocessing instructions are communicated promptly to users.

- Ensure that instructions for each AER specify which endoscope makes and models it can process. And be sure that the instructions for endoscopes, AERs and germicides do not contradict one another. If you become aware that instructions are contradictory, you should proactively notify your customers and provide necessary recommendations.

- Evaluate and recommend reprocessing products and AERs that can be used with your endoscope. Be sure your instructions for use clearly list any reprocessing products that are not compatible with your endoscope. If possible, conduct or facilitate training for personnel in healthcare facilities on the proper processing of your endoscopes or accessories.

- Use your complaint files, as well as information provided by your field staff, to monitor problems in the processing of your endoscopes and accessories. Consider this information in the design of future endoscopes.

- If possible, work with other manufacturers to help ensure that various makes and models of endoscopes, endoscope accessories and AERs are compatible. For example, AER manufacturers should be sure that their AER's channel connections fit properly on the endoscopes specified for use with their product.

- Investigate any reports of infection or pseudoinfection clusters associated with your device so you can take appropriate corrective action. Report to FDA any information or actions that are subject to reporting under current regulations.

- Report to FDA no later than 30 calendar days after becoming aware of information that reasonably suggests that a device has caused or contributed to a death or serious injury or a device has malfunctioned and this device or a similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

BEST PRACTICES FOR RISK REDUCTION

The FDA recommends the following procedures to reduce the risks of transmitting infections in processing endoscopes and accessories.

Administrative Aspects

A Establish an institutional program and procedures for monitoring adherence to the program

1 Establish a comprehensive quality assurance and safety program for all aspects of all endoscopy procedures. It is senior level management's responsibility to establish such a program and to assign responsibility for its implementation. The program should:

a Identify all staff involved in endoscopy procedures, as well as all departments, if appropriate. Include supervisors and all staff involved in these activities, specifying their position descriptions and responsibilities.

b Establish set-up, break-down and reprocessing (i.e., cleaning and disinfecting or sterilizing) procedures for each type of endoscopy performed by your facility.

c Identify all endoscopes, endoscope accessories and endoscope reprocessing equipment used in your facility, including: manufacturer, models, serial numbers or hospital specific equipment tag numbers, and unique device identifiers (UDIs). Include location within the facility, age, and status (e.g., maintenance schedule).

d Establish and document training programs for all staff responsible for the set-up, disassembly, and reprocessing of endoscopy equipment. The program should outline schedules for periodic retraining.

e Develop procedures and responsibilities for tracking the useful life of endoscopes and accessory equipment, including equipment and supplies for reprocessing. These procedures should address specification evaluation, acquisition management, scheduled maintenance, and removal of equipment from use.

f Using information in product labeling, assure that the endoscopes and accessories used in your facility are compatible with your reprocessing equipment and supplies. If the labeling is unclear regarding compatibility, contact the manufacturer. Ensure that new equipment is compatible with your existing products.

g Review and update procedures at regular intervals

h Disseminate procedures to all involved staff, post procedures in prominent locations, and ensure all staff know where full copies of the procedures are located.

2 Establish appropriate standard operating procedures (SOPs) for preparing endoscopes for patient contact. Be sure this information does not conflict with the instructions from the manufacturers of the endoscopes, AERs, and liquid chemical sterilants/high level disinfectants (LCS/HLD). Ensure that your staff adheres to these procedures.

a Confirm that you have the correct versions of the instructions for the endoscope models used at your facility.

b Confirm that you have the correct versions of the instructions for the AERs used in your facility.

c Provide staff with written device-specific instructions for every endoscope model and reprocessing system you use. This may include more detailed explanations than the original manufacturers' instructions. Inform manufacturers, as well as FDA, if you believe their instructions are unclear or inadequate.

d Review the written reprocessing instructions from the AER manufacturers to be sure that they apply to the endoscopes used in your facility, and that they are correctly implemented.

3 Implement a comprehensive quality control program for reprocessing endoscopes and their accessories. Your reprocessing program should include:

a Visual inspections and testing of the equipment to identify conditions that may affect the cleaning or disinfecting processes, such as testing for leaks, examination for cracks, and checking the integrity of fiber optic bundles.

b Assurance that all manufacturer-recommended maintenance schedules and services are performed for all endoscopes and AERs used in your facility.

c The use of appropriate process monitors as recommended by your AER and germicide manufacturers.

d Records of the use of each endoscope, including model, serial number, and unique hospital identifier or standardized unique device identifier. Records should document the patient upon whom the endoscope was used, the date and time of use, the room location of use, and the type of procedure involved. Records should also show the system (particular model and serial number of the AER if applicable) used to reprocess the endoscope and the initials of the person(s) responsible for reprocessing the scope.

e A method for detecting clusters of infections or pseudoinfections associated with endoscopic procedures (e.g., a surveillance system). If a cluster is discovered, this should be reported to the manufacturer of the endoscope, the endoscope accessories, the AER, and the germicide.

f Documentation of all training for all staff.

g Documentation of all repairs for all equipment.

h Documentation of the introduction (and withdrawal from use) of all endoscopes, endoscope accessories, AERs and AER accessories such as scope connection devices.

