Reprocessing semicritical items: Outbreaks and current issues

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Key Words:
Endoscopes
Disinfection
Sterilization
Medical Devices

Semicritical medical devices are defined as items that come into contact with mucous membranes or nonintact skin (eg, gastrointestinal endoscopes, endocavitary probes). Such medical devices require minimally high-level disinfection. As 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 as more outbreaks have been linked to inadequately cleaned or disinfected endoscopes and other semicritical items than any other reusable medical devices.

In the United States in 2010, there were approximately 51.4 million inpatient surgical procedures and an even larger number of invasive medical procedures performed.[1] For example, there were over 6.9 million upper gastrointestinal (GI), 11.5 million lower GI, and 228,000 biliary endoscopies performed in 2009.[2] Each of these procedures involves 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, which can lead to infection. Failure to properly disinfect or sterilize equipment may lead to transmission via contaminated medical and surgical devices (eg, carbapenem-resistant *Enterobacteriaceae* [CRE]).[3,4]

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization.[5] Failure to comply with scientifically-based guidelines has led to numerous outbreaks and patient exposures.[6] In fact, nearly all infections and patient exposures associated with reprocessing medical or surgical instruments involve high-level disinfection (HLD) of reusable semicritical items.[6–8] Because of noncompliance with recommended reprocessing procedures, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) issued a health advisory alerting health care providers and facilities about the public health need to properly maintain, clean, disinfect, and sterilize reusable medical devices in September 2015.[9] In this expanded and updated version of a previous article on this subject,[10,11] we will examine outbreaks associated with semicritical items and current issues associated with reprocessing semicritical items. Because semicritical items carry the greatest risk of infection we also will discuss reprocessing semicritical items such as: GI endoscopes and bronchoscopes, nasal endoscopes, endocavitary probes, transrectal ultrasound-guided prostate biopsy probes, tonometers, laryngoscopes, transesophageal echocardiogram (TEE) probes, infrared coagulation devices, and urologic instruments (eg, cystoscopies, ureteroscopes).

A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

Approximately 50 years ago, Earle H. Spaulding[12] 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.[13–18] 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 (contacts mucous membranes and requires HLD), and noncritical (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.[19]

SEMICRITICAL ITEMS

Semicritical items are those that come in contact with mucous membranes or nonintact skin. Respiratory therapy and anesthesia

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Conflicts of interest: Dr. Rutala is a consultant for Advanced Sterilization Products. Dr. Weber is a consultant for Germitec.

Table 1
Summary of advantages and disadvantages of chemical agents used as chemical sterilants or as high-level disinfectant/chemical sterilant*

Sterilization method	Advantages	Disadvantages
Peracetic acid/hydrogen peroxide	• No activation required	• Material compatibility concerns (lead, brass, copper, zinc) both cosmetic and functional • Limited clinical experience • Mucous membrane and respiratory health effects • Potential for eye and skin damage
Glutaraldehyde	• Numerous use studies published • Relatively inexpensive • Excellent material compatibility	• Respiratory irritation from glutaraldehyde vapor • Pungent and irritating odor • Relatively slow mycobactericidal activity (unless other disinfectants added such as phenolic, alcohol) • Coagulates blood and fixes tissue to surfaces • Allergic contact dermatitis • ACGIH recommends limiting employee exposure to ceiling concentration of 0.05 ppm
Hydrogen peroxide (standard)	• No activation required • May enhance removal of organic matter and organisms • No disposal issues • No odor or irritation issues • Does not coagulate blood or fix tissues to surfaces • Inactivates *Cryptosporidium* at 6%-7.5% • Use studies published	• Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional • Serious eye damage with contact
OPA	• Fast acting high-level disinfectant • No activation required • Odor not significant • Excellent materials compatibility claimed • Does not coagulate blood or fix tissues to surfaces claimed • Relatively rapid mycobactericidal activity	• Stains protein gray (eg, skin, mucous membranes, clothing, and environmental surfaces) • More expensive than glutaraldehyde • Eye irritation with contact • Slow sporicidal activity • Anaphylactic reactions to OPA in bladder cancer patients with repeated exposure to OPA through cystoscopy
Peracetic acid	• Standardized cycle (eg, liquid chemical sterilant processing system using peracetic acid, rinsed with extensively treated potable water) • Low temperature (50°C-55°C) liquid immersion sterilization • Environmental friendly by-products (acetic acid, O_2, H_20) • Fully automated • Single-use system eliminates need for concentration testing • May enhance removal of organic material and endotoxin • No adverse health effects to operators under normal operating conditions • Compatible with many materials and instruments • Does not coagulate blood or fix tissues to surfaces • Sterilant flows through scope facilitating salt, protein, and microbe removal • Rapidly sporicidal • Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)	• Potential material incompatibility (eg, aluminum anodized coating becomes dull) • Used for immersible instruments only • Biological indicator may not be suitable for routine monitoring • One scope or a small number of instruments can be processed in a cycle • More expensive (endoscope repairs, operating costs, purchase costs) than HLD • Serious eye and skin damage (concentrated solution) with contact • Point-of-use system, no sterile storage • An AER using 0.2% peracetic acid not FDA-cleared as sterilization process but HLD
Improved hydrogen peroxide (2.0%); high-level disinfectant	• No activation required • No odor • Nonstaining • No special venting requirements • Manual or automated applications • 12 month shelf life, 14 day reuse • 8 min at 20°C high-level disinfectant claim	• Material compatibility concerns because of limited clinical experience • Organic material resistance concerns because of limited data

