American Journal of Infection Control 41 (2013) S60-S66

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Original research article

New developments in reprocessing semicritical items

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Key Words:
High-level disinfection
Endoscopy
Bronchoscope
Health care-associated infection

Semicritical medical devices are defined as items that come into contact with mucous membranes or nonintact skin (eg, gastrointestinal endoscopes). Such medical devices require minimally high-level disinfection. Because many of these items are temperature sensitive, low-temperature chemical methods must be used rather than steam sterilization. Strict adherence to current guidelines is required because more outbreaks have been linked to inadequately cleaned or disinfected endoscopes undergoing high-level disinfection than any other medical device.

All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic microbes leading to infection. Failure to properly disinfect or sterilize reusable medical equipment carries a risk associated with breach of the host barriers.

Multiple studies in many countries have documented a lack of compliance with established guidelines for disinfection and sterilization; however, most infections associated with reprocessing medical or surgical instruments involve high-level disinfection (HLD) of semicritical items.[1-7] In this expanded and updated version of a previous paper on this subject, we will examine new technologies and issues for HLD of semicritical items. Because semicritical items carry the greatest risk of infection, we also will discuss reprocessing semicritical items such as endoscopes (and automated endoscope reprocessors [AERs]), nasopharyngoscopes, endocavitary probes, prostate biopsy probes, tonometers, laryngoscopes, infrared coagulation devices, and urologic instruments.[8,9]

A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

Over 45 years ago, Earle H. Spaulding[10] devised a rational approach to disinfection and sterilization of patient care items or equipment. This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization.[11-17] Spaulding believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into 3 categories based on the degree of risk of infection involved in the use of the items. The 3 categories he described were critical (enters sterile tissue and must be sterile), semicritical (contact mucous membranes and requires HLD), and noncritical (comes in contact with intact skin and requires low-level disinfection). Although the scheme remains valid, there are some examples of disinfection studies with viruses, mycobacteria, and protozoa that challenge the current definitions and expectations of high- and low-level disinfection.[18]

Semicritical items

Semicritical items are those that come in contact with mucous membranes or nonintact skin. Respiratory therapy and anesthesia equipment, gastrointestinal endoscopes, bronchoscopes, laryngoscopes, esophageal manometry probes, anorectal manometry catheters, endocavitary probes, prostate biopsy probes, infrared coagulation devices, nasopharyngoscopes, cystoscopes, and diaphragm fitting rings are included in this category. These medical devices should be free of all microorganisms (ie, mycobacteria, fungi, viruses, bacteria), although small numbers of bacterial spores may be present. Intact mucous membranes, such as those of the lungs or the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms such as bacteria, mycobacteria, and viruses. Semicritical items minimally require HLD using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde (OPA), peracetic

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Publication of this article was supported by Advanced Sterilization Products (ASP).

Conflicts of interest: W.A.R. provides consultation to Advanced Sterilization Products and Clorox, and D.J.W. provides consultative service to Clorox.

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http://dx.doi.org/10.1016/j.ajic.2012.09.028

acid with hydrogen peroxide, and chlorine are cleared by the Food and Drug Administration (FDA)[19] and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met. The exposure time for most high-level disinfectants varies from 8 to 45 minutes at 20°C to 25°C. When a disinfectant is selected for use with certain patient care items, the chemical compatibility after extended use with the items to be disinfected also must be considered.

Semicritical items that will have contact with mucous membranes should be rinsed with sterile water, filtered water, or tap water followed by an alcohol rinse.[16,20] An alcohol rinse and forced air-drying markedly reduces the likelihood of contamination of the instrument (eg, endoscope), most likely by removing the wet environment favorable for bacterial growth.[21] After rinsing, items should be dried and stored in a manner that protects them from damage or contamination. Drying also retards biofilm formation.[22]

