The Dirt on Flexible Endoscope Reprocessing

ABSTRACT

To avoid cross contamination of infectious pathogens, endoscopes and their associated accessories are cleaned and disinfected or sterilized (reprocessed) between each patient use. Failure to properly reprocess endoscopes and accessories could potentially expose patients to bloodborne pathogens and harmful bacteria, which may result in serious patient injury or death. Often, these exposures affect large numbers of patients who must be notified of the potential risk and may need to return to the facility for testing. Patient notification of endoscopy-related cross contamination or suspected contamination can be challenging when appropriate identifying information associating a specific endoscope with a specific patient is not captured. Between 2004 and 2009, the Pennsylvania Patient Safety Authority 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, while the remainder described potentially contaminated endoscopes getting to the patient (e.g., surgical field), but not used, or lacked information to determine patient involvement. To reduce the likelihood of cross contamination, healthcare facilities need to consider developing and adhering to comprehensive, model-specific reprocessing protocols. (Pa Patient Saf Advis 2010 Dec;7[4]:135-40.)

Endoscopes* are optical instruments used to visually examine internal organs or cavities within the human body to diagnose and treat various medical conditions. Endoscopes and their accessories (e.g., irrigation tubing) need to be reprocessed (cleaned and disinfected or sterilized) between each patient use. Failure to reprocess or inadequate reprocessing of endoscopes and accessories places patients at risk of exposure to various pathogens. Because of the severity of this potential risk, ECRI Institute designated cross contamination from flexible endoscopes as the number 1 hazard of the top 10 medical technology hazards for 2010.† A March 2006 Patient Safety Advisory article described potential contamination of surgical instruments, including endoscopes, due to inadequate cleaning and inspection of the instruments before sterilization.

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. 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 sixstep protocol that includes precleaning, leak testing, manual cleaning, high-level disinfecting or sterilizing, rinsing and drying, and endoscope storing (for more information on the reprocessing steps, see the sidebar “Typical Endoscope Reprocessing Protocol”). 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.†

Large-Scale Cross-Contamination Risks and Analyses

Reports of endoscopy-related patient cross contamination have garnered media attention due in part by the large number of potentially affected patients. Between December 2008 and April 2009, the U.S. Department of Veteran Affairs (VA) notified approximately 10,000 patients who received endoscopic procedures at 3 VA facilities between April 2003 and March 2009 that they may have been exposed to bloodborne pathogens due to improperly processed endoscopy equipment.† In 2004, the California Department of Health Services called for a review of endoscope reprocessing procedures in the wake of reports of improper reprocessing of flexible endoscopes from eight healthcare facilities.¶ As a result of these breakdowns in reprocessing procedures from the 8 facilities, more than 5,000 patients were notified of potential exposure to hepatitis B, hepatitis C, and in some cases, HIV.† Palomar Medical Center notified 3,400 patients that received endoscopically related care between December 2008 and March 2010 to return for tests for infectious diseases because the endoscopic equipment used in their care may not have been properly disinfected.†

* There are two basic types of endoscopes: rigid and flexible. While reprocessing procedures are similar for rigid and flexible endoscopes, this article focuses on flexible endoscope reprocessing because of the complexity of the procedures.
‡ The process of high-level disinfection and sterilization of endoscopes can be automated using automated endoscope reprocessors (AERs) and sterilizers, respectively. For convenience, the term endoscope reprocessors or reprocessors will be used in this article to refer to both AERs and sterilizers.

Analyses

Large-Scale Cross-Contamination Risks and Analyses

Reports of endoscopy-related patient cross contamination have garnered media attention due in part by the large number of potentially affected patients. Between December 2008 and April 2009, the U.S. Department of Veteran Affairs (VA) notified approximately 10,000 patients who received endoscopic procedures at 3 VA facilities between April 2003 and March 2009 that they may have been exposed to bloodborne pathogens due to improperly processed endoscopy equipment.† In 2004, the California Department of Health Services called for a review of endoscope reprocessing procedures in the wake of reports of improper reprocessing of flexible endoscopes from eight healthcare facilities.¶ As a result of these breakdowns in reprocessing procedures from the 8 facilities, more than 5,000 patients were notified of potential exposure to hepatitis B, hepatitis C, and in some cases, HIV.† Palomar Medical Center notified 3,400 patients that received endoscopically related care between December 2008 and March 2010 to return for tests for infectious diseases because the endoscopic equipment used in their care may not have been properly disinfected.†
Typical Flexible Endoscope Reprocessing Protocol