B Train, retrain and establish a chain of accountability for endoscope processing procedures

1 Provide and document comprehensive and intensive training for all staff assigned to reprocessing endoscopes to ensure that they understand how to perform their assigned duties and the importance of proper reprocessing of all endoscopes used in your facility. All staff involved in endoscope reprocessing should be identified, provided appropriate education for their duties before beginning, observed for competence, and retrained at designated intervals.

Establish a comprehensive quality assurance and safety program for all aspects of all endoscopy procedures.

Training should include:

a Instruction in proper procedures, equipment connections, and which items are single use only and must be discarded after each use and which items are to be reprocessed after each use.

b Hands-on training for each endoscope and AER used at your facility, using the written instructions provided with each make and model. Work should be closely supervised until competency is documented for each reprocessing task from cleaning through storage of the endoscope.

c Additional training and documentation of competency whenever a new model of endoscope or AER is introduced into your facility

d Frequent reminders to all staff not to deviate from the written instructions for preparing endoscopes for patient contact.

2 Re-evaluate and document competency at periodic intervals.

Technical Aspects

A. Read and the follow the manufacturer's operating manual and instructions for use.

1 Clean, disinfect or sterilize and assemble the endoscope according to the endoscope manufacturer's instructions.

2 Follow the endoscope manufacturer's instructions for high level disinfection or sterilization. If you do not use an AER, or in the absence of technical instructions for automated reprocessing of your endoscope, follow the manufacturers' recommendations for the detergent products and liquid chemical sterilant/high-level disinfectant products used at your facility. Ensure that staff understands that enzymatic detergent solutions are single use and must be discarded after every use.

3 Check with your endoscope manufacturers to determine whether your endoscopes can be reprocessed in an AER and the steps that should be taken before reprocessing. Not all endoscopes can be reliably reprocessed in an AER. For example, the elevator-wire-channel of most duodenoscopes cannot be accessed by the AER. Such devices require manual reprocessing (manual cleaning and high level disinfection) for that channel, if not for the entire device. If not specifically indicated in the AER labeling, it is advisable to ask the AER manufacturer if the endoscope model you are using has been tested with their system.

4 Compare the reprocessing instructions provided by the endoscope and AER manufacturers and resolve any conflicting recommendations. Contact the manufacturers to resolve any conflicts, particularly when they involve the use of channel connections or capping/non-capping of specific lumens or channels.

B Manually clean endoscopes before disinfection or sterilization

Follow the endoscope manufacturer's instructions for high-level disinfection or sterilization.

Ensure that all staff who handle soiled endoscopes understand the importance of manually cleaning the endoscope thoroughly before it is disinfected or sterilized, and that they have access to and comply with the endoscope manufacturer's instructions.

1 Ensure that all staff who handle soiled endoscopes understand the importance of manually cleaning the endoscope thoroughly before it is disinfected or sterilized, and that they have access to and comply with the endoscope manufacturer's instructions. It is imperative that staff flush all endoscopes immediately following each clinical procedure. Use of an enzymatic cleaner that is compatible with the endoscope is important in breaking down proteins that

make up a large portion of common soil. In addition, staff should meticulously remove any debris or residuals collected in or on the endoscope, perform leak tests, and visually inspect the endoscope to ensure that it is in proper working order in accordance with the endoscope manufacturer's recommendations. These steps are critical regardless of whether your facility manually reprocesses endoscopes or uses an AER.

2 Ensure that flexible fiberoptic endoscopes used as semi-critical devices undergo at least high level disinfection before each use. Semi-critical devices are those that contact intact mucous membranes such as the respiratory tract and the gastrointestinal tract. Most flexible fiberoptic endoscopes are semi-critical devices and require high level disinfection between patients.