Semicritical items represent the greatest risk of disease transmission as far more health care associated infections have been caused by semicritical items than critical or noncritical items.[16] There is virtually no documented risk of transmitting infectious agents to patients via noncritical items[23] when they are used as noncritical items and do not contact nonintact skin and/or mucous membranes. Critical items have a high risk of infection if such an item is contaminated with any microorganism; however, sterilization cycles that are designed for hospitals are usually based on the over-kill approach. The time required for a 6-$\log_{10}$ reduction of highly resistant spores by the process is considered a half-cycle, and the full-cycle exposure time is the time for the half-cycle doubled. Thus, a sterilization processes can achieve a 12-$\log_{10}$ reduction of highly resistant spores while medical/surgical devices are contaminated with low numbers of microorganisms (85% of instruments $<$100 bacteria) after use in surgery.[24] This results in a huge margin of safety and a sterility assurance level of 10^{-6}, which means there is less than 1 chance in 1 million that a contaminant will survive on a medical product after the sterilization process.[16] In contrast, semicritical items (eg, gastrointestinal endoscopes), by virtue of the body cavities they enter, may be contaminated with 1 billion bacteria.[25] A further complication is that many of these devices are constructed in such a way that makes cleaning them very difficult (eg, long, narrow lumens) before the HLD procedure. Thus, the result is a device with a sterility assurance level of 10^{0} to 10^{-3}, which means there is a greater chance that a contaminant will survive on a medical device after the HLD procedure than after sterilization (ie, greater than 1 in 1,000 chance that a contaminant will survive).[26] Thus, reprocessing semicritical items has a narrower margin of safety, and any deviation from the reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection.

Reprocessing semicritical items

Reprocessing of endoscopes

Physicians use endoscopes to diagnose and treat numerous medical disorders. Whereas endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with use has been reported as very low (about 1 in 1.8 million procedures),[27] more health care-associated outbreaks have been linked to contaminated endoscopes than to any other medical device.[1-3,7,28-30] To prevent the spread of health care-associated infections, all heat-sensitive endoscopes (eg, gastrointestinal endoscopes, bronchoscopes, nasopharygoscopes) must be properly cleaned and at a minimum subjected to HLD following each use. HLD can be expected to destroy all microorganisms, although when high numbers of bacterial spores are present, a few spores may survive.

Flexible endoscopes, by virtue of the types of body cavities they enter, acquire high levels of microbial contamination (bioburden) during each use.[31] For example, the bioburden found on flexible gastrointestinal endoscopes following use has ranged from 10^5 colony-forming units (CFU)/mL to 10^{10} CFU/mL, with the highest levels being found in the suction channels.[31-34] The average load on bronchoscopes before cleaning was 6.4×10^4 CFU/mL. Cleaning reduces the level of microbial contamination by 4 to 6 $\log_{10}$.[35,36] Using HIV-contaminated endoscopes, several investigators have shown that cleaning completely eliminates the microbial contamination on the scopes.[37,38] Similarly, other investigators found that ethylene oxide (ETO) sterilization or HLD (soaking in 2% glutaraldehyde for 20 minutes) was effective only when the device was first properly cleaned.[39] Three products that are commonly used for reprocessing endoscopes in the United States are orthophthalaldehyde, glutaraldehyde, and an automated process that uses peracetic acid.[40]

Recommendations for the cleaning and disinfection of endoscopic equipment have been published and should be strictly followed.[20,29,41-44] Unfortunately, recent audits have shown that personnel do not consistently adhere to guidelines on reprocessing[45] and that outbreaks of infection continue to occur.[46] To ensure that reprocessing personnel are properly trained, there should be initial and annual competency testing for each individual who reprocesses endoscopic instruments.[47,48]

In general, endoscope disinfection or sterilization with a liquid chemical sterilant involves 5 steps after leak testing: (1) clean: mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion); (2) disinfect: immerse endoscope in high-level disinfectant (or chemical sterilant) and perfuse (eliminates air pockets and ensures contact of the germicide with the internal channels) disinfectant into all accessible channels such as the suction/biopsy channel and air/water channel and expose for a time recommended for specific products; (3) rinse: rinse the endoscope and all channels with sterile water, filtered water (commonly used with AERs), or tap water (ie, high-quality potable water that meets federal clean water standards at the point of use); (4) dry: rinse the insertion tube and inner channels with alcohol and dry with forced air after disinfection and before storage; and (5) store: store the endoscope in a way that prevents recontamination and promotes drying (eg, hung vertically).

