

Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee



Preface

The Healthcare Infection Control Practices Advisory Committee (HICPAC) is a federal advisory committee chartered to provide advice and guidance to the Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services (HHS) regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance and related events in United States healthcare settings. **At the July 2015 HICPAC Meeting, CDC asked HICPAC for guidance on ways to improve facility-level training and ensuring competency for reprocessing endoscopes.** To develop recommendations for HICPAC to consider, a HICPAC workgroup was formed that contained the following key stakeholder organizations: Accreditation Association for Ambulatory Health Care (AAAHC), Association for the Advancement of Medical Instrumentation (AAMI), American Gastroenterological Association (AGA), American Society for Gastrointestinal Endoscopy (ASGE), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), Centers for Medicare & Medicaid (CMS), Council of State and Territorial Epidemiologists (CSTE), DNVGL Healthcare, Food and Drug Administration (FDA), International Association of Healthcare Central Service Material Management (IAHCSMM), Public Health Agency of Canada (PHAC), Society of Gastroenterology Nurses and Associates (SGNA), Society for Healthcare Epidemiology of America (SHEA), and The Joint Commission (TJC). The Workgroup provided updates and obtained HICPAC input at the November 2015, March 2016, and July 2016 HICPAC Meetings. HICPAC voted to finalize the recommendations at the July 2016 meeting. Additional information about HICPAC is available on the HICPAC Website (<https://www.cdc.gov/hicpac/>).

Introduction

Healthcare facilities should have a reliable, high-quality system for endoscope reprocessing which minimizes infection risks. To achieve this goal, all reprocessing programs must have an infrastructure that supports training and competencies, quality measurement, and management. The following guidance is provided to assist healthcare facilities, including clinical and administrative staff, to achieve a reliable, high-quality reprocessing program. A toolkit of sample documents accompanies this guidance to help facilities create and maintain the infrastructure to support their flexible endoscope reprocessing program (available from: <https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html>).

Recommendations

Essential Steps for Flexible Endoscope Reprocessing

To ensure flexible endoscopes are safe for patient use, all staff involved in reprocessing this equipment must understand and consistently follow a number of steps which have been distilled down to seven essential steps. Ensuring adherence to these steps requires a complete and effective reprocessing program. These recommendations apply to all settings where endoscopic procedures are performed and where endoscopes are reprocessed.

1. Pre-cleaning

- a. Pre-clean flexible endoscopes and reusable accessories by following the device manufacturer's instructions for use (IFU). Perform pre-cleaning immediately following completion of the endoscope procedure to help prevent the formation of biofilm.

2. Leak Testing

- a. For endoscopes that require leak testing, perform the leak test using manufacturer's IFU after each use and prior to manual cleaning. Leak testing detects damage to the external surfaces and internal channels of the endoscope that can lead to inadequate disinfection and further damage of the endoscope.

3. Manual Cleaning

- a. Perform meticulous manual cleaning including brushing and flushing channels and ports consistent with the manufacturer's IFU before performing high-level disinfection (HLD) or sterilization. Perform manual cleaning within the timeframe specified in the manufacturer's IFU. Manual cleaning is the most critical step in the disinfection process since residual organic material can reduce the effectiveness of HLD and sterilization.

4. Visual Inspection

- a. After manual cleaning, visually inspect the endoscope and its accessories. Visual inspection provides additional assurance that the endoscope and its accessories are clean and free of defects. Complex devices such as flexible endoscopes may require the use of lighted magnification or additional methods to assist with the inspection process.

5. Disinfection or Sterilization

- a. Following cleaning and visual inspection perform HLD or sterilization in accordance with the manufacturer's IFU. Carefully review and adhere to the endoscope manufacturer's reprocessing instructions and to the IFU for chemicals or sterilants and any equipment (e.g., automated endoscope reprocessors) used for reprocessing to help ensure that effective disinfection occurs.

6. Storage

- a. After reprocessing is complete, store endoscopes and accessories in a manner that prevents recontamination, protects the equipment from damage, and promotes drying. Store processed flexible endoscopes in a cabinet that is either:
 1. of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet OR

2. designed and intended by the manufacturer for horizontal storage of flexible endoscopes

7. Documentation

- a. Maintain documentation of adherence to these essential steps each time an endoscope is reprocessed. Documentation is essential for quality assurance purposes and for patient tracing in the event a look back is necessary.