3 Ensure that endoscopes used as critical devices are sterilized before each use. Critical devices are those that contact sterile tissue or the vascular system. Endoscopes used in normally sterile body sites are critical devices and must be sterilized.

a Low-temperature sterilizers are available for reprocessing thermolabile flexible endoscopes. Some endoscopes, especially rigid ones, can be steam sterilized. Before sending

an endoscope for sterilization, be sure to check the manufacturer's instructions for both the endoscope and the sterilizer to be sure that the devices are compatible and that the sterilizer is able to sterilize devices with the lumen length and diameter of the endoscope to be reprocessed.

b Sterilization with a liquid chemical sterilant may not convey the same sterility assurance as sterilization achieved using thermal or low temperature chemical gas/plasma/vapor sterilization methods. Liquid chemical sterilants should be limited to reprocessing only critical devices that are heat-sensitive and incompatible with other sterilization methods. For more information see Guidance for Industry and FDA Reviewers: Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants. Also refer to the CDC/HICPAC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.

4 Incorporate a final drying step in your reprocessing protocol, as long as this is not listed as a precaution or contraindication in the manufacturer's instructions. This applies whether

you manually reprocess your endoscope or use an AER. Studies have demonstrated that a final drying step that includes flushing all channels with alcohol, followed by purging the channels with air (to remove the alcohol), greatly reduces the possibility of recontamination of the endoscope by water-borne microorganisms. After reprocessing, store endoscopes in a manner that will minimize the likelihood of contamination or collection/retention of moisture.

The Pennsylvania Patient Safety Authority says that to reduce the likelihood of endoscopy-related cross contamination between patients, healthcare facilities can develop and adhere to comprehensive, model-specific reprocessing protocols. In developing endoscope reprocessing protocols, consider the following strategies to minimize cross-contamination risks:

- Establish model-specific reprocessing protocols for each model flexible endoscope in the facility's inventory. Identify (i.e., through device manuals or endoscope manufacturers) and include in each protocol document specific requirements for reprocessing each endoscope (e.g., cleaning procedure, channel adapters). This strategy also applies for each newly purchased endoscope model or related equipment.

- Regularly review each reprocessing protocol for clarity and comprehension, and ensure that they match the current setting (e.g., the protocols do not include obsolete workflows or equipment).

- Ensure that each reprocessing protocol contains all the steps involved in the process, from pre-cleaning in the procedure room to aseptic transport back to the procedure room for subsequent use.

For endoscope reprocessor use, ensure that:

- The facility's endoscopes (and related accessories) are compatible with the reprocessor and the disinfecting/sterilizing agent;

- Where applicable, all appropriate channel adapters are readily available to connect the endoscope to the reprocessor and that staff are familiar with the correct endoscope-adapter combinations; and

- All appropriate staff are familiar with and adhere to the endoscope reprocessor maintenance schedules, including periodic replacement of particulate and bacterial filters, when applicable.

- Ensure that documented protocols are readily available to all reprocessing staff and that staff are properly trained to understand and follow the protocols.

- Assign responsibility to appropriate staff for monitoring compliance (competency review) with the reprocessing protocols.

To reduce the likelihood of endoscopy-related cross contamination between patients, healthcare facilities must develop and adhere to comprehensive, model-specific reprocessing protocols.

REGULATORY OVERSIGHT

As we have seen, the FDA is looking very closely at how medical devices are being reprocessed, and a draft guidance for manufacturers' design and validation efforts is currently on the table. The Centers for Medicare and Medicaid Services (CMS) has become acutely aware of infection prevention and control lapses in ambulatory surgery centers and other outpatient-care facilities that are associated with the improper reprocessing of medical devices, among other infection control breaches. (See accompanying articles at the end of this report.)

According to the ASC Quality Collaboration, CMS surveyors will be looking for some of the following practices at ambulatory care facilities:

High-level disinfection

- Semi-critical equipment is high-level disinfected or sterilized
- Whether high-level disinfection is performed on site or if a contract with an off-site vendor exists
 - Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to high-level disinfection
 - Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection
 - High-level disinfection equipment is maintained according to manufacturer instructions
 - Chemicals used for high-level disinfection are prepared according to manufacturer instructions; tested for appropriate concentration according to manufacturer's instructions; replaced according to manufacturer's instructions; and documented to have been prepared and replaced according to manufacturer's instructions
 - Instruments requiring high-level disinfection are disinfected for the appropriate length of time as specified by manufacturer's instructions or evidence-based guidelines; disinfected at the appropriate temperature as specified by manufacturer's instructions on evidence-based guidelines; items that undergo high-level disinfection are allowed to dry before use; following high-level disinfection, items are stored in a designated clean area in a manner to prevent contamination

Sterilization

- Critical equipment is sterilized
- Whether sterilization procedures are performed on site (A "No" answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement. The surveyor will confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)
 - Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to sterilization
 - Whether the following practices were performed:
 - a Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization
 - b A chemical indicator is placed in each load
 - c A biologic indicator is performed at least weekly and with all implantable loads
 - d Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)

- Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load
 - Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use
 - After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised
 - Sterile packages are inspected for integrity and compromised packages are reprocessed