In the past several years, much of the new literature associated with endoscope reprocessing involves nonendoscopic transmission of infection (eg, unsafe injection practices) and several unresolved issues requiring further study.[20] First, there have been several outbreaks in endoscopy centers related to improper handling of intravenous sedation tubing, multidose and/or single dose vials, and/or reuse of needles or syringes.[49,50] Second, there remains no consensus on the value of microbiologic monitoring of endoscopes; some investigators have suggested it is too time-consuming and costly and process controls are preferable,[51] whereas others believe that bacterial surveillance should be part of a quality assurance program.[42,52] Reprocessed endoscopes should be free of microbial pathogens except for small numbers of relatively avirulent microbes that represent exogenous environmental contamination (eg, coagulase-negative *Staphylococcus*, *Bacillus* species, diphtheroids). One investigator recently suggested a bioburden benchmark in reprocessed endoscope channels of $<$100 CFU/mL.[53] Third, whether endoscopes need to be reprocessed immediately before use continues to be debatable. Based on studies that have assessed the microbiologic stability of endoscopes after HLD, it appears that reprocessing after storage for a week or 2 weeks is unnecessary.[54-56] Fourth, reduced susceptibility of *Pseudomonas*

aeruginosa to glutaraldehyde[57] and tolerance of mycobacteria to glutaraldehyde disinfectants leading to disinfectant failure and infections have been reported.[58] Fifth, audit tools to monitor the adequacy of cleaning are being developed for endoscopes and other instruments. One rapid test strip assesses the level of residual protein, hemoglobin, and carbohydrates within the channels of flexible endoscopes that have been manually cleaned.[59] Another method uses an adenosine triphosphate (ATP) bioluminescence test for use in monitoring proper endoscope cleaning.[60] Whereas these tests have been validated as measures of a specific chemical[59] or levels of organic soil and cleanliness,[60] there are no studies correlating these parameters with microbial contamination[60] or a risk for endoscope-associated infection. Thus, there are no clinical interpretations associated with these data (eg, increased infection risk associated with increased ATP or protein).

There also has been an introduction of new technologies such as high-level disinfectants (such as improved hydrogen peroxide)[19] and improved AERs. A variety of capabilities has been incorporated into the available AERs, and these capabilities have been summarized.[61] All models have disinfection and rinsing cycles, and some have detergent cleaning, alcohol flush, and/or extended forced air-drying cycles. Additional features may include the following: variable cycle times; printed documentation of the process; low-intensity ultrasound waves; high-level disinfectant vapor recovery systems; heating to optimize the high-level disinfectants efficacy; a variable number of endoscopes processed per cycle; automated leak testing; automated detection of channel obstructions; and table top, floor standing, and cart-mounted models.[61] Not all reprocessors are compatible with all high-level disinfectants or with endoscopes from all manufacturers. One newer AER integrates cleaning and has achieved an FDA-cleared cleaning claim (EVOTECH®, Advanced Sterilization Products, Irvine, CA).[62] The users must continue to do the "bedside" cleaning (wipe external surfaces and flush each lumen with a detergent solution) and then place the scope directly (within 1 hour) into the EvoTech machine. This eliminates the labor-intensive manual cleaning, and one report shows EvoTech as less costly than manual cleaning followed by AER disinfection.[63] EvoTech also automatically detects leaks, alcohol is flushed through the channels prior to cycle completion to promote drying, and the AER integrates minimum effective concentration monitoring. In addition, the printer provides complete monitoring of critical cycle parameters including minimum effective concentration of the high-level disinfectant (ortho-phthalaldehyde), disinfection time, channel blockage detection, temperature, pressure, and time to ensure compliance throughout the process. Manufacturer's residual data for cleaning of the internal channels as well as external insertion tube surfaces were below the limit of <6.4 μg/cm^2 for protein and <1.8 μg/cm^2 for lipid.

Infection preventionists should ensure that institutional policies are consistent with national guidelines and conduct infection control rounds periodically (eg, at least annually) in areas where endoscopes are reprocessed to make certain there is compliance with policy. Breaches in policy should be documented and corrective action instituted. In incidents in which endoscopes were not exposed to a HLD process, patients were assessed for possible acquisition of HIV, hepatitis B virus, and hepatitis C virus. A 14-step method for managing a failure incident associated with HLD or sterilization has been described.[64] The possible transmission of bloodborne pathogens and other infectious agents highlights the importance of rigorous infection control.[65,66]

Nasopharyngoscopes

Flexible nasopharyngoscopes are a valuable tool enabling easy visualization of the upper aerodigestive tract. Three techniques are available to reprocess nasopharyngoscopes: manual HLD, use of an AER, and use of a disposable sheath.[16,67,68] However, because sheaths/condoms/covers may have tears or breaks that compromise their integrity, there was hesitation to allow the use of a sheath to alter the recommendation of HLD. There are now 2 peer-reviewed publications that validate the integrity of the sheath.

