Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes

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Preface

These standards are presented by the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) to be used for all settings where gastrointestinal endoscopy is practiced. These standards have been developed to complement the position statement, *Reprocessing of Flexible Gastrointestinal Endoscopes-An American Society for Gastrointestinal Endoscopy White Paper* (Walter,1996) and developed by the American Society of Gastrointestinal Endoscopy (ASGE), Association for Professionals in Infection Control and Epidemiology (APIC) and SGNA and serve as the interpretive document for the 1994 guidelines of the American Society for Testing and Materials (ASTM) F 1518, *Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera* (ASTM, 1994). The current version complements SGNA's *Guidelines for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* (SGNA, 2007).

Proper reprocessing of endoscopes and accessories is critical to the safe and successful treatment of patients (ASGE, 2001). SGNA and ASGE support increased research in the areas of endoscope design and encourage manufacturers to develop flexible gastrointestinal endoscopes that can be easily disassembled for reprocessing and verification of cleaning and high level disinfection. The use of non-immersible endoscopes is no longer acceptable because endoscopes which cannot be completely immersed in liquid cannot be adequately cleaned and high-level disinfected (ASGE, 2001).

Endoscopes reprocessed appropriately in accordance with reprocessing and infection control guidelines pose virtually no risk of transmission of patient-borne or environmental microorganisms. In the absence of defective equipment, every reported case of nosocomial infection associated with a contaminated GI endoscope have been linked to a breech or violation of at least one of several requisite reprocessing steps (ASGE, 2001, Nelson & Muscarella, 2006).

The FDA has recently approved new labeling for some automated endoscope reprocessors . The new labeling clears these machines as washer-disinfectors that do not require prior manual cleaning and channel brushing. However, bedside pre-cleaning is still required. While the introduction of automated, brushless washing of endoscope channels represents a potentially significant advancement, the existing Multi-Society Guidelines and other international standards emphasize the importance of manual cleaning and brushing for the overall efficacy of high level disinfection (HLD). The redundancy achieved by adding an automated washing step following manual cleaning can undoubtedly provide an extra level of safety. Users are cautioned about dispensing with manual cleaning endoscope reprocessing and brushing steps before the capabilities of the new machines are confirmed in independent studies and in clinical practice. Diligence in application of all steps of cleaning and disinfection remains paramount in the safe delivery of endoscopic services (ASGE, 2007, Alfa 2006).

Definitions

For the purpose of this document, SGNA has adopted the following definitions:
Anionic detergent: Detergent in which the hydrophilic function is fulfilled by an anionic grouping. A class of synthetic detergents in which the molecules do not ionize in aqueous solutions.

Automated endoscope reprocessor (AER) refers to machines designed for the purpose of cleaning and disinfecting of endoscopes and accessories. Meticulous manual cleaning must precede the use of AERs (Alvarado, 2000).

Biofilm refers to a matrix of different types of bacteria and exopolysaccharides, secreted from the bacteria and adherent to the interior surfaces of endoscopes (Miner, 2007).

Endoscope refers a tubular instrument used to examine the interior of the hollow viscera (ASTM, 2000). In this document, endoscope refers only to flexible gastrointestinal endoscopes.

Enzymatic detergent refers to low-foaming detergents which add enzymes capable of digesting organic material such as blood and mucous.

High-level disinfectant (HLD) refers to a chemical germicide that has been cleared by the FDA as capable of destroying all viruses, vegetative bacteria, fungi, mycobacterium and some, but not all, bacterial spores (Rutala, 1996).

High-level disinfection (HLD) refers to the destruction of all microorganisms with the exception of high levels of bacterial spores (FDA, 2002, Rutala, 1996).

Material Safety Data Sheet (MSDS) refers to a descriptive sheet that accompanies a chemical or chemical mixture, providing the identity of the material; physical hazards, such as flammability; acute and chronic health hazards associated with contact with or exposure to the compound.

Minimum effective concentration (MEC) refers to the lowest concentration of active ingredient necessary to meet the label claim of a reusable high-level disinfectant/sterilant (AAMI, 2006).

Reprocessing refers to the process of cleaning and disinfecting endoscopes and accessories.

Reuse life refers to a statement by the manufacturer indicating the maximum number of days a reusable high-level disinfectant/sterilant might be effective (AAMI, 2006).