The ASC Quality Collaboration recommends that every outpatient-care facility have a policy on endoscope reprocessing to ensure appropriate reprocessing of flexible endoscopes and accessories. Here are some suggested points for inclusion in an endoscope policy and procedure:

- Endoscopes are considered semi-critical devices on the Spaulding Scale and require, at a minimum, high-level disinfection with a FDA approved disinfectant.
- Personnel performing reprocessing of flexible endoscopes shall demonstrate competency in the care and reprocessing of endoscopes and related equipment. Personnel shall also demonstrate competency in infection control and safe use of chemicals
- Appropriate personal protective equipment must be worn.
- All endoscopes shall be pre-cleaned according to the manufacturer's guidelines immediately following the procedure.
- After each use, all endoscopes shall be disassembled and leak tested according to manufacturer's instructions.
- All endoscopes and accessories will be thoroughly and properly cleaned with an enzymatic detergent prior to high-level disinfection and/or sterilization. Manufacturer's instructions for preparation and use of the enzymatic detergent shall be followed. The prepared detergent shall be discarded after each use. Appropriately sized brushes will be used for cleaning. All endoscopes will be properly rinsed after cleaning according to manufacturer guidelines.
- Reprocessing for each endoscope shall be performed according to the manufacturer's instructions specific to that endoscope. An EPA-registered disinfectant solution will be utilized for all endoscopes and compatible accessories for high level disinfection and/or sterilization. Manufacturer instructions shall be followed in the preparation, testing and use of the disinfectant solution. Manufacturer guidelines for exposure time and temperature will be followed. Each endoscope and it components shall be completely immersed in the disinfectant solution and all channels must be disinfected during reprocessing.
- Following high-level disinfection, all endoscopes and accessories shall be rinsed and dried in accordance with manufacturer instructions.
- When an automated endoscope processor is used in lieu of high-level disinfection, manufacturer's directions for processing shall be followed.
- Disinfected and dried endoscopes shall be properly stored in a vertical position away from the reprocessing area in a location that will provide protection from contamination.
- Reusable endoscopic accessories that break the mucosal barrier will be mechanically cleaned and sterilized after each patient use.
- When a sterilizer is used, manufacturer's instructions for use shall be followed.
- When automated processors and/or sterilizers are used, maintenance and repair shall be performed according to manufacturer instructions and shall be documented.
- Personnel shall routinely inspect endoscopes and all related equipment and supplies for integrity, function, and cleanliness. Damaged or soiled endoscopes or accessories shall not be used.

Reprocessing Competencies

The University of North Carolina, Chapel Hill, has developed an endoscope reprocessing set of competencies that managers may use to check the quality of their personnel's reprocessing skills:

- Verbalizes knowledge of cleaning and disinfecting solutions used, labeling, length of effective use life and soak times.
- Documents concentration of glutaraldehyde appropriately (e.g., if used daily, test daily).
- Wears personal protective equipment, including gown, gloves, and eyewear.
- Demonstrates initial gross decontamination of exterior of scope and accessories. Wipes exterior of scope with clean cloth soaked in detergent or enzymatic cleaner.
- Leak-tests scope.
- Uses suction to fill channels with detergent or enzymatic cleaner.
- Demonstrates the process of manual washing and brushing all channels, ports and valves with appropriately prepared detergent or enzymatic cleaner.
- Brushes lip of biopsy port.
- Rinses exterior of scope, uses suction to rinse interior until fluid is clear, ends by suctioning air to clear fluid from scope.
- Fills interior channels with glutaraldehyde and immerses completely to prevent air bubbles. Utilizes 20 minute immersion time.
- Demonstrates the proper use of the automatic processor. Verbalizes knowledge of test cycles before and after use. Uses biological and chemical indicators.
- Avoids contaminating clean and/or disinfected items with dirty gloves. Washes hands after removing dirty gloves. Dons clean gloves prior to removing scope/accessories from glutaraldehyde.
- Rinses scope with sterile water, filtered water, or tap water. Uses "clean" suction.
- Rinses the insertion tube and inner channels with 70 percent alcohol.
- Uses forced air to dry the scope before storage.
- Demonstrates proper cleaning, high-level disinfection, rinsing and drying of all accessories.
- Demonstrates proper cleaning and sterilization of biopsy forceps and other cutting instruments that enter sterile body sites.
- Labels or packages disinfected scopes/accessories to indicate disinfection has been done.
- Is able to state conditions indicating a scope has not been disinfected (e.g., if not labeled or packaged, scope is considered contaminated and requires high-level disinfection prior to use).
- Properly stores scope/accessories in a clean location.
- Empties and disinfects water bottles.
- Disinfects brushes.
- Empties and cleans pans.
- Removes personal protective gear and discards appropriately.
- Washes hands before leaving reprocessing room.