One study showed that the use of a high-quality, snugly fitting, sterile, disposable polyurethane sheath on flexible nasopharyngoscopes (FNLPs) during a clinical examination, combined with enzymatic detergent cleaning and disinfection with 70% ethanol, provided a reliably decontaminated, patient-ready instrument that eliminated the need for HLD of nasopharyngoscopes.[69] Another study found that the contamination rate on nasopharyngolaryngoscopes (FNLP) with the sheath alone was similar to the contamination rate with the high-level disinfected scope. The authors concluded that using the individually packaged disposable sterile sheath of a FNLP prevented microbes from adhering to the shaft of the scope, thus providing a safe method of avoiding the transmission of infection from one patient to the next patient when using a FNLP successively in multiple patients in an otolaryngology clinic.[70] Because we now have 2 studies[69,70] that corroborate the integrity of the sterile polyurethane sheaths used with nasopharyngoscopes, this practice (use of a high-quality, snugly fitting, sterile, disposable sheath on a nasopharynoscope during a clinical examination, combined with enzymatic detergent cleaning and disinfection with 70% ethanol) can provide a reliably decontaminated, patient-ready instrument and may be an option to HLD. Thus, we believe that, with this specific sheath and this device (ie, nasopharyngoscope), this practice of using this sheath plus cleaning plus alcohol may be an option to HLD.

Tonometers

Disinfection strategies for other semicritical items (eg, applanation tonometers, rectal/vaginal probes, cryosurgical instruments, and diaphragm fitting rings) are highly variable. Currently, the FDA requests that the device manufacturer include at least one validated cleaning and disinfection/sterilization protocol in the labeling for their device. As with all medications and devices, users should be familiar with the label instructions. In view of the potential for transmission of viruses (eg, herpes simplex virus, adenovirus type 8, or HIV)[71] by tonometer tips, the Centers for Disease Control and Prevention (CDC) recommended[72] that the tonometer tips be wiped clean and disinfected for 5 to 10 minutes with either 3% hydrogen peroxide, 5,000 ppm chlorine, 70% ethyl alcohol, or 70% isopropyl alcohol. However, more recent data suggest that 3% hydrogen peroxide and 70% isopropyl alcohol are not effective against adenovirus capable of causing epidemic keratoconjunctivitis and similar viruses and should not be used for disinfecting applanation tonometers.[73-75] For this reason, the CDC guideline now recommends to wipe clean tonometer tips and then disinfect them by immersing for 5 to 10 minutes in either 5,000 ppm chlorine or 70% ethyl alcohol.[16,72-76] Structural damage to Schiotz tonometers has been observed with a 1:10 sodium hypochlorite (5,000 ppm chlorine) and 3% hydrogen peroxide.[77] After disinfection, the tonometer should be thoroughly rinsed in tap water and air-dried before use. We believe that wiping the tonometer tips with a 70% isopropyl alcohol wipe is insufficient because 2 reports have found that disinfection of pneumotonometer tips between uses with a 70% isopropyl alcohol wipe contributed to outbreaks of epidemic keratoconjunctivitis caused by adenovirus type 8.[78,79]

Endocavitary probes

Vaginal probes are used in sonographic scanning. A vaginal probe and all endocavitary probes without a probe cover are semicritical devices because they have direct contact with mucous