All products effective in presence of organic soil, relatively easy to use, and have a broad spectrum of antimicrobial activity (bacteria, fungi, viruses, bacterial spores, and mycobacteria). The characteristics in the Table are documented in the literature; contact the manufacturer of the instrument and HLD/chemical sterilant for additional information. All products listed in the Table are FDA-cleared as chemical sterilants except OPA and 2% accelerated hydrogen peroxide, which are FDA-cleared high-level disinfectants.
ACGIH, American Conference of Governmental Industrial Hygienists; *AER*, automated endoscope reprocessor; *FDA*, Food and Drug Administration; *HLD*, high-level disinfection; *OPA*, ortho-phthalaldehyde.
*Modified from Rutala and Weber[10,11,13-17]

equipment, GI endoscopes, bronchoscopes, laryngoscopes, TEE probes, tonometers, endocavitary probes, transrectal ultrasound-guided prostate biopsy probes,[20] cystoscopes, hysteroscopes, infrared coagulation devices, and diaphragm fitting rings are included in this category. These medical devices should be free of all microorganisms (ie, mycobacteria, fungi, viruses, and bacteria), although small numbers of bacterial spores may be present. Intact mucous membranes, such as those of the lungs or the GI 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 acid, peracetic acid with hydrogen peroxide, and a chlorine-based system are cleared by the FDA[21] and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met. Table 1 lists the FDA-cleared high-level disinfectants and chemical sterilants with the advantages and disadvantages of each. The exposure time for most high-level disinfectants varies from 8-45 minutes at 20°C-25°C.[21] As with all medications and devices, users must be familiar with the manufacturer's instructions for use (IFU). 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. Disinfection strategies for some semicritical items (eg, applanation tonometers, rectal/vaginal probes) are highly variable.[22]

Because semicritical equipment has been associated with reprocessing errors that result in patient look-back and patient notifications, it is essential that control measures be instituted to prevent patient exposures.[6] Before new equipment (especially semicritical equipment as the margin of safety is less than that for sterilization)[23] is used for patient care on more than 1 patient, reprocessing procedures for that equipment should be developed. The FDA requests that the device manufacturer include at least 1 validated cleaning and disinfection and sterilization protocol in the labeling for their device. Staff should receive training on the safe use and reprocessing of the equipment and be competency tested. At the University of North Carolina Hospitals, to ensure patient-safe instruments, all staff that reprocess semicritical instruments (eg, instruments that contact a mucous membrane such as vaginal probes, endoscopes, prostate probes) are required to attend a 3-hour class on HLD of semicritical instruments initially and a 1-hour refresher class annually. The 3-hour class includes the rationale for and importance of HLD, discussion of high-level disinfectants and exposure times, reprocessing steps, monitoring minimum effective concentration, personal protective equipment, and the reprocessing environment (establish "dirty-to-clean" flow). Infection control rounds or audits should be conducted at least annually in all clinical areas that reprocess critical and semicritical devices to ensure adherence to the reprocessing guidelines, manufacturers' instructions-for-use, and institutional policies. This includes reprocessing critical and semicritical medical and surgical instruments in outpatient care facilities as many patient exposures and infections have occurred in this setting.[24] Results of infection control rounds should be provided to the unit managers and deficiencies in reprocessing should be corrected and the corrective measures documented to infection control within 30 days. Patient safety issues such as the wrong contact time, temperature, or concentration of high-level disinfectant require immediate correction.

Semicritical items that will have contact with mucous membranes of the GI tract or upper respiratory tract should be rinsed with sterile water or filtered water or tap water followed by an alcohol rinse.[17,25] 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.[26] After rinsing, items should be dried and stored in a manner that protects them from damage or contamination. Drying also retards biofilm formation.[27] There is no recommendation to use sterile or filtered water rather than tap water for rinsing semicritical equipment that will have contact with the mucous membranes of the rectum (eg, rectal probes, anoscope) or vagina (eg, vaginal probes).[17]

Semicritical items represent the greatest risk of disease transmission as far more health care–associated infections have been caused by reusable semicritical items than critical or noncritical items.[11] There is virtually no documented risk of transmitting infectious agents to patients via noncritical items[28] when they are used as noncritical items and do not contact nonintact skin and/or mucous membranes. Similarly, critical items are rarely[29] associated with disease transmission. In contrast, semicritical items (eg, GI endoscopes), by virtue of the body cavities they enter, may contain $10^{7\text{-}10}$ (7-10-$\log_{10}$) enteric microorganisms.[30,31] Investigations have demonstrated that the cleaning step in endoscope reprocessing results in a 2-6-$\log_{10}$ reduction of microbes and the HLD step results in another 4-6-$\log_{10}$ reduction of mycobacteria for a total 6-12-$\log_{10}$ reduction of microbes.[30–32] Thus, the margin of safety associated with cleaning and HLD of GI endoscopes is minimal or nonexistent (level of contamination: 4-$\log_{10}$ [maximum contamination, minimal cleaning/HLD] to −5-$\log_{10}$ [minimum contamination, maximum cleaning/HLD]).[23] Therefore, any deviation from proper reprocessing (such as crevices associated with the elevator channel) could lead to failure to eliminate contamination with a possibility of subsequent patient-to-patient transmission. This low (or nonexistent) margin of safety associated with endoscope reprocessing compares to the 17-$\log_{10}$ margin of safety associated with cleaning and sterilization of surgical instruments.[23] This is the reason that semicritical items represent the greatest risk of disease transmission via a reusable medical or surgical instrument and critical items are rarely[29] associated with infection.