"We are among the agencies, organizations and consumer groups that are watching news of outbreaks and are working with a multitude of partners to try to improve practice."

– Louise Kuhny, RN, MPH, MBA, CIC, Joint Commission's senior associate director of standards interpretation

Since last year, the Joint Commission has been encouraging healthcare organizations to review their high-level disinfection (HLD) and sterilization processes in detail to ensure they are up to date with relevant guidelines – something that surveyors will be looking for during their visits; a similar survey process is slated to begin on cleaning and HLD of endoscopes. The Joint Commission encourages compliance with evidence-based guidelines, such as those from the Association for the Advancement of Medical Instrumentation (AAMI) and the Centers for Disease Control and Prevention (CDC)'s Healthcare Infection Control Practice Advisory Committee (HICPAC). As the Joint Commission (2011) explains, "By observing the actual sterilization or HLD of instruments, leaders can gain valuable information that may help in identifying opportunities for improvement."

"We are among the agencies, organizations and consumer groups that are watching news of outbreaks and are working with a multitude of partners to try to improve practice," says Louise Kuhny, RN, MPH, MBA, CIC, the JC's senior associate director of standards interpretation at the Joint Commission. "We are partnering with our accredited organizations to help patients receive the highest quality healthcare at all times. It's not just about surveys anymore, as we are providing a number of educational opportunities for our accredited organizations and a number of free resources. For example, our Center for Transforming Healthcare is a forward-looking organization that provides real-world, targeted solutions to our accredited organizations. Other tools include the Leading Practice Library, with more than 400 solutions that have been approved by standards experts and are in compliance with our standards that healthcare professionals can use with confidence." The Leading Practice Library is a complimentary tool available to organizations that are currently accredited or certified by the Joint Commission. The library's documents represent real-life solutions that have been successfully implemented by healthcare organizations and reviewed by Joint Commission standards experts. "We also have a set of tools called Booster Packs, targeted toward our standards that have higher levels of non-compliance," Kuhny adds. "There are two more Booster Packs with infection control implications in the works currently – one on high-level disinfection and one on sterilization – and these should be ready in the next several months. We also offer guidance on SCIP initiatives or the prevention of SSIs, called the Solution Exchange, and those are proven solutions submitted by other accredited organizations to help with meeting core measures."

According to Kuhny, the Joint Commission has undertaken a number of initiatives to increase surveyors' ability to detect issues with high-level disinfection and sterilization in accredited facilities. "These issues, of

course, carry serious problems of morbidity and even mortality, and we address them through our various National Patient Safety Goals. In 2009 we changed our infection control standards through a standards improvement initiative to better reflect the seriousness of high-level disinfection and sterilization. They are now what we call an 'A standard,' which means that only one detected problem will trigger a requirement for improvement citation. That particular element for performance is also what we call a 'direct impact' or a 'level 3' standard, which is more serious and it requires that evidence of standards compliance (ESC) be submitted in a shorter period of time."

Kuhnny continues, "In addition to these standards revisions, we have also conducted extensive surveyor education and some training on the steam sterilization standard in partnership with the Association for the Advancement of Medical Instrumentation (AAMI), so that our surveyors' ability to survey in this area is enhanced. As a result, they are finding quite a few problems. The percentage of non-compliance with disinfection and sterilization standards has greatly increased since we provided that surveyor education. The advice I give to accredited organizations is that they should be very familiar with current science-driven guidelines for disinfection and sterilization – especially the CDC guideline on disinfection and sterilization (2008), and also the current edition of AAMI ST79. In addition to being knowledgeable of those two documents, healthcare organizations also must be prepared to demonstrate how their processes meet the FDA requirements as outlined in the manufacturers' instructions for use (IFU). We're finding a number of difficulties related to the basic steps of the disinfection and sterilization process – for example, maybe the temperature, pressure and time required for all of the instruments in the load is set correctly, but there might be one or two instruments in that load where the IFU calls for special processing and it is not being performed. So during the survey process our surveyors will be asking organizations for those IFUs and to demonstrate how the guidelines match up to how these processes are performed."

Kuhnny emphasizes that healthcare organizations seeking (and maintaining) accreditation are required to walk the talk, as it were, in order to demonstrate reprocessing personnel's competencies. "The information is definitely out there, but organizations need to have the appropriate resources and trained staff who know how to process these instruments correctly according to those guidelines and standards," Kuhnny says. "Upon survey, we look for individuals who have demonstrated competency in these practices. We examine whether personnel have the appropriate materials and equipment with which to perform the processing. For example, if an organization owns an instrument where the manufacturer's IFU specifies that they must be decontaminated using an ultrasonic cleaner, and they don't have an ultrasonic cleaner – they are simply hand-washing them and putting them into the steam sterilizer – that's not okay. So they must have it all – the appropriate equipment, the appropriate competencies, the right people with the right knowledge."