Sterilant refers to a chemical germicide that has been cleared by the FDA as capable of destroying all microorganisms, including all bacterial spores (Rutala, 1996).

Sterile refers to the state of being free from all living organisms.

Sterilization refers to a process that results in the complete elimination or destruction of all forms of microbial life. The Spaulding Classification identifies sterilization as the standard for medical devices that enter the vascular system or sterile tissue, such as biopsy forceps (WHO, 2003, Rutala, 1996).

Surfactant is a substance which has both a hydrophilic group and a hydrophobic group. They are a broad class of molecules that function to bind and lift soil. They may be natural i.e. soap (anionic) or synthetic, derived from petroleum products. Some types of surfactants serve as wetting agents to lower the surface tension of the cleaning solution (Kern, 2007).

Introduction

The field of gastroenterology continues to expand as new instruments, products, and procedures are introduced into the endoscopy arena. While the transmission of infectious organisms during gastrointestinal endoscopy are considered rare, 1 in 1.8 million cases (ASGE, 2001), the need for continued emphasis on infection control issues remain paramount. Failure to adhere to established reprocessing guidelines account for most, if not all, of the reported cases of bacterial and viral transmissions (ASGE, 2001).

Dr. Earl Spaulding developed a classification system to determine what type of disinfection or sterilization is appropriate for medical devises. These 3 classes, critical, semi-critical and non-critical, stratify the risk of infection associated with each device. Critical devices break the mucosal barrier and should be sterilized (e.g. reusable biopsy forceps). Semi-critical devices (e.g. endoscopes) come in contact with mucous membranes or non-intact skin and should be sterilized or receive high level

disinfection. Blood pressure cuffs and stethoscopes come into contact with intact skin and fall into the non-critical category. These items can be cleaned with soap and water or disinfected with a germicide.

Endoscopes are considered semi-critical and should at a minimum receive high level disinfection with a liquid sterilant/disinfectant approved by the FDA (Alvarado, 2000). Complex endoscope design features may allow organic debris and microorganisms to accumulate making manual cleaning essential. Biofilm formation may harbor microorganisms making strict and meticulous adherence to reprocessing guidelines imperative in order to prevent cross-contamination between patients and nosocomial infections (Alvarado, 2000).

The following topics require specific adherence to infection control principles which are based on the current literature and professional standards.

Personnel

Only individuals, who are able to read, understand, and implement instructions on the proper cleaning and high level disinfection of gastrointestinal endoscopes and accessories should be given the responsibility to reprocess such instruments (ASTM, 2000). In addition, these individuals must meet annual competency standards for endoscope reprocessing (Rutala & Weber, 2004). Temporary personnel should *not* be allowed to clean or disinfect instruments in either a manual or an automated reprocessing system (ASTM, 2000).

Education and Training

All staff in any setting where gastrointestinal endoscopy is performed must adhere to infection control principles that will maintain a safe environment, free from the possibility of spreading disease to patients and co-workers. This is true regardless of setting, (hospital, clinic, ambulatory care center and office), relative to any and all types of gastrointestinal (GI) procedures performed.

Flexible endoscope reprocessing has been shown to have a narrow margin of safety. Any slight deviation from recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection (Alfa, 2006).

Infection control education is a critical part of the orientation and continuing education for all personnel, including physicians, nurses, and assistive personnel who work in the gastrointestinal endoscopy setting. According to ASTM (2000) and Occupational Safety and Health Administration (OSHA) Law 29 CRF part 1910, components of this education program should cover the following topics:

1. Standard precautions
2. Personal protective equipment
3. OSHA rules on occupational exposure to blood-borne pathogens;
4. Reprocessing procedures for endoscopes and accessory equipment;
5. Mechanisms of disease transmission;
6. Maintenance of a safe work environment;
7. Safe handling of high level disinfectants (HLD) and sterilants; and
8. Procedures for waste management.

Additional training with documented competency must be completed for new models of endoscopes or automatic endoscope reprocessors as they are introduced in the facility. Annual updates are recommended to ensure compliance with current standards and manufacturers' guidelines (Rutala & Weber, 2004).
Decisions must be made in each endoscopy setting regarding the number and category

of personnel who will be responsible for instrument reprocessing. All persons involved must be properly trained and their performance subject to periodic review and continuing education. All individuals who reprocess endoscopes and accessories require detailed knowledge of the instruments and the specific methods required to produce an instrument safe for use. This knowledge is developed through repetition and the guidance of a preceptor. Each individual who reprocesses instruments should complete the initial infection control orientation/reprocessing competency and subsequent annual competency review and infection control updates, and documentation should accompany each (ASTM, 2000, Nelson et al, 2003).