Table 2
Infections and outbreaks associated with semicritical medical devices*

Instruments	# Outbreaks/ Infections	# Outbreaks/ Infections with bloodborne pathogens
Vaginal probes	0**	0
Nasal endoscopes	0	0
Hysteroscopes	0	0
Laryngoscopes	2[43-45]	0
Urologic instrumentation (eg, cystoscopes, ureteroscopes)	8[46-53]	0
Transrectal-ultrasound guided prostate probes	1[40]	0
Transesophageal echocardiogram	5[51,54-57]	0
Applanation tonometers	2[41,42]	
GI endoscopes/bronchoscopes	~130[7,8]	3 HBV[34]; HCV[35,36]

GI, gastrointestinal; *HBV*, hepatitis B virus; *HCV*, hepatitis C virus.
*These infections/outbreaks were found in the peer-review literature through PubMed and Google.
**Does not include outbreaks associated with contaminated ultrasound gel used with vaginal probes or transmission via health care personnel.

OUTBREAKS

Transmission of infections (and bloodborne pathogens) associated with the use of semicritical medical devices

GI endoscopes and bronchoscopes have been associated with far more outbreaks of infections (>130 outbreaks) than any other reusable medical or surgical device in health care.[7,8] Other semicritical items (eg, urologic instruments, TEE probes) have also been associated with outbreaks of infection. To assess the frequency of infections/outbreaks associated with all semicritical medical devices (Table 2), a systematic review of the literature was conducted.[33] The databases used were PubMed and Google and the search terms and subject heading terms were: hepatitis, hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), endoscopes, medical devices, semicritical medical items, vaginal probes, nasal endoscopes, hysteroscopes, urologic instruments, GI endoscopes, bronchoscopes, transrectal-ultrasound guided prostate probe, applanation tonometers, TEE, infrared coagulation, infection, and outbreaks. The reference lists of articles retrieved were also searched for relevant articles. There was no language restriction; articles were evaluated for inclusion when an English translation of the article or abstract was available. Abstracts from scientific meetings were not included.

HCV and HBV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare. Three reports related to breaches in semicritical device reprocessing were found involving HBV and HCV, and all involved GI endoscopes.[34–36] There is 1 report of HBV transmission via GI endoscopy[34] and 2 reports of HCV transmission associated with GI endoscopes.[35,36] In general, transmission of HBV and HCV in health care in the United States is uncommon and typically associated with unsafe injection practices.[37] No articles relating to possible transmission of HIV via medical instruments, including semicritical medical devices, were identified. The articles for HBV and HCV transmission associated with GI endoscopes were written prior to the comprehensive endoscope reprocessing guidelines that are now available.

There are limitations to this type of review. For example, only published literature was included, and it is more likely that instances of transmission were published than instances of nontransmission. This would likely overestimate the frequency of transmission. In contrast, many outbreaks go undetected and almost certainly outbreaks associated with semicritical medical devices have gone unreported. For example, most persons with incident HCV and HBV infections are asymptomatic. Even when symptomatic persons are identified, many hospitals and health departments do not have the resources to thoroughly investigate all individuals with HBV or HCV.[38] We have the greatest risk of transmission associated with GI endoscopes and bronchoscopes owing to the high microbial load in GI endoscopes (10^7-10^{10} in internal channels of a GI endoscope) and complexity of the instrument. The microbial load associated with a vaginal probe, nasal endoscopes, and cystoscopes is thought to be less owing to the presence of fewer organisms at those sites (eg, vagina, oropharynx [10^1-10^5/mL in nasal washings], urinary tract) compared to the GI tract (10^9-10^{12}/mL in the colon). Additionally, endoscopic instruments with channels may allow the development of biofilms when the instruments are not completely dry.[23,27] For these reasons, there are over 130 reported outbreaks of infections associated with GI endoscopes and bronchoscopes. Many of these outbreaks were related to breeches in endoscope reprocessing (eg, inadequate cleaning, disinfection, and drying procedures) but between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different outbreaks of multidrug-resistant organisms (MDROs) that sickened at least 250 patients worldwide.[8] Since 2010, there have been at least 9 outbreaks of duodenoscope-related infections of MDROs without reprocessing breaches. In these outbreaks, the CDC and/or other investigators monitored endoscope reprocessing procedures and concluded they were compliant with the manufacturer's IFU and professional organizational recommendations.[39]

Transmission of bloodborne pathogens (BBP) (ie, HBV, HCV, HIV) or other infectious agents related to improper reprocessing of a vaginal probe have not been documented. In addition, there are no outbreaks of BBP, or other infections related to lapses in reprocessing of nasal endoscopes and hysteroscopes. Outbreaks associated with the use of vaginal probes have occurred but they have involved the use of a contaminated ultrasound gel or noncompliance with the manufacturer's IFU.[33] There has been 1 outbreak associated with the transrectal-ultrasound guided prostate probe,[40] 2 outbreaks associated with applanation tonometers.[41,42] and at least 2 outbreaks connected to laryngoscopes.[43–45]