Typically, an endoscope reprocessing protocol will include the following steps in order:

**Precleaning.** This step is performed in the procedure room. An enzymatic detergent solution is used to wipe the exterior of the endoscope and to flush all the channels. During precleaning, irrigating the channels with an enzymatic detergent solution helps moisten and soften debris in preparation for the subsequent, more vigorous manual cleaning step.\(^1\)\(^,\)\(^2\)

**Leak testing.** This step is performed in the processing room after precleaning but before manual cleaning begins. This test consists of pressurizing the endoscope with air and submerging it in water to check for damage (i.e., 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.\(^1\)\(^,\)\(^2\)

**Manual 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 endoscope is then rinsed with water. Rinsing may also include using forced air to remove excess water from the endoscope before disinfection or sterilization.\(^1\)\(^,\)\(^2\)

**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.\(^1\)\(^,\)\(^2\) The decision to disinfect or sterilize an endoscope is typically based on the Spaulding classification system (accepted by the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration).\(^3\)

The Spaulding classification system is described as follows:\(^3\)

- **Critical devices:** devices that enter sterile tissue or the vascular system are sterilized (e.g., scalpel).
- **Semicritical devices:** devices that come into contact with mucous membranes and do not penetrate sterile tissue are, at a minimum, high-level disinfected (e.g., bronchoscope).
- **Noncritical devices:** devices that do not touch the patient or that touch only intact skin are cleaned, followed by low-level disinfection (e.g., stethoscope).

Flexible endoscopes typically fall into the semicritical device category, requiring at least high-level disinfection. However, endoscopes that enter sterile body cavities are classified as critical devices requiring sterilization.\(^3\)

**Rinsing and drying (with alcohol flush).** The first part of rinsing includes flushing the endoscope with filtered water. This is typically performed for endoscopes that are exposed to a liquid chemical germicide. Pressurized air is then passed through the endoscope to remove the water. For endoscopes subjected to high-level disinfection, the endoscope channels are then flushed with 70% to 90% ethyl or isopropyl alcohol and dried using forced air. Most automated endoscope reprocessors can perform this step; however, this step can be performed manually.\(^1\)\(^,\)\(^2\)

**Storing.** For endoscopes that have undergone high-level disinfection, the endoscope is hung vertically with caps, valves, and other detachable components removed. Endoscopes are stored in a well-ventilated area that is not prone to moisture collection. However, some endoscope reprocessor manufacturers recommend not storing sterilized endoscopes but using them immediately after sterilization to ensure that the endoscope’s sterility is not compromised. Other reprocessor manufacturers may require that sterile endoscopes be wrapped for storage and only unwrapped in a sterile environment.\(^1\)\(^,\)\(^2\)

**Notes**


---

If a risk of endoscopy-related contamination has been identified, a review is typically undertaken to determine at which point a breakdown in procedures may have occurred that led to the potential exposure. For example, staff may review documentation of endoscope reprocessing procedures for a specific endoscope in which cleanliness and/or sterility is in question. This review may reveal that one or more steps involved in reprocessing this particular endoscope were not followed, leading to a review of reprocessing documentation for other endoscopes. From this, a timeframe may be found as to when the deviation from the reprocessing procedures occurred (e.g., failing to perform the precleaning step). Once a timeframe is determined, to identify exposures or as a precaution, a facility will notify all patients who had an endoscopic procedure during that period to be tested even though there may have been no actual exposure.
Additionally, even if a patient tests positive for an infection, such as hepatitis C, there may not be a definitive link between an improperly reprocessed endoscope and the infection. For example, in the VA incident described, some patients tested positive for hepatitis B, hepatitis C, or HIV; however, these infections could not be directly linked to the endoscopic procedures. Subsequently, VA undertook an epidemiologic study to determine whether an association between the infections and the procedures existed.3 Properly tracking and documenting endoscope use—capturing appropriate identifying information such as patient information, procedure date, procedure type, the responsible physician’s name, and endoscope-unique identification number2—so that the endoscope can be linked to the patient should a gap in reprocessing occur is an important part of the process to improve patient notification.