Quality Assurance

Quality assurance is of the highest priority in settings where gastrointestinal endoscopy is performed. Such settings must have an effective quality assurance program with special emphasis on cleaning and high level disinfection of flexible endoscopes. Elements of the quality assurance program include supervision, training, annual competency review, methods of assuring the availability of appropriate equipment and supplies, and procedures for reporting infections (ASTM, 2000; Rutala & Weber, 2004).

Supervisory personnel must be familiar with the principles and practices of instrument reprocessing if they are to properly train and monitor staff. Knowledgeable supervisors also serve to impress upon peer groups and subordinates the importance of these functions.

There must be a policy of invariable adherence to the reprocessing protocol. The protocol should be reviewed according to institutional policy to ensure that it is being followed routinely and that there is no new information that would require a modification. Modifications should be made with care. Consultation with an infection control advisor should be considered when modifications to the reprocessing protocol are made. The review process and protocol modifications should be documented.

An individual in the endoscopy setting should be designated and assigned to monitor compliance with the reprocessing protocol (SGNA, 2007). The understanding and performance of each individual involved in reprocessing should be reviewed at least annually (Rutala & Weber, 2004; SGNA, 2007).

Staff should monitor reusable HLDs and sterilants for minimum effective concentrations according to the label on the test strips and maintain a log of results (SGNA, 2000). HLDs and sterilants must be changed when the solutions fail to meet minimum effective concentration or exceed the HLD manufacturer's recommended reuse life, whichever comes first (ASGE, 2001; Nelson et. al., 2003).

According to the Department of Employment, Training and Industrial Relations (1999) high-level disinfectant and sterilant vapor levels should be monitored and documented when:

1. a change in the disinfection phase of the reprocessing protocol occurs;
2. a different high-level disinfectant or sterilant is used; or
3. a staff member exhibits symptoms of overexposure.

For details, refer to SGNA's *Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* (SGNA, 2007).
A preventive maintenance plan should be in place for all automated reprocessors. Quality controls recommended by manufacturers of automated endoscope reprocessors

(AER) should be adhered to and documented.

As part of a quality control program, documentation may include but is not limited to the following (Nelson et al., 2003; Muscarella, 2001):

1. the procedure date and time;
2. the patient's name and medical record number;
3. the endoscopist;
4. the endoscope's model and serial number or other identifier;
5. the AER (if used) model and serial number or other identifier; and
6. the staff member(s) reprocessing the endoscope.

Report any suspected or identified infections to those responsible for infection control in the endoscopy setting. Performing routine cultures of endoscopes is not currently recommended, but may be done in the event of an identified outbreak (Nelson et al., 2003).

Procedure Rooms

To prevent cross-contamination in an endoscopic procedure room, most areas of the room should be designated as clean areas. Contaminated areas where accessories and specimens are handled should be separated from clean counter areas. All contaminated areas must be cleaned and decontaminated between patients with an Environmental Protection Agency (EPA)-registered, hospital-grade disinfectant (Rey, et al, 2005).

When endoscopy is performed on patients with known or suspected tuberculosis, rooms with air circulated through high-efficiency particulate air (HEPA) filters, also known as negative pressure rooms, are recommended (CDC, 2000).

Biofilms

Biofilm, a matrix of different types of bacteria and exopolysaccharides, secreted from the bacteria and adherent to the interior surfaces of endoscopes are generally considered as one on the many causes of cleaning and disinfectant failure (Miner, 2007). Biofilms develop inside endoscope channels even when valid endoscope reprocessing protocols are applied. A scratched or damaged channel surface could better allow adhesion of bacteria to the surface or protect bacteria from disinfectants.

Biofilms represent not only a reservoir of pathogenic bacteria that can detach and contaminate the patient but also are a source of endotoxins that may enter the circulation (Bisset, 2006). The use of an efficient biocide is not sufficient if channels are not cleaned thoroughly prior to disinfection (Marion, 2006). Prompt efficient cleaning processes are the best defense against biofilm formation.