membranes (eg, vagina, rectum, pharynx). Whereas one could argue that the use of the probe cover changes the category, the CDC guideline proposes that a new condom/probe cover should be used to cover the probe for each patient; and, because condoms/probe covers may fail,[80-84] HLD of the probe also should be performed.[16] The relevance of this recommendation is reinforced with the findings that sterile transvaginal ultrasound probe covers have a very high rate of perforations even before use (0%, 25%, and 65% perforations from 3 suppliers, respectively).[83] After oocyte retrieval use, Hignett and Claman found a very high rate of perforations in used endovaginal probe covers from 2 suppliers (75% and 81%, respectively),[83] whereas Amis et al[85] and Milki and Fisch[80] demonstrated a lower rate of perforations after use of condoms (0.9% and 2.0%, respectively). Rooks et al found that condoms were superior to commercially available probe covers for covering the ultrasound probe (1.7% for condoms vs 8.3% leakage for probe covers).[86] These studies underscore the need for routine probe HLD between examinations. Although most ultrasound manufacturers recommend the use of 2% glutaraldehyde for HLD of contaminated transvaginal transducers, the use of this agent has been questioned[87] because it may shorten the life of the transducer and may have toxic effects on the gametes and embryos.[88] An alternative procedure for disinfecting the vaginal transducer has been offered by Garland and deCrespigny.[89] It involves the mechanical removal of the gel from the transducer, cleaning the transducer in soap and water, wiping the transducer with 70% alcohol or soaking it for 2 minutes in 500 ppm chlorine, and rinsing with tap water and air-drying. The effectiveness of this method or newer technologies such as an ultraviolet C chamber[84] or a vaporized hydrogen peroxide chamber (eg, Trophon EPR for ultrasound transducers) have not been validated in rigorous laboratory experiments. High-level disinfection with a product (eg, hydrogen peroxide) that is not toxic to staff, patients, probes, and retrieved cells should be used until such time as the effectiveness of alternative procedures against microbes of importance at the cavitary site is demonstrated by well-designed experimental scientific studies. Other probes such as rectal, cryosurgical, and transesophageal probes/devices should also be subjected to HLD between patients.

Ultrasound probes may also be used during surgical procedures and have contact with sterile body sites. These probes may be covered with a sterile sheath to reduce the level of contamination on the probe and reduce the risk of infection. However, because the sheath does not provide complete protection of the probe, the probes should be sterilized between each patient use as with other critical items. If this is not possible, minimally high-level disinfect the probe and cover it with a sterile probe cover.

Some cryosurgical probes are not fully immersible. When reprocessing these probes, the tip of the probe should be immersed in a high-level disinfectant for the appropriate time (eg, 20 minutes exposure with 2% glutaraldehyde), and any other portion of the probe that could have mucous membrane contact could be disinfected by immersion or wrapping with a cloth soaked in a high-level disinfectant to allow the recommended contact time. After disinfection, the probe should be rinsed with tap water and dried before use. Health care facilities that use nonimmersible probes should replace them as soon as possible with fully immersible probes.

As with other HLD procedures, proper cleaning of probes is necessary to ensure the success of the subsequent disinfection.[90] Muradali et al demonstrated a reduction of vegetative bacteria inoculated on vaginal ultrasound probes when the probes were cleaned with a towel.[91] No information is available on either the level of contamination of such probes by potential viral pathogens such as hepatitis B virus and human papilloma virus or their removal by cleaning (such as with a towel). Because these pathogens may be present in vaginal and rectal secretions and contaminate probes during use, HLD of the probes after such use is recommended.

The CDC guideline states that, even if probe covers have been used, clean and high-level disinfect other semicritical devices such as rectal probes, vaginal probes, and cryosurgical probes with a product that is not toxic to staff, patients, probes, and retrieved germ cells (if applicable). Use a high-level disinfectant at the FDA-cleared exposure time. When probe covers are available, use a probe cover or condom to reduce the level of microbial contamination. Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms may fail (see exception for nasopharyngoscopes and one tested sheath above). Following HLD, rinse all items. Use sterile water, filtered water, or tap water followed by an alcohol rinse for semicritical equipment that will have contact with the mucous membranes of the upper respiratory tract (eg, nose, pharynx, esophagus).[16]

Prostate biopsy probes

Transrectal ultrasound-guided prostate biopsies are among the most common outpatient diagnostic procedures performed in urology practice to evaluate patients for prostate cancer after an elevated prostate-specific antigen level or abnormal digital rectal examination findings.[92] It involves obtaining multiple prostate tissue cores by passing a disposable biopsy needle through a needle guide under ultrasound guidance. All prostatic biopsy procedures likely result in contamination of the probe with blood or feces. During this procedure, the transducer assembly is generally covered with a barrier sheath.[93] Breaches in the reprocessing of prostate biopsy probes can pose a risk of disease transmission.[92,94]