Eight outbreaks that involved urologic instruments and reprocessing failures were identified. None of those outbreaks involved transmission of BBP such as HIV, HBV and HCV.[46–53] The lapses in reprocessing included: inadequate camera head cleaning;[47] improper cleaning and disinfecting cystoscopes for >10 years;[49] incomplete cleaning and disinfection of the cystoscope;[48] and incorrect cystoscope reprocessing.[46]

Transmission of BBP related to improper reprocessing of a TEE probe has not been documented; however, 5 outbreaks of infection have occurred associated with the use of TEE probes.[51,54–57] The outbreaks were associated with a damaged or defective probe;[54,55] noncompliance with reprocessing procedure;[56] and the use of a TEE probe rinsed with contaminated water.[57] Outbreaks associated with contaminated ultrasound gel in multiuse bottles used for TEE and other endocavitary probe procedures are not included as they do not represent failure of disinfection, but rather intrinsic or extrinsic contamination of the gel. Recommendations for minimizing the health risks of using gels involve use of single-use, sterile gels for invasive procedures that pass through a tissue, for all studies involving neonates, for all procedures involving sterile equipment or nonintact skin, and for procedures on intact mucous membranes.[58]

A look-back or exposure investigation of patients potentially exposed to BBP via medical instruments

When there is a failure to follow reprocessing guidelines for semicritical items, health care facilities should assess the risk of exposed patients to BBP using a 14-step protocol.[6] On occasion, health care facilities have considered evaluating exposed patients for not only for BBP but also for other epidemiologically important pathogens such as multidrug resistant *Enterobacteriaceae* or *C difficile*. Regarding an epidemiologic look-back investigation (ie, systematic notification of patients by health care facilities) for transmission of other pathogens, we are not aware of any health care facility that conducted an epidemiologic look-back study of improperly reprocessed semicritical medical devices (such as endoscopes) that assessed other pathogens such as multidrug resistant *Enterobacteriaceae* or *C difficile*. Large-scale epidemiologic look-back investigations of improperly reprocessed semicritical instruments (ie, GI endoscopes) for transmission of BBPs have been conducted.[6,59,60] In 1 investigation involving endoscopes in a nonhospital endoscopy clinic's endoscope reprocessing failures were not associated with an increased risk of BBP among individuals tested.[59] In another study involving almost 10,000 persons tested for BBPs, the investigation revealed that exposure to improperly reprocessed ear-nose-throat endoscopes did not result in viral transmission in those patients who had genetic analysis performed. Any potential transmission of BBP from colonoscopy remains unknown because case/proximate patient testing could not be performed.[60]

In addition, some health care facilities have considered evaluating medical charts for evidence of risks or transmission of infection among a certain population. The weakness of such an evaluation is the absence of comparator data. That is, let us say you recognize noncompliance with reprocessing urologic instruments and you look for *E coli* in patients undergoing cystoscopies in an outpatient urology office. Certainly, you will find a percentage (eg, 10%) of patients undergoing cystoscopy with *E coli* in the urinary tract. Unfortunately, you do not have a control population to compare your *E coli* frequency in the urology clinic. The control population could be a group of persons that underwent cystoscopies in an outpatient urology clinic that reprocessed the endoscope in complete compliance with the professional organization guidelines and manufacturer's IFU. Additionally, to compare the numbers between the 2 outpatient urology clinics, the facilities would have to use the same surveillance methodology, and identify methods to risk adjust the population studied as there are many risk factors for *E coli* in the urine such as older age, female sex, urinary catheterization, enlarged prostate, diabetes, not receiving antibiotics, malnutrition, et cetera. Therefore, the question you must consider before beginning a chart review is how the data will help you make a decision as you will likely find persons with any outcome you consider (eg, HCV prevalence in US population is 1.3%, HBV is 0.4%, and HIV is 0.3%). If you decide to do a chart review, you will need to consider the surveillance method, the outcome indicator to monitor, the time period for observation and benchmarking, and comparator data. Of course, a chart review would be unlikely to completely identify all persons infected (eg, HCV) or colonized (eg, *E coli* in the urine) because testing asymptomatic patients for colonization or infection is rarely indicated. Active surveillance for such patients would be both logistically difficult and expensive.

REPROCESSING SEMICRITICAL ITEMS

Reprocessing of GI endoscopes and bronchoscopes

More health care–associated outbreaks (>130 outbreaks) and patient exposures have been linked to contaminated GI endoscopes

and bronchoscopes than to any other reusable medical device.[7,8] Because the risk of transmission via GI endoscopes and bronchoscopes will be reviewed in another article in this journal,[61] the reason for reprocessing failure will only be briefly discussed. There are at least 2 (and probably 3) reasons for this reprocessing failure and why outbreaks continue to occur.[23] First, studies have shown that the internal channel of GI endoscopes, including duodenoscopes, may contain $10^{7\text{-}10}$ (7-10-$\log_{10}$) enteric microorganisms.[30,31] Investigations have demonstrated that the cleaning step in endoscope reprocessing results in a 2-6-$\log_{10}$ reduction of microbes and the HLD step results in another 4-6-$\log_{10}$ reduction of mycobacteria for a total 6-12-$\log_{10}$ reduction of microbes.[30–32] Thus, the margin of safety associated with cleaning and HLD of GI endoscopes is minimal or nonexistent (level of contamination: 4-$\log_{10}$ or 10,000 microbes [maximum contamination, minimal cleaning/HLD] to −5-$\log_{10}$ [minimum contamination, maximum cleaning/HLD]). Therefore, any deviation from proper reprocessing (such as crevices that harbor microorganisms associated with the elevator channel) could lead to failure to eliminate contamination with a possibility of subsequent patient-to-patient transmission. This low (or nonexistent) margin of safety associated with endoscope reprocessing compares to the 17-$\log_{10}$ margin of safety associated with cleaning and sterilization of surgical instruments.[23]