Reprocessing Room

Reprocessing of contaminated patient equipment should be done in an area designated and dedicated for this function. This should be a room separate from where endoscopic procedures are performed (Alvarado & Reicheldelfer, 2000). Current local and state codes and federal guidelines should be incorporated in the design of any reprocessing area. Considerations include adequate space for reprocessing activities, proper airflow and ventilation requirements, work flow patterns, work surfaces, lighting, adequate utilities such as electrical support and water, hand washing and eye washing facilities, air drying capability, and storage.

Tap water and/or water that has been filtered by passage through a 0.2 micron filter or

water of equivalent quality (i.e., suitable for drinking) should be available in the reprocessing area (Rutala & Weber, 2004). Bottled sterile water may be used.

Reagents needed for manual cleaning include one or more of the following:

- a medical grade low-foaming, neutral pH detergent
- a specially formulated bacteriocidal endoscope detergent designed specifically to detach and destroy biofilm
- an enzymatic detergent formulated for endoscopes
- a detergent formulated to remove synthetic lipids

Enzyme detergents require a specified contact time to be effective and are not bacteriocidal. Bacteriocidal detergents are designed to penetrate, detach and disrupt protective biofilm colonies. This capacity to kill microorganisms and to clean patient soil from endoscopes would also provide protection for health care workers (Alfa, 2001, Marion, et al, 2006).

A Food and Drug Administration (FDA) cleared high-level disinfectant or sterilant, and 70% isopropyl alcohol is needed in the reprocessing room for high level disinfection. An EPA-registered hospital-grade disinfectant should be used for surface cleaning (ASTM, 2000).

High-Level Disinfectant or Sterilant Spill Containment Plan

Each endoscopy setting should have a spill containment plan specific for the high-level disinfectant or sterilant used.

The information from the specific Material Safety Data Sheet should be incorporated into the plan. The plan should include written procedures for actions to contain the spill and deactivate the chemical, an intra- and inter-departmental communication plan, and an evacuation plan. Upon assignment to the department and annually thereafter, all persons working in the setting must be trained in the safe handling of high-level disinfectants or sterilants, and spill containment procedures. Refer to the manufacturer's instructions for information on the specific solution.

Accessories

The FDA requires manufacturers of reusable devices to provide instructions for cleaning and high-level disinfection or sterilization (Nelson et al., 2003). Refer to the manufacturer's guidelines for specifics on reprocessing of endoscopic accessories. Accessories which are classified as critical devices (those which break the mucus membrane and/or come into contact with sterile tissue or the vascular system) require sterilization. Critical items labeled for single-use should not be reprocessed and/or reused (Rutala, 1996; SGNA, 2005).

Infection Control Principles

Every patient must be considered a potential source of infection and all endoscopes must be decontaminated with the same degree of rigor following every endoscopic procedure. Infection control measures which can disrupt the chain of infection include (Rey et al, 2005):

1. Disinfection and sterilization of medical equipment
2. Proper use of personal protective equipment
3. Personal hygiene
4. Engineering controls (ventilation, room design, water supply)

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5. Cleaning and disinfection of environmental surfaces
6. Adequate administrative monitoring and support
7. Training and continuing education
8. Adequate written protocols

Endoscope Reprocessing Protocol

The reprocessing protocol presented here outlines basic steps to clean and perform high-level disinfection of gastrointestinal endoscopes. Endoscope manufacturers' instructions should always be consulted for design features unique to a particular instrument, which may require specific reprocessing detail (SGNA, 2007).

While the following protocol specifically addresses gastrointestinal endoscopes, its steps may be applied to reprocessing other types of flexible endoscopes (ASTM, 2000; Nelson et al., 2003).

Guidelines for endoscope reprocessing prescribe the following six steps (Rey et al, 2005, SGNA, 2007):

1. cleaning
2. rinsing
3. disinfection
4. rinsing
5. drying
6. storage

A. PREPARING THE ENDOSCOPE FOR CLEANING

The initial steps in the reprocessing protocol begin in the patient room immediately after removal of the insertion tube from the patient and prior to disconnecting the endoscope from the power source.