Disinfection or sterilization of ultrasound transducer components is based on the function or use of each component. Because the biopsy needle penetrates sterile tissue for biopsy, it should be sterile. Ideally, the needle guide should be sterilized between patient uses. However, if this is not possible (ie, clinic does not have a sterilizer because biopsy needles are likely purchased as single-use sterile devices), then HLD after disassembly and cleaning is acceptable because it has contact with mucous membranes but not sterile tissue. The FDA alert[93] and a CDC article[92] recommend that the needle guide be sterilized because the biopsy needle contacts the needle guide before it penetrates sterile tissue. This recommendation is inconsistent with current recommendation for the disinfection of endoscopes. It is currently recommended that gastrointestinal endoscopes be high-level disinfected minimally but that medical devices that pass through the endoscope and enter sterile tissue (eg, biopsy forceps) be sterilized. There is no recommendation that the lumen or channel through which they pass should also be sterilized. One possible explanation for the inconsistency in this FDA recommendation is that the gastrointestinal endoscopes are high-level disinfected because there is no practical way to sterilize them, whereas the reusable needle guide for prostate probes can be sterilized (MJ Arduino, August 2006, written communication). While a barrier sheath is used on the transducer assembly during the biopsy procedure, the sheath is compromised by the penetration of the needle.[93] Although prostate probes and other endocavitary probes are often covered with a disposable sheath or condom,[93] such covers do not adequately protect the probe from microbial contamination because of leakage (9%),[95] and thus the use of a cover does not alter the requirement for HLD minimally.[16] The FDA specifies the use of a sterile barrier sheath in their recommendation for reprocessing reusable ultrasound transducer assemblies.[93] It is appropriate to use a sterile barrier sheath when an ultrasound probe is entering a sterile body cavity, but, when the probe is entering the rectum, the need for a sterile barrier sheath is unclear.

Table 1
Recommendation for reprocessing the transrectal ultrasound prostate biopsy probes*

Cleaning
- Clean immediately after use
- Disassemble the transducer (remove needle guide from the probe)
- Brush clean (if possible) or flush each lumen and thoroughly clean all surfaces of reusable components with enzymatic or nonenzymatic detergent
- Rinse with tap water
- Dry with disposable cloth/towel or air-dry
- Visibly inspect the entire device to ensure it is clean

High-level disinfection or sterilization
- Steam sterilize all heat stable reusable components
- Alternatively, high-level disinfect the probe and the needle guide separately following disassembly
- High-level disinfect all heat sensitive components (ensure disinfectants reaches all areas inside the lumens and the minimum effective concentration of the high-level disinfectant is monitored)
- Rinse with sterile water, filtered water, or tap water (FDA specifies sterile water for rinsing)
- If filtered water or tap water is used, follow with an alcohol rinse (not immersion of the probe in alcohol) to enhance drying (and no residual water is left for microbial growth)
- Dry the device
- Appropriately store the device to ensure the device is not recontaminated

*Users should be familiar with the manufacturer's recommendations for use and disinfection of the specific device used by the facility.NOTE. Modified from Rutala et al.[96]

All semicritical and critical medical devices must be thoroughly cleaned with enzymatic or nonenzymatic detergents before it is subjected to a HLD or sterilization process, respectively. Brushes should be used, when possible, to effectively clean the transducer assemblies, especially the lumens. Our investigation shows that the needle guide and prostate probe can be effectively disinfected with glutaraldehyde, but the needle guide must be disassembled from the transducer assembly.[96]

The FDA issued a Public Health Notification in June 2006 as a result of follow-up to the Department of Veterans Affairs' Veterans Health Administration Patient Safety Alert related to a particular company's ultrasound transducer assemblies. During patient safety rounds, the lumen of a needle guide of an ultrasound transducer assembly was found to be soiled. The FDA guidance consisted of several steps (see http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062086.htm for complete method recommend by the FDA). We have evaluated the FDA steps and suggest some modifications (Table 1). Do not reuse items labeled for single use (eg, single-use biopsy needles). Additional recommendations may be available in the operator's manuals or user guides. It is important that these recommendations be consistent with disinfection and sterilization guidelines/principles or that these recommendations have been validated by appropriate scientific studies. Do not use any disinfectant that can cause irreparable damage to the materials used to construct the probe. For example, if an alcohol rinse is not compatible with the probe, rinse with sterile water (not filtered water or tap water) and do not rinse with alcohol. These recommendations could be adapted to all ultrasonic prostate probes to include those with an external needle guide attachment.