Second, GI endoscopes not only have heavy microbial contamination (10^7-10^{10} bacteria) but they are complex with long, narrow channels; right angle turns; and difficult to clean and disinfect components (eg, elevator channel). The elevator channel in duodenoscopes is unique to side-viewing endoscopes. It has a separate channel and provides orientation of catheters, guide-wires and accessories into the endoscopic visual field.[23] This channel is complex in design and has crevices that are difficult to access with a cleaning brush and may impede effective reprocessing.[62] Based on this and other recent studies, it is likely that MDROs are acting as a "marker" or "indicator" organism for ineffective reprocessing of the complex design of duodenoscopes, which is an infectious risk to patients.

Third, biofilms could impact endoscope reprocessing failure and continued endoscope-related outbreaks.[63] Biofilms are multilayered bacteria plus exopolysaccharides that cements cells to surfaces. They develop in a wet environment. If reprocessing is performed promptly after use and the endoscope is dry the opportunity for biofilm formation is minimal.[64,65] However, the formation of endoscopic biofilm during clinical practice may be related to reuse of reprocessing methods such as reuse of detergent, manual cleaning, and incomplete drying.[66] Ideally, reprocessing should be initiated within 1 hour of use; however, there are no evidence-based guidelines on delayed endoscope reprocessing.[67] It is unclear, but possible, that biofilms contribute to failure of endoscope reprocessing.

Infection preventionists should ensure that institutional policies are consistent with national guidelines[17,25] and manufacturers' instructions-for-use, and conduct infection control rounds periodically (eg, at least annually) in areas where endoscopes and other semicritical items are reprocessed to make certain there is compliance with policy. Based on the infection data and risks, the transition to sterilization of duodenoscopes was recommended by an FDA Panel in May 2015. Technologies to allow this change to occur are being developed[68] and FDA-cleared and should be used when acceptable in terms of sterilization performance, scope performance (for disposable scopes), cost, throughput, and compatibility of materials (eg, adhesives) to sterilization technology. Device and sterilization manufacturers, regulatory agencies, GI physicians, inpatient and outpatient endoscope reprocessing centers as well as professional organizations must reach a general agreement regarding the need for sterilization and the willingness to replace existing disinfection technologies. This transition will occur when we put "*the needs of the patient first*" and offer every patient an endoscope that is sterile, and thus, devoid of potential pathogens.[39]

Nasal endoscopy

There are several types of scopes that are used to examine the nose and throat (eg, nasopharyngoscope, rhinolaryngoscopes). Because they become contaminated during use, there is a risk of transmission of infection between patients. Flexible nasopharyngoscopy is a valuable tool enabling easy visualization of the upper aerodigestive tract. In the United States, 3 techniques are available to reprocess nasopharyngoscopes: manual HLD; use of an automated endoscope reprocessor; and use of a disposable sheath with low-level disinfection.[17,68–70] 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 with nasopharyngoscopes along with low-level disinfection.[71,72]

One study showed that the use of a high quality, snugly fitting, sterile, disposable polyurethane sheath on nasopharyngoscopes during a clinical examination, combined with enzymatic detergent cleaning and disinfection with 70% ethanol, provided a reliably decontaminated, patient-ready instrument, which eliminated the need for HLD of nasopharyngoscopes.[71] Another study found that the contamination rate on nasopharyngolaryngoscope (NPL) 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 on an NPL prevented microbes from adhering to the shaft of the scope, thus providing a safe method of avoiding the transmission of infection from 1 patient to the next patient when using an NPL successively in multiple patients in an otolaryngology clinic.[72] These 2 studies 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 nasopharyngoscope 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.

Applanation tonometers

Applanation tonometers are a possible vector for the transmission of infectious disease and outbreaks of epidemic keratoconjunctivitis (caused by adenovirus),[41,42] and have been related to incompletely disinfected tonometers.[22,41,42] In view of the potential for transmission of viruses (eg, herpes simplex virus, adenovirus type 8, or HIV)[73] by tonometer tips, the CDC recommended[74] that the tonometer tips be wiped clean and disinfected for 5-10 minutes with either 3% hydrogen peroxide, 5,000 ppm chlorine, 70% ethyl alcohol, or 70% isopropyl alcohol. However, 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.[75–77] For this reason, the CDC guideline now recommends to wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5,000 ppm chlorine or 70% ethyl alcohol.[17,74–77] Structural damage to Schiotz tonometers has been observed with a 1:10 sodium hypochlorite (5,000 ppm chlorine) and 3% hydrogen peroxide.[78] 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 to prevent patient-to-patient transmission considering that 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.[79,80]

Of course, intraocular instruments must be cleaned and sterilized between patients. Eye instruments are very delicate and require special handling to prevent damage. Recommended practices are derived from evidence-based recommendations for cleaning and sterilizing all surgical instruments in general, from outbreaks of toxic anterior segment syndrome, and from manufacturers' IFU.[81] Toxic anterior segment syndrome is an acute severe inflammatory reaction of the anterior chamber of the eye to a toxic contaminant (eg, detergent residues) introduced into the anterior chamber during intraocular surgery.[81]