Essential Elements of a Reprocessing Program for Flexible Endoscopes

Administrative

1. Leadership of the healthcare organization or practice setting where flexible endoscopes are used and/or reprocessed is accountable for:
 - a. Allocating sufficient human and material resources to ensure that the selection, use, and reprocessing of endoscopes and related accessories are managed in a manner that minimizes infection risk and supports patient and healthcare worker safety.
 - b. Supporting and empowering the authority of those responsible for managing infection prevention practices to ensure effectiveness of the program.
 - c. Ensuring that the essential elements of an endoscope reprocessing program are followed and that endoscopes are reprocessed according to manufacturers' IFU.
2. Policies
 - a. In all practice settings where endoscopy is performed, policies related to the reprocessing of endoscopes should be developed by a multidisciplinary team that includes physicians, nurses, endoscope reprocessing personnel, infection preventionists, and other personnel who are involved in the use and reprocessing of endoscopes. For facilities with limited personnel where formation of a multidisciplinary team is not possible, consider seeking external expertise to obtain multidisciplinary input.
 - b. Policies should address the selection, use, transport, reprocessing, and storage of endoscopes and accessory devices to ensure compliance with endoscope and reprocessing equipment manufacturers' IFUs. In addition, policies should clearly include requirements for documentation of adherence to essential reprocessing steps, parameters regarding the physical setting where endoscope reprocessing occurs, staff education, training, and assessment of competency, ongoing quality assurance procedures, and protocols for responding to equipment and HLD/sterilization failures or breaches (see sections below).
 - c. Policies should include the management of "loaner" endoscopes (i.e., endoscopes that are not owned by the healthcare facility but are provided for temporary use by manufacturers, equipment suppliers or other healthcare facilities) to ensure adherence to the same reprocessing standards described above required for facility-owned equipment. This includes:
 1. Assessing the condition (i.e., visual inspection, leak testing) of loaner endoscopes prior to use.
 2. Cleaning and high level disinfection or sterilization of loaner endoscopes supplied by the manufacturer or another healthcare facility prior to use.
 - d. Policies must be in compliance with all federal and local regulatory (e.g., FDA, CMS, OSHA, state health departments) and relevant accrediting organization (e.g. AAAASF, AAAHC, DNVGL Healthcare, TJC) standards and requirements. Policies should also take into consideration the

standards and recommendations from professional organizations (e.g., AAMI, AGA, AORN, ASGE, SGNA).

3. Management should ensure that:
 - a. Policies related to the reprocessing of endoscopes are in place and are reviewed on a regular basis as required by the facility governing body and any applicable regulatory organization. In addition, policies should be updated regularly when new equipment/products are purchased and when new information is published.
 - b. Single-use devices should not be reprocessed. If a facility chooses to reprocess a single use device, FDA regulations for reprocessing of single use devices must be followed.
 - c. Occupational health needs are addressed that include but are not be limited to the provision of hepatitis B vaccine, prevention of exposure to infectious agents (e.g., bloodborne pathogens, enteric pathogens) and availability of post-exposure prophylaxis when indicated, convenient access to and appropriate use of personal protective equipment (PPE), and monitoring for exposure to chemicals used for reprocessing when applicable. The CDC provides multiple resources related to occupational health.^{1,2}
 - d. Patient scheduling and staffing levels are adequate to allow for enough time to consistently perform adequate reprocessing of endoscopes and to avoid delays between completion of an endoscopic procedure and initiation of reprocessing of the endoscope used for that procedure. Management should be knowledgeable about the manufacturer's IFUs related to delayed reprocessing to ensure that appropriate steps are taken if a reprocessing delay occurs.
 - e. Staff has access to personnel with infection prevention knowledge and training to support the development and implementation of infection prevention policies and procedures.
 - f. All personnel involved in the reprocessing of endoscopes, including the supervisors and managers of reprocessing personnel, receive ongoing education, training and assessment of competency as outlined in the Education, Training and Competencies section.
 1. If personnel are responsible for reprocessing more than one type of endoscope, verify reprocessing competency for each type of endoscope, including the appropriate use of all equipment required for reprocessing.
 2. Endoscope reprocessing certification is encouraged but does not negate the need for ongoing assessments of competency.
 - g. At minimum, water used for reprocessing of endoscopes meets the specifications that are recommended by the device and reprocessing equipment manufacturers.^{3,4} Professional society guidelines that recommend more stringent water specifications should be considered.⁵
 - h. All the essential elements of an effective endoscope reprocessing program are met and maintained.