**Patient Notification**

Patient notification of endoscopy-related cross contamination or suspected contamination can be challenging when appropriate identifying information associating a specific endoscope with a specific patient is not captured. If an outbreak occurs or is suspected due to an inadequately reprocessed endoscope, a healthcare facility should assess the risk to patients whose procedures were performed with the suspect endoscope. A 2004 report from the California Department of Health Services (DHS) on endoscope reprocessing established the following recommendations to aid investigation of endoscope sterility issues:5

- Maintain a log of the patient’s name, medical record number, date of procedure, specific procedure(s) performed, physician’s name performing the procedure(s), and endoscope type and model/serial number (or other unique identifier).
- Identify each automated endoscope reprocessor (AER) used to process each endoscope (for multiple AERs) and the endoscope reprocessing cycles used on each endoscope. (Note that although the California DHS recommendations specify only AERs, the same recommendations can be applied to sterilizer units.)

Not addressed in the California DHS recommendations is identification of endoscopes in the patient record. However, implementing this identification practice may be difficult due to the following:2

**Inaccurate recording.** Some endoscopes can have long serial numbers and may often be affixed with other identifiers (e.g., model number) that are not unique and could be mistaken for unique identifiers.

**Changing inventory.** For healthcare facilities that take part in leasing or repair programs, endoscopes are typically returned to the supplier for repair or replacement. Often, the endoscopes are replaced with new or loaner devices, which can make tracking these instruments difficult.

**Clinical resistance.** Some users may shy away from following an endoscope identification practice, believing that it will add work without providing clear-cut benefit to the practice. Notwithstanding these challenges, developing and following unique endoscope identification practices will help facilities associate contaminated or potentially contaminated endoscopes with specific patients during the notification process. For consistent compliance, any practices must be highly efficient.

**Pennsylvania Patient Safety Authority Data**

From June 2004 through 2009, the Pennsylvania Patient Safety Authority received 107 reports describing potential patient contamination due to inadequate or improper endoscope reprocessing techniques. While this article focuses on flexible endoscope reprocessing, the data submitted to the Authority may also include reports related to rigid endoscopes because in some reports the term “scope” was the only descriptor identifying the equipment involved. 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. Authority analysts established five categories based on a review of the narratives in the event description field of the reports.

**Not Cleaned or Deviation from Endoscope Reprocessing Protocol (65 Reports)**

This category captures reports to the Authority that describe endoscopes that either were not cleaned or were improperly cleaned during reprocessing. Reports include the following:

- A bronchoscope that was used on 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.

  [Staff] obtained a clean gastroscope from instrument room; upon testing the scope, blood leaked out of the end of the scope.

**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 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 scope not sterilized for procedure.
Contamination

Knowingly Used Unsterile Endoscope (3 Reports)

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

Reprocessing Breakdowns That Risk Cross Contamination

Other reported breakdowns that produced cross-contamination were reported in the VA studies. Endoscopes used for ear, nose, and throat procedures may not have been adequately disinfected or sterilized. Colonoscopy patients may have been exposed to cross contamination due in part to a failure to disinfect tubing between procedures. In one facility, staff were not following manufacturer’s recommendations when reprocessing auxiliary water tubing and other irrigation components between patients. Additionally, while not a reprocessing issue but a cross contamination issue, staff had, in some cases, connected the irrigation channel of the colonoscopes to irrigation pumps using tubing with an incorrect valve. This incorrect connection could potentially allow backflow of contaminated fluid into the irrigation system.

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 Authority 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 precleaning 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, precleaning 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.

Propre Reprocessing Technique

Endoscope reprocessing equipment and endoscope compatibility are important aspects in reducing the risk of cross contamination. Flexible endoscopes can be reprocessed completely by manual means (e.g., manual cleaning, manual disinfection); however, a common part of the process involves using an endoscope reprocessor. After manual cleaning, endoscopes and endoscope channels must undergo exposure to a germicidal agent for high-level disinfection or sterilization. Endoscope reproprocessors help automate this process by exposing the endoscope to a germicidal agent at a particular temperature and for a particular duration to achieve adequate decontamination. Some units also rinse the endoscope with filtered water to remove any germicidal agent residues. Typically, the reprocessor and endoscope manufacturers provide users with information on models-specific compatibility with respective products. Compatibility means that a specific model endoscope can be used with a specific model endoscope reprocessor. This compatibility ensures that the components of the processor (e.g., connectors) match the components of the endoscope (e.g., air/water channel) for proper reprocessing.