"We have conducted extensive surveyor education and some training on the steam sterilization standard in partnership with the Association for the Advancement of Medical Instrumentation (AAMI), so that our surveyors' ability to survey in this area is enhanced."

– Louise Kuhnny, RN,
MPH, MBA, CIC

Sterile processing personnel and infection preventionists must work together to ensure that proper reprocessing protocols are being followed, and healthcare institution leadership must ensure that these departments have the staff and resources necessary for a high-functioning reprocessing program.

Conclusion

As we have seen, high-profile outbreaks have been associated with improper medical device reprocessing, and despite a preponderance of guidelines and recommended practices, sterile processing personnel are challenged by real-world conditions that impact practices significantly. Sterile processing personnel and infection preventionists must work together to ensure that proper reprocessing protocols are being followed, and healthcare institution leadership must ensure that these departments have the staff and resources necessary for a high-functioning reprocessing program.

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BEST PRACTICES FOR ENDOSCOPE REPROCESSING

By Michelle Beaver

As most endoscopy technicians and managers know all too well, the consequences can be significant if endoscopes are not handled properly during the decontamination, cleaning, high-level disinfection and/or sterilization process. Multisociety guidelines on this topic are available for reference, and they are indeed valuable resources; conversational information from experts is, too. For this reason, we've asked important questions of two leading endoscopy associations, the American Society for Gastrointestinal Endoscopy (ASGE), and the Society of Gastroenterology Nurses and Associates, Inc. (SGNA).

From ASGE we spoke with Bret T. Petersen, MD, FASGE, chairman of ASGE's Quality Assurance in Endoscopy Committee, and from SGNA we spoke with LeaRae Herron-Rice, MSM, BSN, RN, CGRN, SGNA board director, and administrative director at Indiana University Health-University Hospital. Their insightful responses are below.

ASGE's Bret T. Petersen

Q: What are the biggest challenges to the scope cleaning/decontamination/sterilization process in the outpatient and inpatient settings?

A: In gastrointestinal endoscopy the standard for endoscope reprocessing is high-level disinfection (HLD). This standard is reliably met with conscientious performance of well-established reprocessing steps involving pre-cleaning at the bedside, cleaning, HLD employing appropriate contact times of well-established agents, rinsing, and drying. The HLD step is usually accomplished in automated endoscope reprocessing machines. The biggest challenge in this process is consistency in the repetition of all steps in a thorough sequential fashion. When this is done, experience suggests that the outcome is highly reliable and infection transmission does not occur. Reprocessing is essentially the same in the inpatient setting. The major difference is performance of endoscopy in a variety of environments at widely varied hours of the day. Hence, the challenge of consistency of performance of all reprocessing steps is greater when procedures are performed after-hours in settings distant from the endoscopy suite, perhaps by personnel with varied concurrent demands and expectations.



Bret T. Petersen



LeaRae Herron-Rice

"The biggest challenge in this process is consistency in the repetition of all steps in a thorough sequential fashion."

– Bret T. Petersen

Q: Do you think that scope cleaning/decontamination/sterilization methods, products and compliance are improving year to year? Which are improving and which aren't?

A: Yes, I believe all three are improving: Methods are becoming simplified by the addition of more sophisticated machines, some of which accomplish elements of the process independently, and many of which document their performance more completely than in the past; products are improving, with both the noted developments in automated reprocessing machines, as well as alternate cleaning solutions with shortened contact times; and compliance is gradually improving with the increasing emphasis and publicity given to lapses in reprocessing and the intensified oversight given during both accreditation and surveys from state health departments.

Compliance is also enhanced by the increasing attention lent to it by the professional societies, including excellent training videos from the Society of Gastroenterology Nurses and Associates (SGNA) and the focused emphasis on infection control in the quality courses and the Endoscopy Unit Recognition Program of the American Society for Gastrointestinal Endoscopy (ASGE).

Q: Do you think mandatory technician certification would improve overall quality of scope and device cleaning?

A: No, I don't believe that mandatory technician certification would significantly improve overall quality of endoscope and device cleaning. These tasks are straightforward. I believe their performance is primarily dependent upon provision of basic training, consistency, diligence, and appropriate supervision. I don't believe the challenge in accomplishing them relates to difficulty in understanding or complexity. They are done by a variety of personnel.