1. Have the following available:
    a. personal protective equipment (gloves, eye protection, impervious gown, face shield or simple surgical mask that will not trap vapors);
    b. container with detergent solution;
    c. sponge or soft, lint-free cloth;
    d. air and water channel cleaning adapters per manufacturer's instruction; and
    e. protective video caps (if using video endoscopes).

2. Immediately after removing the endoscope from the patient, wipe the insertion tube with the wet cloth or sponge soaked in the freshly prepared detergent solution. Note that the cloth/sponge should be disposed of, sterilized, or high-level disinfected between cases (Rutala & Weber, 2004).

3. Place the distal end of the endoscope into the detergent solution. Suction the solution through the biopsy/suction channel, alternate suctioning detergent solution and air several times until the solution is visibly clean. Finish by suctioning air. Note that:
    a. Alternate suctioning of fluid and air is more effective than suctioning fluid alone in the removal of debris from internal lumens.
    b. 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.

4. Flush or blow out air and water channels in accordance with the endoscope manufacturer's instructions.

5. Detach the endoscope from the light source and suction pump.

6. Attach protective video cap (if using video endoscope).

7. Transport the endoscope to the reprocessing area in an enclosed container. Note that:

a. Containers, sinks, and basins should be large enough that the endoscope will not be damaged by being coiled too tightly.
b. A container will prevent contamination during transport.
c. Reprocessing should occur in a room separate from the procedure room.

B. CLEANING THE ENDOSCOPE IN THE REPROCESSING AREA

1. Have the following available:
a. personal protective equipment (gloves, eye protection, impervious gown, face shield or simple surgical mask that will not trap vapors);
b. leak-testing equipment;
c. channel cleaning adapters (per manufacturer's instructions);
d. large basin of endoscope detergent solution prepared according to manufacturer's instructions;
e. channel cleaning brushes; and
f. sponge and/or lint-free cloth.

C. LEAK TESTING

Leak testing detects damage to the interior or exterior of the endoscope. The leak test is done before immersion of the endoscope in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure. Leak test the endoscope following manufacturer's instructions.

1. Manual leak testing

a) Remove suction valves, air water valves, and biopsy valves

b) 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.

c) 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.

2. Computerized leak testing

a) Remove suction valves, air water valves, and biopsy valves.
b) Attach the leak tester to the computer
c) Input data including scope ID, and user
d) Move knobs and depress the freeze and release buttons when indicated
e) Reprocess when test is complete

3. Follow the endoscope manufacturer's instructions if a leak or high humidity is detected or if the endoscope appears damaged.

D. CLEANING SOLUTIONS

The composition of soil found on endoscopes includes, proteins, fats, carbohydrates and the various chemical salts that exist in blood and other body fluids. Ideally, a cleaning solution should have a broad spectrum of effectiveness against these various contaminants and not harm the device being cleaned. 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 (Kern, 2001).

Enzymatic cleaning solutions use surfactants 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 rinsability. Specific product labeling will define the time required for this enzyme activity to take place and must be incorporated into the cleaning process.

Comparatively, anionic detergents rely solely on mechanical action for removal of bioburden.

E. CLEANING

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. Retained debris may inactivate or interfere with the capability of the active ingredient of the chemical solution to effectively kill and/or inactivate microorganisms.

1. Fill a sink or basin with freshly-made solution of water and one or more of the following:

- a medical grade low-foaming, neutral pH detergent
- a specially formulated bacteriocidal endoscope detergent designed specifically to detach and destroy biofilm
- an enzymatic detergent formulated for endoscopes
- a detergent formulated to remove synthetic lipids

2. Dilute and use according to the detergent manufacturer's instructions. Note that:
   a. Fresh detergent solution should be used for each endoscope to prevent cross-contamination.
   b. Low-foaming detergents are recommended such that the device can be clearly visualized during the cleaning process to preclude personnel injury and to allow for complete cleaning of lumen surfaces. Excessive foaming can inhibit good fluid contact with the device surfaces.

3. Immerse the endoscope.

4. 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.

5. Detach the suction and air/water valves, the biopsy channel cover, the distal end hood, if present, and all other removable parts. Discard those parts that are designated as disposable. Note that the endoscope must be completely disassembled so that all surfaces may be reached for thorough cleaning.

6. 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.

7. Brush all accessible endoscope channels including the body, insertion tube and the umbilicus of the endoscope. Use a brush size compatible with each channel.