In 2005, a Pennsylvania hospital notified approximately 200 patients that they may have been at risk of exposure to hepatitis and HIV infections due to improper disinfection procedures of colonoscopes. The hospital purchased two new colonoscopes that included a water-jet channel to flush gastrointestinal mucosa under observation. This water-channel feature was not included in the facility’s previous model colonoscopes, and hospital staff did not recognize this difference during reprocessing. Subsequently, the water-jet channel was not disinfected during reprocessing procedures. This event demonstrates the need to ensure compatibility of reprocessing equipment and endoscopes and to ensure that models-specific reprocessing protocols are developed and followed.

Healthcare facilities can provide the endoscope reprocessor supplier with a model-specific list of its
endoscopes to ensure compatibility with the supplier’s unit; the facility can also obtain a written statement confirming compatibility and specific reprocessing instructions when possible. Consideration also needs to be given to the compatibility of endoscopes with the germicidal agent. Endoscope and reprocessor manufacturers provide information on the specific germicidal agents that have been tested for compatibility with their respective products; germicidal agent product compatibility statements can also be obtained. In addition to germicidal agent compatibility, the potency of the reusable agent is to be regularly tested and documented (single-use agents are used with some endoscope reprocesors and would not be subject to this check). The strength/potency of a germicidal agent decreases with each use. Additionally, in the case of some germicidal solutions, once the solution container (single- or multi-use solution) is opened, the agent has a finite use period (e.g., 28 days) for optimal effectiveness.

The channel terminations of various endoscope models may require specific channel adapters to ensure proper reprocessing in the endoscope reprocessor. Not only will a facility need to maintain a supply of endoscope-specific adapters and, if necessary, purchase new compatible adapters for each newly purchased endoscope, but staff must be knowledgeable about which adapter correctly connects each endoscope to the reprocessor. Using an incorrect adapter may not provide adequate fluid flow (e.g., germicidal solution, water) through the endoscope channel during reprocessing in the endoscope reprocessor. The proper use and maintenance of endoscope reprocesors helps reduce the risk of endoscope contamination. For example, some reprocesors use tap water as a rinsing agent and therefore include a water filtration system with a bacterial filter to prevent waterborne bacteria from contacting the endoscope during rinsing. According to the reprocessor manufacturer’s instructions, it is important to periodically change this filter as part of the reprocessor maintenance process.

Endoscopes, including insertion tubes and channels, that are processed using liquid chemical germicides must be rinsed with filtered or sterile water to remove any chemical residue. Endoscopes that undergo high-level disinfection are typically flushed with alcohol and then dried with forced air after being disinfected. Drying prevents microbial growth from a moist environment. Even improper storage of reprocessed endoscopes can lead to cross-contamination risks. Proper storage reduces the likelihood of contamination of or damage to endoscopes (storage and handling instructions depend on the type of reprocessing method). Endoscopes subject to high-level disinfection are to be hung vertically—without touching each other—in a well-ventilated area with control valves, caps, and other detachable components removed to facilitate drying. However, endoscopes subjected to gas sterilization processes are wrapped for storage (to maintain sterility) and unwrapped only in a sterile environment. Some reprocessor manufacturers may require that a sterilized endoscope be used immediately after sterilization.

**Risk Reduction Strategies**

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 precleaning 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-adapters 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.

**Notes**


3. ECRI Institute. U.S. Veterans Health Administration announcements highlight need for comprehensive endoscopy-reprocessing protocols [action item S0193]. Health Devices Alerts 2009 Apr 16.


The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the Pennsylvania Patient Safety Authority, see the Authority’s website at http://www.patientsafetyauthority.org.

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute’s expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures and drug technology.

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP’s efforts are built on a nonpunitive approach and systems-based solutions.