Endocavitary probes (vaginal probes)

Vaginal probes are used in sonographic scanning. A vaginal probe and all endocavitary probes without a probe cover are semicritical devices as they have direct contact with mucous membranes (eg, vagina, rectum, and pharynx). Although one could argue that the use of the probe cover changes the category, the CDC guideline for disinfection and sterilization[17] proposes that a new condom/probe cover should be used to cover the probe for each patient and because condoms/probe covers may fail,[82–86] HLD of the probe also should be performed.[17,87] 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).[85] After oocyte retrieval use, Hignett and Claman[85] found a very high rate of perforations in used endovaginal probe covers from 2 suppliers (75% and 81%), whereas Amis et al[88] and Milki and Fisch[82] demonstrated a lower rate of perforations after use of condoms (0.9% and 2.0%, respectively). Rooks et al[89] 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). These studies underscore the need for HLD of endocavitary probes between examinations. Although most ultrasound manufacturers have recommend the use of 2% glutaraldehyde for HLD of contaminated transvaginal transducers, the use of this agent has been questioned[90] because it may shorten the life of the transducer and may have toxic effects on the gametes and embryos.[91] Another probe disinfection method that uses a UV-C chamber has been evaluated and is used in Europe and Canada but is not yet FDA-cleared for use in the United States.[86,92]

HLD with an FDA-cleared high-level disinfectant (eg, accelerated hydrogen peroxide) that is nontoxic to staff, patients, probes, and retrieved cells should be used until 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 and cryosurgical probes/devices should also be subjected to HLD between patients.

Cryosurgery is the use of freezing temperatures to elicit a specific response in tissue (eg, inflammatory response with minor freezing). Some cryosurgical probes (eg, used in prostate cancer) 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 should 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.[93] Muradali et al[94] demonstrated a reduction of vegetative bacteria inoculated on vaginal ultrasound probes when the probes were cleaned with a towel. No information is available on either the level of contamination of such probes by potential viral pathogens, such as HBV and human papillomavirus (HPV),[95] 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.

Concerning low-level disinfection of vaginal probes, M'Zali et al[96] demonstrated the persistence of microbial contamination on transvaginal ultrasound probes after low-level disinfection with a quaternary ammonium compound and chlorhexidine gluconate. Meyers et al[97] demonstrated that some high-level disinfectants (eg, glutaraldehyde, OPA) may not be effective against HPV but this requires corroboration. At the present time, we do not believe that this report should result in an alteration of current cleaning/disinfection recommendations.

The CDC guideline for disinfection and sterilization states that even if probe covers have been used, clean and high-level disinfect the 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 unless scientific studies and guidelines recommend an alternative time and temperature (eg, glutaraldehyde at 20 minutes, 20°C).[17,25] 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 (eg, low-level 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 described earlier). After HLD, rinse all items.

Ultrasound transducer disinfection for assessment and insert of peripheral and central catheters

At present, there is no consistency in the practice of cleaning/disinfecting ultrasound probes used for the assessment and insertion of peripheral and central catheters.[98] This begs the question: do ultrasound transducers used for placing peripheral or central venous access devices require HLD or sterilization? A recent publication has interpreted the CDC and the American Institute for Ultrasound in Medicine guidelines to recommend that the probe used for ultrasound-guided central venous catheter insertion be either sterilized or HLD and used with a sterile sheath and sterile gel.[98] The same article recommended that the probe used to scan across unhealthy skin should be high-level disinfected and used with a clean sheath and clean gel.[98] The American Institute for Ultrasound in Medicine and Association of Vascular Access guidelines are similar and recommend that all transducers used for peripheral or central venous access device insertion should undergo, at a minimum, low-level disinfection (ie, step 1-clean, step 2-low-level disinfect) and be used in conjunction with a single-use sterile probe cover.[99,100] Should such a probe on occasion become contaminated with blood or other potentially infectious material, appropriate cleaning and low-level disinfection would eliminate the key BBPs (ie, HIV, HBV, and HCV).

Transrectal ultrasound-guided 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.[40] It involves obtaining multiple prostate tissue cores by passing a disposable biopsy needle through a needle guide under ultrasound guidance. All prostatic biopsy procedures result in contamination of the probe with blood or feces. During this procedure,

the transducer assembly is generally covered with a barrier sheath.[101] Breaches in the reprocessing of prostate biopsy probes can pose a risk of disease transmission.[40,102]

Disinfection or sterilization of ultrasound transducer components is based on the function or use of each component. Considering that 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 as biopsy needles are likely purchased as single-use sterile devices) then HLD after disassembly and cleaning is acceptable as it has contact with mucous membranes but not sterile tissue**.** The FDA alert[101] and a CDC article[40] recommends that the needle guide be sterilized as the biopsy needle contacts the needle guide before it penetrates sterile tissue. This recommendation is inconsistent with current recommendation for the disinfection of GI endoscopes. It is currently recommended that GI endoscopes be high-level disinfected minimally but that medical devices that pass through the endoscope and enter sterile tissue (eg, biopsy forceps) be sterilized.[17,25] 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 GI endoscopes can only be high-level disinfected as there is no practical way to sterilize them, whereas the reusable needle guide for prostate probes can be sterilized (written communication, MJ Arduino, August 2006). Although a barrier sheath is used on the transducer assembly during the biopsy procedure, the sheath is compromised by the penetration of the needle.[101] Although prostate probes and other endocavitary probes are often covered with a disposable sheath or condom,[101] such covers do not adequately protect the probe from microbial contamination because of leakage (9%),[103] and thus, the use of a cover does not alter the requirement for HLD minimally.[17] FDA specifies the use of a sterile barrier sheath in their recommendation for reprocessing reusable ultrasound transducer assemblies.[101] 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.