8. After each passage, rinse the brush in the detergent solution, removing any visible debris before retracting and reinserting it.

9. Continue brushing until there is no debris visible on the brush.

10. Clean and high-level disinfect reusable brushes between cases. Note that reusable brushes should be inspected between uses and replaced when worn, frayed, bent, or otherwise damaged. Worn bristles are ineffective in cleaning, and damaged brushes may damage endoscope channels.

11. 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.

12. Attach the manufacturer's cleaning adapters for special endoscope channels (e.g., elevator channel, auxillary channel and double-channel scopes).

a. To achieve adequate flow through all lumens, various adapters or channel restrictors may be required. Refer to the manufacturer's instructions.

Because the elevator channel of a duodenoscope is a small lumen, force greater than can be generated by an automated reprocessor is needed to force fluid through it. This channel requires manual reprocessing (all steps) using a 2- to 5-milliliter syringe (Rutala & Weber, 2004). Although the elevator channel of these scopes has channel adapters that may be made to fit reprocessors, this channel must be manually reprocessed.

13. Flush all channels with the detergent solution to remove debris.

14. Soak the endoscope and its internal channels for the period of time specified by the label, if using an enzymatic detergent.
Note: If, due to time constraints, it is not possible to complete the reprocessing immediately, the endoscope should be leak-tested, flushed, brushed, and allowed to soak in a detergent solution until it can be thoroughly reprocessed. Follow manufacturer's recommendations for the maximum liquid exposure time (ASTM, 2000, Olympus Reprocessing Manual).

F. RINSE AFTER CLEANING

1. Thoroughly rinse the endoscope and all removable parts with clean water to

remove residual debris and detergent.

2. Purge water from all channels using forced air. Dry the exterior of the endoscope with a soft, lint-free cloth to prevent dilution of the liquid chemical germicide used in subsequent steps.

G. HIGH LEVEL DISINFECTION

High level disinfection (HLD) is recognized as the standard for reprocessing of gastrointestinal endoscopes by SGNA, the American Society for Gastrointestinal Endoscopy (ASGE), the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), the Association for Professionals in Infection Control and Epidemiology (APIC), and ASTM. Agencies such as the Centers for Disease Control and Prevention (CDC) and The Joint Commission (JC) recognize HLD as appropriate for gastrointestinal endoscopes. The only circumstance where sterilization of the endoscope is required is when it is used in a sterile, operative field.

HLD destroys all vegetative microorganisms but not necessarily all bacterial spores (Rutala, 1996). The high-level disinfectant or sterilant used should be prepared in accordance with manufacturer's directions. Because most high-level disinfectants/sterilants are typically reused, they must be tested to assure that they remain above their minimum effective concentration [MEC] (Rutala & Weber, 1995). Refer to the *Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* (SGNA, 2007) for additional information on this topic.

Follow disinfectant/sterilant manufacturer's recommendations to achieve high-level disinfection of endoscopes.

However, in cases where non-surfactant 2% glutaraldehyde products are used, multiple scientific studies and professional organizations support the following position: after meticulous cleaning, high-level disinfection is achievable with a 20-minute soak at room temperature using a 2% glutaraldehyde solution that tests above its MEC (SGNA, 2007, Nelson et al., 2003).

To use high-level disinfectants and sterilants:

1. Prepare the product according to disinfectant/sterilant manufacturer's label instructions.

2. Test the product for the MEC according to the label on the test strip container. Note that:

a. 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 (Rutala, 1996, AAMI, 2006).
b. In each facility, a quality study is recommended to assist in determining guidelines for your particular circumstances (Rutala & Weber, 1995).

3. The MEC may never be used to extend the reuse life claim of the product. The MEC may never be used beyond the date specified on activation (Rutala & Weber, 1995).

4. Use a product-specific test strip, and keep a log of the test results (ASGE, 2001).

H. MANUAL DISINFECTION

1. Completely immerse the endoscope and all removable parts in a basin of high-level disinfectant/sterilant.
    a. 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 (ASGE, 2001).
    b. To prevent damage to the endoscope, the endoscope should not be soaked with other sharp instruments that could potentially damage the endoscope.

2. 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. Note that:
    a. Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical (ASGE, 2001).
    b. Since internal contact cannot be visually confirmed because of scope design, purging until a steady flow of solution observed is necessary.