For all staff involved in these activities, including technicians and varied levels of nursing staff, appropriate training and competency testing is already mandated, and existing accreditation and state licensure processes provide opportunities for review and audit of competency records. I believe mandated certification of a focused class of staff would provide similar training and assurance of competency, with reduced flexibility of staffing and greatly increased expense to individual staff and endoscopy facilities.

Several important messages are present in the newly updated "Multi-society guideline on reprocessing flexible gastrointestinal endoscopes: 2011," including: high-level disinfection is highly efficacious when appropriately performed; reported infections after gastrointestinal endoscopy frequently relate to inappropriate medication administration and not reprocessing lapses at all; in those few instances when guidelines for performance of HLD differ between specialty groups or between practitioners and manufacturers, there are insufficient data to deem one or another guidance as superior or correct; and when considered as a whole, the pertinent professional societies of nurses, physicians, and infection control experts are

"I don't believe that mandatory technician certification would significantly improve overall quality of endoscope and device cleaning."

– Bret T. Petersen

in remarkable agreement regarding appropriate disinfection practices for safe delivery of gastrointestinal endoscopic services.

This guideline can be found on ASGE's website at www.asge.org under "Practice Guidelines," or at this direct link: <http://www.asge.org/PublicationsProductsIndex.aspx?id=352>.

SGNA's LeaRae Herron-Rice

Q: What are the biggest challenges to the scope cleaning/decontamination/sterilization process in the outpatient setting and inpatient settings?

A: Both inpatient and outpatient endoscopy leaders and staff are challenged every day to provide an environment that supports safe infection prevention for reprocessing of endoscopes and accessories. Unfortunately, it can be overwhelming for the endoscopy nurse to decipher multiple guidelines and product information. SGNA strongly believes that, by providing educational programs and resources based on evidence-based research practices, we can provide endoscopy nursing professionals with the tools they need to overcome these challenges.

In February 2010, SGNA hosted the first Infection Prevention Summit, which included nurse and physician organizations, clinical experts, regulatory agencies and representatives from the industry. From this meeting, the Infection Prevention Consortium was formed. The Consortium's first recommendation was to develop an Infection Prevention Champions Program. This program will include up-to-date guidelines and information related to the endoscopy lab from various sites, including those from regulatory agencies and industry resources. A curriculum and a tool kit are in creation to assist the champions. The Champions Program will be available to all endoscopy nurses and associates, and encourages champions to work with management to ensure effective infection prevention in the GI setting. This program will be unveiled in the coming months.

Q: Do you think that scope cleaning/decontamination/sterilization methods, products and compliance are improving year to year? Which are improving and which aren't?

A: The focus on infection prevention increases each year, and that increasing focus on reprocessing methodologies ultimately benefits healthcare providers and the patients they serve. At the same time, there are many new products that come out on the market each year as well as variations of reprocessing standards and guidelines. It can be overwhelming for healthcare providers to decide what will or will not work, which products are best and the current standards of care.

SGNA will continually strive to assist GI/endoscopy nurses and technicians as they navigate through this ever-changing landscape. SGNA's standards and guidelines and position statements on infection prevention give endoscopy units the proven processes and methodologies they need to ensure safe, effective patient care. Recently, the SGNA Practice Committee reviewed

"SGNA will continually strive to assist GI/endoscopy nurses and technicians as they navigate through this ever-changing landscape."

– LeaRae Herron-Rice

and submitted comments to the FDA's report "Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings." Overall, the FDA report reinforces statements in the SGNA practice documents related to processing and reprocessing endoscopes and accessories, giving further evidence that SGNA's standards and guidelines are a flagship in the industry.

With the Infection Prevention Champions Program's education and training tools, SGNA can play an even larger role in helping endoscopy nurses make informed decisions on new products when they become available. Clearly, education and training are necessary with any new product or change in the process.

Q: Do you think mandatory technician certification would improve overall quality of scope and device cleaning?

A: In 2010, SGNA published a report outlining minimum requirements, knowledge and skills for the GI/endoscopy technician. While this report does not specifically call for mandatory technician certification, we firmly believe that technicians should have a baseline entry-into-practice skill set and competencies. This requires education,

and SGNA remains committed to providing that education and training to assist technicians in further developing their skills and knowledge.

Without question, most endoscopy facilities and units struggle with a lack of resources for training and education. However, investing in learning is paramount to helping nurses and technicians become more prepared for the challenges they face every day.

SGNA offers two educational programs specifically designed for the needs of technicians—the Associates Program and the Advanced Associates Program. Both are affordable, online courses that allow technicians to complete the programs over a period of time, without having to take time off from work. These programs address the full range of technicians' roles and responsibilities in the unit—infection prevention, reprocessing procedures, risk management, anatomy and physiology, critical thinking and more.