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. One 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.[20]

The FDA issued a Public Health Notification in June 2006, because of follow-up to the Department of Veterans Affairs, Veterans Health Administration Patient Safety Alert related to a 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 recommended by the FDA). We have evaluated the FDA steps and suggest some modifications.[11] Do not reuse items labeled for single use (eg, single-use biopsy needles, needle guides). 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.

TEE probes

TEE probes are another semicritical device that has a potential for infection between sequential patients. Five outbreaks have been associated with TEE probes used in cardiovascular surgical operations.[51,54–57] In 2 outbreaks, a defect in the probe was identified.[54,55] Once the damaged TEE probes were removed from use, no additional cases were identified in the cardiac surgery patients. The defect presumably prevented exposure of the bacteria to the high-level disinfectant. To ensure proper HLD, health care facilities should ensure the probes are not damaged and comply with recommendations from professional organizations and the manufacturer. The basic principle for successful reprocessing of the probe involves: clean the probe shaft and probe tip (via immersion or wiped with a wipe moistened with detergent/enzymatic) to remove gross contamination (a second wipe is used to wipe nonimmersible parts higher up including the handle); inspect to ensure no structural damage; disinfect with a high-level disinfectant (distal tip and flexible shaft are immersed in the high-level disinfectant, wipe the higher portions with a compatible disinfectant); thoroughly rinse; and dry before storage.[104] Protective sheaths are an additional physical barrier to infection and probe damage; however, they do not remove the possibility of infection as sheaths do not cover all of the TEE probes and the sheaths are subject to perforations.[105] Strict adherence to manufacturers' instructions when using chemical disinfectants such as OPA for TEE probe reprocessing are required to avoid aerodigestive tract chemical injury.[106] TEE probes require HLD regardless of whether a sheath is used. Many hospitals use a vapor control system that reduces exposure of staff to toxic vapors and damage to the instrument (eg, wall rack holder such as glutaraldehyde user station). Follow the manufacturer's instructions and/or professional organizational guidelines for soak times and cleaners.

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 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 as 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) and after that was completed, wiping the probe with sterile water and letting 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.[107]

Laryngoscopes

Laryngoscopes are a potential source of infection[108] and have been associated with at least 2 outbreaks.[43–45] Laryngoscopes 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, which usually contains 2 batteries that powers the light source. Limited guidelines are available for reprocessing laryngoscope blades and handles and hospital practices vary.[45,109,110] For example, some guidelines recommend and hospitals use low-level disinfection of the handle as it does not have direct contact with a mucous membrane, whereas others

recommend that the handle be high-level disinfected to prevent disease transmission. Although 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[45,111–113] 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. At University of North Carolina Hospitals we were sterilizing the blades and handles (ie, blades via hydrogen peroxide gas plasma, handle [without batteries] by steam), but we have transitioned to sterile, disposable blades and handles. This practice saves time, eliminates the risk of cross contamination and reduces the likelihood on nonperforming equipment. A few specialty areas continue to sterilize the blade and handle. Per the Joint Commission, the laryngoscope blade and handle must be packaged in a way that prevents recontamination after processing. 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).

Advances in video-technology have led to the development of video laryngoscopes such as the GlideScope (Verathon, Bothell, MA) and McGrath video laryngoscopes (Medtronic, Minneapolis, MN). These new intubation devices assist in difficult airway management. The manufacturer's IFU should be followed for reprocessing the reusable component of these scopes.

Other channeled endoscopes (cystoscopes, ureteroscopes, hysteroscopes)

In the United States, it is estimated that over 4 million cystoscopies are performed each year. Cystoscopy is a diagnostic procedure that uses an endoscope especially designed to examine the bladder, lower urinary tract, and prostate gland or is used to collect urine samples, perform biopsies, and remove small stones. A flexible or rigid scope can be used to carry out the procedure. Considering that the procedure involves a medical device in contact with the patient's mucous membranes, it is considered a semicritical device that must minimally be high-level disinfected. Failure to properly high-level disinfect or sterilize semicritical equipment can lead to contamination[114] and transmission of infection.[46]

A recent study demonstrated how important it is to perfuse the high-level disinfectant into the channel of cystoscopes and other channeled scopes (eg, hysteroscopes, ureteroscopes). This study demonstrated that disinfection (ie, a reduction in bacterial load of >7-$\log_{10}$ CFU) did not occur unless the channel was actively perfused with the glutaraldehyde. In fact, failure to perfuse the channel led to only minimal, if any, reduction in bacterial contamination. However, complete inactivation of 10^8 CFU of both vancomycin-resistant *Enterococcus* and CRE was achieved when the channel was actively perfused. It appears that no high-level disinfectant entered the channel unless it was actively perfused via a syringe, as the level of microbial contamination was not reduced by immersion. This occurs because the air pressure in the channel is stronger than the fluid pressure at the fluid-air interface. Recommendations are provided for cystoscope HLD and include actively perfusing the device while immersed in the high-level disinfectant.[115]

