

Always a Critical Issue!

BY DAVID A. GREENWALD, MD

Reprocessing of endoscopic equipment safely and effectively is a critical part of any procedure. While perhaps not as “sexy” as other endoscopic techniques, endoscope reprocessing must be done correctly each and every time; a breach of protocol leading to transmission of infection has the potential to bring the field of endoscopy to a screeching halt. Physicians and associates working in ASCs need to be ever mindful of strict adherence to all reprocessing guidelines.

The rate of transmission of infection via gastrointestinal endoscopy is exceedingly low. The much quoted rate is 1 in 1.8 million procedures. That number was generated from a comprehensive review of the topic detailing transmission of infection in endoscopy from 1966-1992. Guidelines for cleaning and reprocessing endoscopes were widely disseminated beginning in 1988. In that review, 28 reported infections occurred between 1988 and 1992, while 40 million procedures were estimated to have been done, yielding a rate of 1 in 1.8 million. Pathogen transmission rate may be still lower based on more current estimates, and may be as rare as 1 in 6-10 million. Heightened awareness of possible cross-contamination via gastrointestinal endoscopy is evident given recent media attention to breaches in protocols in various parts of North America.

What is abundantly clear, however, is that every patient must be considered a potential source of infection, and all endoscopes must be reprocessed in a standardized fashion. It is critical to understand that all cases of pathogen transmission related to endoscopy since

the advent of guidelines has been the result of a breach in following the accepted protocol. Standards are published, updated, and widely available, and include Multisociety Guidelines (2003), SGNA (2009), ASGE (2008), ESGE (2003), and BSG (2003). In short, meticulous attention to the following protocols is crucial. Variations to reprocessing protocols in ASCs, office based endoscopy centers and hospital endoscopy suites are not acceptable; the same procedures are universally applicable.

The aforementioned guidelines have several key points. Critical steps in endoscope reprocessing include: cleaning, rinse, disinfection, rinse, dry and storage.

The two most basic components in reprocessing are manual cleaning and disinfection.

Simply put, manual cleaning is the most critical step in endoscope reprocessing. Indeed, manual cleaning reduces the bioburden on the endoscope by many logs (>99.99%), dramatically reducing the load of organisms and debris. Manual cleaning alone may well eradicate HBV, HCV, and HIV (which are among the easiest organisms to eradicate), although further disinfection is part of all reprocessing protocols. Manual cleaning does not obviate the need for liquid chemical disinfection,

but is the first and most critical step in reprocessing.

Manual cleaning includes several maneuvers; the first of which is precleaning, where the endoscope is rinsed and wiped down immediately after use in the procedure room using a detergent solution and sponge. The endoscope must then be properly transported to the reprocessing area in an enclosed container, in order to prevent cross contamination. At this point, leak testing before cleaning should be done. While leak testing has nothing to do with endoscope reprocessing, it is critical to assure no damage will be done to the instrument upon exposure to liquids. The endoscope and all removable parts are to be placed in a fresh basin of enzymatic detergent and all accessible channels should be flushed, brushed and flushed repeatedly.

The crucial importance of manual cleaning cannot be overstated. Without proper manual cleaning, disinfection may not be possible because microorganisms and pyrogens may remain imbedded in debris.

Manual cleaning is followed by disinfection; the standard for GI endoscopy is high level disinfection, and not sterilization. Recall that it is possible to sterilize an endoscope. Heat will work, but would melt the endoscope. Ethylene oxide gas is fine as a sterilant, but is associated with a 24-hour turnaround time, making this generally impractical for busy ASCs and endoscopy centers. High level disinfection is defined as the absence of all microbial life, including vegetative microorganisms, mycobacte-

▼ *Manual Cleaning – the most critical step*



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ria, viruses, fungi, and some, but not all, bacterial spores. This is an appropriate level of reprocessing for use of an endoscope in a subsequent patient. To reiterate, when proper protocol is followed, including manual cleaning and high level disinfection, transmission of pathogens via endoscopy does not occur.

Many liquid germicides (high-level disinfectant - HLD) are available, with the "benchmark" high-level disinfectant still being glutaraldehyde. Glutaraldehyde is now frequently replaced by other agents, including orthophthaldehyde (OPA) and peracetic acid. These allow shorter reprocessing cycles, and are not associated with the toxic fumes that are by product with glutaraldehyde use.

Disinfection may be done in a basin or (more commonly) in an automated reprocessing machine. It is critical to recall that such automated machines are not a substitute for manual cleaning, and should not be referred to as washing machines. Endoscopes must be fully immersed and the disinfection process must complete the entire recommended time, as transmissions of pathogens have been associated with breakdowns in both of these areas.

The final steps in endoscope reprocessing are to rinse the endoscope and flush channels with water (filtered or sterile water is reasonable). Following that, channels should be flushed with 70% EtOH and dried with forced air. This greatly reduces the possibility of re-contamination of the endoscope with water-borne organisms. Lastly, the endoscope should be stored vertically (not coiled in a case) to facilitate drying.

Several other issues are apparent in busy endoscopy centers. Water bottles have been implicated as the source of some pathogen outbreaks (especially *Pseudomonas*). They should be high-level disinfected or sterilized frequently (e.g., daily).

High-level disinfectants (HLD) must be tested for potency regularly. The HLD becomes diluted with repeated use

which is caused by several factors including, but not limited to, dilution, time/temperature, and number of uses. HLD product specific test strips must be used on every cycle and results properly recorded to monitor that the high-level disinfectant is maintained above the minimum effective concentration for germicidal action. Attempts to cut costs by cutting test strips or using them sporadically or not at all is inappropriate and leaves no way to ensure that the HLD will be effective. Moreover, high-level disinfectants have a shelf life, and must be discarded at the end of the shelf life (topping off with some fresh material is not appropriate).

Standardization of procedures is critical. Variations in reprocessing protocols are not acceptable. Appropriate protective clothing should be worn at all times by personnel involved in preprocessing. Items marked for single-use only (single-use brushes and sponges) must only be used once; efforts to contain costs must not lead to variations from the accepted guidelines.

Lastly, but very importantly, while everyone involved in endoscopy should be familiar with the essentials of reprocessing, the task of endoscope reprocessing should be the domain of trained staff who regularly perform this function. It should not be assigned to temporary personnel unfamiliar with reprocessing. Personnel must strictly follow SGNA/ASGE/Multisociety Guidelines. In addition to having adequately trained staff, attention must be paid to having adequate staffing levels at all times and the scheduling of trained personnel.

Endoscopy is a valuable and sometimes life-saving procedure. Appropriate infection control measures are essential for safe procedures, and this includes following guidelines during endoscope reprocessing and meticulously using accepted general infection control proce-

dures during endoscopy. Future efforts in this area will continue to focus on improved adherence to guidelines, standardization of reprocessing equipment to make the process easier and less prone to variation, and development of improved endoscope and reprocessor design to minimize the potential for errors.

Resources

SGNA Guidelines, Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes, 2008

ASGE Guidelines, Infection Control during GI Endoscopy, 2008

Multisociety Guidelines for Reprocessing Flexible Gastrointestinal Endoscopes, 2003

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