Documentation

1. Documentation requirements vary depending upon the methods and the products that are used for HLD or sterilization.
2. For all methods of reprocessing using HLD or sterilization, document endoscope and patient identifiers. Tracking is essential in the event of a disinfection failure and for responding to device or product recalls.

3. Ensure that there is a process in place to record the procedure end time and the start time for manual cleaning. Recording these times enables reprocessing personnel to ascertain how long the endoscope has been awaiting reprocessing, to prioritize reprocessing of specific endoscopes, and to determine whether routine reprocessing within the manufacturer's recommended time to cleaning is achievable, and if not, to implement the manufacturer's procedures for delayed processing.
4. Maintain documentation of the effectiveness of the products used for cleaning and disinfection (e.g., document the results of testing for effective concentrations of the chemical disinfectant, expiration dates for test strips and chemical disinfectants).
5. Maintain records of preventive maintenance and repair of endoscopes and reprocessing equipment (e.g., leak testers, automated endoscope reprocessors [AERs], sterilizers).
6. Documentation should include the investigation of critical or potential critical events such as HLD or sterilization process failures or equipment failures.
7. Retain documentation as designated by the facility record retention policy. This includes documentation for AERs and retired endoscopes.

Inventory

1. Conduct an endoscope inventory to identify all endoscopes and method of reprocessing in use by the facility. Information reviewed for each endoscope should include but is not limited to the:
 - a. Endoscope manufacturer and model
 - b. Location of use
 - c. Number of procedures performed
 - d. Location of the endoscope manufacturer's IFUs
 - e. Location for reprocessing
 - f. Equipment used for HLD and/or sterilization
 - g. Status of the endoscope (i.e., retired, out for repair, in use)
2. Ensure that each endoscope has a unique identifier to facilitate tracking. Tracking should include the ability to determine when specific endoscopes were used for specific patients, loaned to other units or facilities, reprocessed, or repaired. Tracking is also essential for responding to device or product recalls.

Physical Setting

1. The reprocessing area should be in a space that is separate from the patient procedural area.
2. Review the physical setting to ensure a "one way" work flow that separates contaminated work spaces from clean work spaces.
3. If a separate room is used for manual cleaning of endoscopes, ensure a directional airflow that maintains negative pressure within that room relative to adjoining spaces.
4. Ensure that heating, ventilation, and air conditioning parameters are appropriate for the chemicals and equipment in use.
5. Staff should have access to a handwashing sink that is separate from the reprocessing sink(s).
6. Install eyewash stations, either plumbed or self-contained, within the endoscopy reprocessing room where chemicals that are hazardous to the eyes are used. Eyewash stations should not be installed in a location that requires flushing of the eyes in the decontamination sink.

7. Ensure that manufacturer's IFUs for reprocessing of the endoscopes and for use of the AERs and associated chemicals are readily available.
8. Provide designated space to enable access to files electronically (e.g., computer) or hard copy (e.g., in binders for IFUs and Safety Data Sheets for chemicals used to reprocess flexible endoscopes).

Education, Training, and Competencies

1. Education and training should include the rationale for each of the seven essential steps of reprocessing outlined in this document. Training and competency assessments should be based upon the endoscope manufacturer's IFUs as well as the reprocessing equipment and chemicals used. If more than one type/model of endoscope is used, staff should be able to demonstrate they are competent to reprocess each specific type of endoscope.
 - a. Model-specific competency assessment check lists may be required.
 - b. Post visual educational aids and standard operating procedures to reinforce best reprocessing practices.
2. Education and training should also address decontamination, cleaning and sterilization of reusable accessories that breach the mucosal barrier (e.g., biopsy forceps).
3. Ensure that trainers and managers are competent to reprocess endoscopes and are able to adequately train and verify the competency of their staff.
4. Perform staff competencies:
 - a. Initially upon hire and periodically as required by facility policy. An educational update followed by direct observation of staff performing endoscope reprocessing is recommended.
 - b. Whenever a new model of endoscope, reprocessing equipment (e.g., AER, leak tester), or chemical is purchased.
 - c. Whenever there are updates to the manufacturer's IFUs.
 - d. That include essential steps of reprocessing from pre-clean to storage and documentation.
 - e. That include a review of procedures to be followed in the case of equipment failure (e.g., use of manual reprocessing methods as per manufacturer's IFU or use of an alternative automated reprocessor that is validated for the endoscope).
 - f. That include how and when to perform supplemental testing or other assessments of endoscope cleaning (e.g., tests that measure residual organic material or adenosine triphosphate) when those tests are used by the facility.
5. Certification in reprocessing of endoscopes does not mitigate the need for orientation, ongoing education training/education and competency assessments.