Infrared coagulation

Infrared coagulation is a widely used method for treating hemorrhoids. The procedure involves applying infrared light to compress and seal hemorrhoid veins. The manufacturer of the device sells a sterile disposable sheath and states that removing and soaking light guides between procedures is no longer required. The manufacturer also states that the light guide is damaged by immersion in a disinfectant because the light guide is not sealed at the end, and the disinfectant gets between the quartz glass and the covering.

As mentioned, the CDC guideline recommends immersion for reprocessing endocavitary probes with covers because integrity of the cover is compromised. Because the light guide cannot be immersed, we investigated an alternative procedure. This procedure involved wiping the probe for 2 minutes with a 1:10 bleach (5,000 ppm) solution, and, after that is completed, wipe the probe with sterile water and let the probe air-dry. This procedure has been found effective in eliminating $\sim$7 $\log_{10}$ reduction (7.8×10^6) of *Mycobacterium terrae* and is used at our hospital for decontamination of the sheathed device after use.[97]

Laryngoscopes

Laryngoscope are routinely used to view the vocal cords and larynx and for airway management. It typically consists of a blade that connects to a handle that usually contains 2 batteries that power the light source. Limited guidelines are available for reprocessing laryngoscope blades and handles, and hospital practices vary.[98-100] For example, some guidelines recommend and hospitals use low-level disinfection of the handle because it does not have direct contact with a mucous membrane, whereas others recommend that the handle be high-level disinfected to prevent disease transmission. Whereas blades have been linked to health care-associated infections, handles have not been directly linked to health care-associated infections. However, reports of contamination with blood (40% of the handles positive for occult blood) and potentially pathogenic microorganisms (86% of the handles deemed "ready for patient use" positive including *Staphylococcus aureus, Acinetobacter*) suggest its potential,[100-103] and the blade and handle function together. For this reason, it is ideal that the blades and handles be high-level disinfected or sterilized even if a protective barrier or sheath is used during the procedure. In 2007, the State of California required that both blades and handles be HLD or sterilized. We are sterilizing our blades and handles (ie, blades via hydrogen peroxide gas plasma, handle [without batteries] by steam). Other methods for HLD or sterilization are acceptable, but ensure that the blade and handle are compatible with the HLD or sterilization process chosen. After sterilization, the blades and handles are checked for function prior to packaging and then packaged in a ziplock bag. Per The Joint Commission, the laryngoscope blade and handle must be packaged in a way that prevents recontamination after processing (FAQ, The Joint Commission; October 24, 2011). Examples of compliant storage include, but are not limited to, a peel pack poststerilization (long-term storage) or wrapping in a sterile towel (short-term storage).

Urologic instruments

Advances in fiberoptic technology have produced flexible and miniaturized ureteroscopes that have facilitated retrograde diagnosis and treatment of upper urinary tract diseases. They are fragile instruments that are reprocessed by low-temperature sterilization

or HLD. The effects of commonly used reprocessing methods on flexible ureteroscopes longevity has been prospectively examined, and it was found that the peracetic acid reprocessor left the flexible ureteroscopes unusable, whereas HLD with OPA had minimal adverse impact (see OPA contraindication below).[104]

Flexible cystoscopes are standard urology procedure instruments that are complex and require reprocessing between patients. A white paper provides a concise reference for the reprocessing of flexible cystoscopes.[105] Because cystoscopes are classified as semicritical items, they require minimally HLD. The standard reprocessing steps (precleaning, leak testing, cleaning, disinfection, rinsing, and drying) should be followed to eliminate contamination of the cystoscope between uses. Anaphylactic reactions have been reported in patients with bladder cancer who underwent repeated cystoscopy using scopes that were HLD with OPA, and, thus OPA is contraindicated in patients with a history of bladder cancer.[105]

CONCLUSION

Strict adherence to current guidelines is required for semicritical items because more outbreaks have been linked to inadequately cleaned or disinfected semicritical items such as endoscopes undergoing HLD than any other medical device.

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