The Infection Prevention Champions program, which is currently under development, will provide all GI/endoscopy units with the tools they need to understand and comply with standards of infection prevention at an affordable cost.

SCOPE REPROCESSING AND INFECTION CONTROL COMPLIANCE IN OUTPATIENT CARE

By Jessica Barreras

After the last few years under scrutiny by the press, the outpatient industry has continued to evolve; increased awareness and compliance-driven tools are being updated to ensure the safety of patients, as well as healthcare workers. Various organizations have made conscious and collaborative efforts to ensure that ASCs will be ready when they open their doors to the Centers for Medicare and Medicaid Services (CMS) surveyor.



Marilyn Dahl

Marilyn Dahl, director for the CMS division of acute-care services, Certification and Surveys, notes, "In the 2010 fiscal year surveys, 62 percent of the ASCs surveyed had a citation for an infection control deficiency, and 22 percent of all ASCs surveyed had a serious infection control deficiency," Dahl states. "We can indicate that the percentage of ASCs cited failed to provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice." This covers a very wide range of infection control practices, from improper hand hygiene to unsafe injection practices to improper cleaning and sterilization.

Compliance competencies in scope cleaning, decontamination and the sterilization process have been a point of concern during surveying. Common scope reprocessing deficiencies include¹:

- Not following manufacturer's instructions
- Re-use of single use devices (bite blocks, polyp traps, dilation syringes)
- No competencies, or not done in last 12 months
- Scopes not contained during transport/improper PPE
- No designated clean and dirty areas
- Reuse of single-use disposable brushes/sponges
- Reusing enzymatic solution/rinse water; mixed incorrectly
- Not cleaning work surfaces between scopes
- Incorrect scope storage- no scope cabinet, storing with valves or video cap
- Unfamiliar with manufacturer instructions
 - Enzymatic cleaner - dilution, soak time
 - High-level disinfectant (HLD) time, temperature, dates
 - Minimum effective concentration (MEC) test strips - checked with each use, dip time, read time, QC
 - Scope washers- settings: cycle time, temp
 - Flushing pumps (procedure and scope room) - tubings changed, decontamination, flow verification
 - Water bottles - HLD or sterilized, sterile water only
 - Scopes - follow most recent instructions

Since the updated conditions for coverage for Medicare were released in May 2008, ASCs are required to have an appointed infection preventionist on staff. When gauging the industry's take on this, Jan Davidson, MSN, RN, a perioperative education specialist for the Association of periOperative Registered Nurses (AORN) is quick to mention that when a new standard or requirement comes out, there is always concern on how it will be implemented and sustained. "However, nurses that work in the perioperative arena also realize they are the eyes, ears and voices for the patients when they undergo surgery, and they want nothing more than to keep their patient safe and well cared for," she says.

If a new standard has been introduced, Davidson also mentions there is always a learning curve of what is expected of them to comply with that standard. "As long as the staff has the training and tools that they need to implement and sustain the new standard it soon just becomes part of their everyday work life," she concludes. "Surveyors just want to know that the ASC staff members are taking the infection prevention program seriously."

Strategies to meet CMS infection control Conditions for Coverage include the creation of a proper infection control program in a facility, suggesting the use of nationally recognized organizations as references and proper training for the appointed infection preventionist. Another important issue to consider is the Spaulding criteria for high level disinfection and sterilization for scopes, which can be found in the Multisociety Guidelines on Reprocessing Flexible Gastrointestinal Endoscopes, which was updated in 2011.



Sharon A. Van Wicklin

There are also a number of organizations that offer educational webinars, literature and guidelines to assist infection control compliance. Sharon A. Van Wicklin, MSN, RN, CNOR/CRNFA, CPSN, PLNC, a perioperative nursing specialist for AORN, states the association offers many resources for all varieties of facilities, not just geared towards ASC or hospital. "The practices are easily put into play and followed. As far as ASCs, as reimbursed in depending on compliance, you'll find that folks will modify their practice and continue to improve and become better in the area of infection prevention," Van Wicklin confirms.

Davidson continues to speak about AORN's continued effort to help the ASC industry stating the association is building a much more robust specifically for ASC. "We are putting a push to support ASCs and their practices in the future," she says.

Dahl concludes that CMS is aware that, since the adoption of the revised infection control regulations and increased survey activity, a number of organizations have made available training aimed at infection control in ASCs. "We are seeing some reduction in deficiencies identified in fiscal year 2011 compared to fiscal year 2010. Over the next two years, all non-accredited ASCs will have been surveyed by the states under the new regulations and survey process. Our expectation is that compliance will improve as all ASCs have had the experience of being surveyed for their infection control practices."

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