Cystoscopes have also been implicated as the source of infection to multiple patients when incorrect disinfection methods were identified.[46] This may, in part, be related to the lack of awareness of recommendations specifically for disinfecting cystoscopes[116] or failing to follow the manufacturer's instructions, which specify perfusing the lumen using a high-level disinfectant. Unfortunately, some cystoscope reprocessing recommendations published in the literature are incorrect. For example, authors have recommended complete immersion of the cystoscope into the high-level disinfectant but did not mention perfusion of the high-level disinfectant into the channel.[46] We suggest following published recommendations[11] and those of the American Urological Association[116] until evidence-based guidelines have been published. 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.[116]

CURRENT ISSUES

Hydrogen peroxide mist system for probes

An alternative procedure for disinfecting the endocavitary and surface probes is a hydrogen peroxide mist system, which uses 35% hydrogen peroxide at 56°C with the probe reaching no more than 40°C (ie, Trophon). In one study, the results demonstrated complete inactivation (>6-$\log_{10}$ reduction) of vancomycin-resistant *Enterococcus* and a CRE-*Klebsiella pneumoniae* strain in both the presence and absence of 5% fetal calf serum (FCS). The Trophon EPR system (Nanosonics, Indianapolis, IN) showed good, but not complete, inactivation of *M terrae* (5.2-$\log_{10}$ reduction for *M terrae* with FCS; 4.6-$\log_{10}$ reduction for *M terrae* without FCS) and *C difficile* spores (5.1-$\log_{10}$ reduction for *C difficile* spores with FCS; 6.2-$\log_{10}$ reduction for *C difficile* spores without FCS).[117] Other data have demonstrated the activity of Trophon to inactivate HPV[118] and other pathogens (eg, bacteria, mycobacteria, viruses) including a >6-$\log_{10}$ reduction of *M terrae* and *C difficile* spores in carrier tests and a >6-$\log_{10}$ reduction in *M terrae* on inoculated ultrasound probes.[119] These results differ slightly from those presented earlier, presumably because of the differences in testing methodology. In our study, only the probe devices were inoculated (carriers of different materials were not tested) and for recovery of bacteria on the probe, the probes were immersed in media (not swabbed, which would likely result in lower recovery).[117] The Trophon system processes the portion of the probe that has mucous membrane contact but also the handle of an endocavitary probe, which may be contaminated, and it is an alternative to high-level chemical disinfection for ultrasound probes.

Storage of semicritical items

In 2011, the Joint Commission recommended that laryngoscope blades be packaged in a way that prevents recontamination. Examples of compliant storage include, but are not limited to, a peel pouch or a closed plastic bag. Examples of noncompliant storage would include unwrapped blades in an anesthesia drawer as well as an unwrapped blade on top of or within a code cart. The packaging not only prevents recontamination but also distinguishes a processed from a nonprocessed semicritical item such as a speculum, laryngoscope blade, or endoscope. The use of a tagging system that separates processed from nonprocessed items minimizes the use of a semicritical item that has not been reprocessed and prevents patient exposures to a nonreprocessed semicritical item.[6] This could involve a tag (eg, green tag = patient ready, red tag = requires reprocessing) for GI endoscopes or a plastic sheath or plastic-paper peel pouch (eg, endocavitary probes). Ideally, hospitals and ambulatory care facilities (as appropriate)[24] should develop a strategy (eg, tagging, storage covers for patient-ready devices) that prevents patient exposures to contaminated devices.

HPV

HPV is an extremely common sexually-acquired infection and is the most important cause of cervical cancer. An article in 2014

demonstrated that the FDA-cleared high-level disinfectants (ie, glutaraldehyde, OPA) tested did not inactivate the HPV, a nonenveloped virus.[97] These findings are inconsistent with many articles in the peer-reviewed literature that demonstrates that high-level disinfectants such as OPA and glutaraldehyde inactivate nonenveloped viruses such as hepatitis A virus, polio, adenovirus, norovirus, et cetera.[17] Because the HLD are commonly used to disinfect endocavitary probes (eg, vaginal probes, rectal probes), there is an urgency to corroborate these data. In a conversation with CDC staff regarding this issue, it was determined hospitals should continue to use the FDA-cleared high-level disinfectants consistent with the manufacturers' instructions until the data can be corroborated. Data have demonstrated the activity of a hydrogen peroxide mist device[118] as well as a UV-C unit[120] to inactivate the HPV. To reduce the risk of transmission of HPV via transvaginal ultrasound, Combs and Fishman[121] recommended disinfection of the transvaginal probe with the hydrogen peroxide mist device and covering them with a condoms during examinations. In October 2018, an abstract by Ozbun et al was presented at the 32nd International Papillomavirus Conference in Australia, which demonstrated that HPV was inactivated by a variety of disinfectants including OPA.

Do not reuse single-use devices

The Department of Justice and the FDA have joined forces in prosecuting health care providers that reuse single-use devices. For example, a physician was criminally prosecuted for reusing needle guides meant for single use during prostate procedures. These prosecutions are based on conspiracy to commit adulteration and Medicare fraud. Third party reprocessing is allowed by the FDA when the reprocessor is considered the device manufacturer as defined under 21 CFR Part 820.

CONCLUSIONS

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

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