Risk Assessment and Quality Assurance

1. A risk assessment or comprehensive gap analysis should be conducted to ensure that:
 - a. All essential steps of reprocessing and essential elements of an endoscope reprocessing program are met and maintained.
 - b. Flexible endoscopes are precleaned at the point of use and transported safely to the reprocessing area.
 - c. Staff competencies are verified
 - d. Sufficient numbers of reprocessing personnel are available when routine and/or emergency endoscopic procedures are performed

- e. Manufacturer's IFUs are readily available and followed
 - f. Necessary reprocessing equipment and supplies are available
 - g. Physical space is adequate for reprocessing
 - h. Heating, ventilation and air conditioning parameters are monitored and controlled
 - i. Storage of endoscopes is appropriate
 - j. Documentation providing complete traceability is maintained.
2. When conducting the risk assessment or gap analysis, if an AER is used, assess for documentation that AER has been validated for reprocessing the endoscope and endoscope components. Obtain the model-specific reprocessing protocols for both the endoscope and AER and verify compatibility.
 3. Perform periodic audits of facility reprocessing protocols and the completeness of documentation to monitor compliance. Gap analyses and risk assessments should be conducted periodically and whenever new endoscopes are purchased, manufacturer's IFUs change, and when changes occur in guidance from professional and regulatory organizations.

Disinfection/Sterilization Breach or Failure

1. Breaches in adherence to essential disinfection and sterilization steps can be a result of malfunctioning of equipment and/or human error. Each breach is a result of unique circumstances and should be evaluated to determine the risk of disease transmission. A multi-disciplinary team that includes infection prevention, risk management, and endoscopy personnel should review each event carefully to determine the necessary corrective steps and the need for patient notification.
2. There are several resources available to assist in a breach evaluation. The multi-disciplinary team should use one or more of these documents to guide their investigation.⁵⁻⁷
3. When a breach involves a suspicion of patient exposure to an improperly reprocessed endoscope, the decision to notify patients of their potential exposure should be made in consultation with an infection preventionist and state and local health departments.
4. If a healthcare provider suspects persistent bacterial contamination of an endoscope following reprocessing, either because of an increase in infections after endoscopic procedures or because of the results of microbiological culturing of endoscopes, the healthcare provider should file a voluntary report through [MedWatch](#), the FDA Safety Information and Adverse Event Reporting program.⁸

Unresolved Issues

1. Supplemental measures for duodenoscope reprocessing following HLD
 - Some healthcare facilities have chosen to use a supplemental method(s) following high level disinfection for reprocessing of duodenoscopes. Because there is currently insufficient evidence to adequately assess the balance between potential benefits and unintended consequences associated with these supplemental methods, these methods have not been included as essential elements of a reprocessing program⁹. Examples of supplemental measures as of July 2016 include but are not limited to:
 - Repeat high level disinfection
 - Microbiological culturing and quarantine until negative culture
 - Liquid chemical sterilant processing system
 - Ethylene oxide sterilization

- FDA-cleared low-temperature sterilization
- 2. Endoscope Storage Interval
 - The available data on the maximum interval of endoscope storage before reprocessing is required prior to use is inconclusive. The length of time may depend on multiple factors as identified on organizational risk assessment that may include endoscope usage/turnover of endoscopes used and manufacturer's instructions-for-use.
- 3. Endoscope Storage Space
 - The storage cabinet features that are optimal for prevention of contamination have not been determined (e.g., cabinet ventilation parameters, capacity to store accessories).
- 4. Replacement of Endoscopes
 - While endoscopes should be serviced no less frequently than indicated in the FDA-cleared manufacturer's IFUs, the optimal time interval for replacement of the endoscope and its associated parts is unknown.

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