3. Cover the soaking basin with a tight-fitting lid to minimize chemical vapor exposure. Note that:
    a. Exposure to chemical vapors may present a health hazard.
    b. The reprocessing area should have engineering controls to ensure good air quality.

4. Soak the endoscope in the high-level disinfectant/sterilant for the time/temperature required to achieve HLD. Use a timer to verify soaking time.

5. Purge all channels completely with air before removing the endoscope from the high-level disinfectant/sterilant. Note that purging the channels preserves the concentration and volume of the chemical, and prevents exposure from dripping and spilling.

I. RINSE AFTER MANUAL DISINFECTION

1. Thoroughly rinse all surfaces and removable parts, and flush all channels of the endoscope and its removable parts with clean water according to disinfectant and endoscope manufacturer's recommendations. Note that:
    a. Rinsing prevents exposure and potential injury of skin and mucous membranes from chemical residue.
    b. Fresh clean water should be used for each rinse of the endoscope.

J. DRYING

1. Purge all channels with air until dry. Note that:
    a. Bacteria such as *Pseudomonas aeruginosa* have been identified in both tap and filtered water, and may multiply in a moist environment (Rutala & Weber, 2004).
    b. Avoid the use of excessively high air pressure which can damage the internal channels of flexible endoscopes.

2. Flush all channels, including accessory channels, with alcohol until the alcohol can be seen exiting the opposite end of each channel.

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a. 70% isopropyl alcohol is used to assist in drying the interior channel surfaces.
b. Use alcohol that has been properly stored in a closed container between uses. Alcohol, when exposed to air, rapidly evaporates, and if below the recommended percentage level, cannot be relied upon to assist in the drying process.
c. Alcohol flushes should be used even when sterile water is used for rinsing.

3. Purge all channels with air. Note 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.

4. Remove all channel adapters.

5. Dry the exterior of the endoscope with a soft, clean lint-free towel.

6. Thoroughly rinse and dry all removable parts. Do not attach removable parts (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.
   Note that drying the endoscope after every reprocessing cycle, both between patient procedures and before storage is a requisite practice crucial to the prevention of bacterial transmission and nosocomial infection. Drying is as important to the prevention of disease transmission and nosocomial infection as cleaning and high level disinfection (Muscarella, 2006, Alvarado &Reicheldelfer, 2000).

K. STORAGE

1. Hang the endoscope vertically with the distal tip hanging freely in a well-ventilated, dust-free area.

a. 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.
b. 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.

L. AUTOMATED REPROCESSING

Endoscope reprocessors standardize the disinfection process and decrease personnel exposure to high-level disinfectants and sterilants (Rutala & Weber, 2004). It is necessary to follow all steps for the manual cleaning of the endoscope prior to using an automated reprocessor (Rutala, 1996). No independent confirmatory data is 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).
An automated endoscope reprocessor should have the following features (SGNA, 2007*):*

a. 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.

b. The detergent and disinfectant cycles should be followed by thorough rinse cycles and forced air to remove all used solutions.
c. The disinfectant should not be diluted with any fluids.
d. The machine should be self-disinfecting.
e. No residual water should remain in hoses and reservoirs.
f. Cycles for alcohol flushing and forced air drying are desirable.
g. The machine should also feature a self-contained or external water filtration system.

In addition, a method to automatically store or print data verification of cycle completion is desirable.

To use an automated reprocessor:

1. Follow steps for manual cleaning of the endoscope.

2. Prepare the endoscope reprocessor according to manufacturer's guidelines.

3. Place the endoscope in the reprocessor and attach all channel adapters according to manufacturer's instructions.

a. The elevator channel of a duodenoscope has a very small lumen. Since most automated reprocessors cannot generate the pressure required to force fluid through the lumen, a 2-5 ml syringe must be used to manually reprocess (all steps) the elevator channel (Rutala & Weber, 2004) unless the AER is validated to perfuse this channel.

b. Users should check with their endoscope manufacturer for model-specific information.

4. 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.

5. 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.

6. Set the machine for the appropriate time and temperature depending on the chemical used.
7. 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.

8. 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 (FDA, 2002). The ERCP elevator channel must be manually perfused and dried.

9. Drying and storage procedures are the same as described in manual disinfection section.

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