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Disinfection and Sterilization in Health Care Facilities: What Clinicians Need to Know

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All invasive procedures involve contact between a medical device or surgical instrument and a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic microbes that could lead to infection. Failure to properly disinfect or sterilize reusable medical equipment carries a risk associated with breach of the host barriers. The level of disinfection or sterilization is dependent on the intended use of the object: critical items (such as surgical instruments, which contact sterile tissue), semicritical items (such as endoscopes, which contact mucous membranes), and noncritical items (such as stethoscopes, which contact only intact skin) require sterilization, high-level disinfection, and low-level disinfection, respectively. Cleaning must always precede high-level disinfection and sterilization. Users must consider the advantages and disadvantages of specific methods when choosing a disinfection or sterilization process. Adherence to these recommendations should improve disinfection and sterilization practices in health care facilities, thereby reducing infections associated with contaminated patient-care items.

In 1996 in the United States, ~46,500,000 surgical procedures and an even larger number of invasive medical procedures were performed [1]. For example, ~5 million gastrointestinal endoscopies are performed per year [1]. 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. For example, failure to properly disinfect or sterilize equipment may lead to person-to-person transmission via contaminated devices (e.g., *Mycobacterium tuberculosis*–contaminated bronchoscopes).

Achieving disinfection and sterilization through the use of disinfectants and sterilization practices is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because it is not necessary to sterilize all patient-care items, health care policies must identify whether cleaning, disinfection, or sterilization is indicated, primarily on the basis of each item's intended use.

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization [2, 3]. Failure to comply with scientifically based guidelines has led to numerous outbreaks of infection [3–7]. In this article, a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes is presented that is based on the results of well-designed studies assessing the efficacy (via laboratory investigations) and effectiveness (via clinical studies) of disinfection and sterilization procedures.

A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

More than 35 years ago, Spaulding [8] 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 [9–15]. Spaulding believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into 3 categories—namely, critical, semicritical, and noncritical—on the basis of the degree of risk of infection involved in the use of the items. This terminology is employed by the Centers for Disease Control and Prevention (CDC) in the documents "Guidelines for Environmental Infection Control in Health-

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Care Facilities" [16] and "Guideline for Disinfection and Sterilization in Healthcare Facilities" [14].

Critical items. Critical items are those associated with a high risk of infection if the item is contaminated with any microorganism, including bacterial spores. Thus, sterilization of objects that enter sterile tissue or the vascular system is critical, because any microbial contamination could result in disease transmission. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. The items in this category should be purchased as sterile or should be sterilized by steam sterilization, if possible. If the item is heat sensitive, it may be treated with ethylene oxide (ETO) or hydrogen peroxide gas plasma or with liquid chemical sterilants if other methods are unsuitable. Tables 1 and 2 list several germicides that are categorized as chemical sterilants. These include ⩾2.4% glutaraldehyde–based formulations, 1.12% glutaraldehyde with 1.93% phenol/phenate, 7.5% stabilized hydrogen peroxide, 7.35% hydrogen peroxide with 0.23% peracetic acid, ⩾0.2% peracetic acid, and 1.0% hydrogen peroxide with 0.08% peracetic acid. The indicated exposure times are within the range 3–12 h, with the exception of ⩾0.2% peracetic acid (sporicidal time of 12 min at 50°C–56°C) [19]. Use of liquid chemical sterilants is a reliable method of sterilization only if cleaning precedes treatment, which eliminates organic and inorganic material, and if the proper guidelines for concentration, contact time, temperature, and pH are followed. Another limitation to sterilization of devices with liquid chemical sterilants is that the devices cannot be wrapped during processing in the liquid chemical sterilant; thus, maintaining sterility after processing and during storage is impossible. Furthermore, after exposure to the liquid chemical sterilant, devices may require rinsing with water that, in general, is not sterile. Therefore, because of the inherent limitations of the use of liquid chemical sterilants

Table 1. Methods for disinfection and sterilization of patient-care items and environmental surfaces.

Process, method	Level of microbial inactivation	Example(s) (processing time)	Health care application (example)
Sterilization			
High temperature	Destroys all microorganisms, including bacterial spores	Steam (~40 min) and dry heat (1–6 h, depending on temperature)	Heat-tolerant critical (surgical instruments) and semicritical patient-care items
Low temperature	Destroys all microorganisms, including bacterial spores	ETO gas (~15 h) and hydrogen peroxide gas plasma (~50 min)	Heat-sensitive critical and semicritical patient-care items
Liquid immersion	Destroys all microorganisms, including bacterial spores	Chemical sterilants:[a] ⩾2.4% glut (~10 h), 1.12% glut and 1.93% phenol (12 h), 7.35% HP and 0.23% PA (3 h), 7.5% HP (6 h), 1.0% HP and 0.08% PA (8 h), and ⩾0.2% PA (~50 min at 50°C–56°C)	Heat-sensitive critical and semicritical patient-care items that can be immersed
High-level disinfection			
Heat automated	Destroys all microorganisms except high numbers of bacterial spores	Pasteurization (~50 min)	Heat-sensitive semicritical patient-care items (respiratory-therapy equipment)
Liquid immersion	Destroys all microorganisms except high numbers of bacterial spores	Chemical sterilants or high-level disinfectants:[a] >2% glut (20–45 min), 0.55% OPA (12 min), 1.12% glut and 1.93% phenol (20 min), 7.35% HP and 0.23% PA (15 min), 7.5% HP (30 min), 1.0% HP and 0.08% PA (25 min), and 650–675 ppm chlorine (10 min)	Heat-sensitive semicritical patient-care items (GI endoscopes and bronchoscopes)
Intermediate-level disinfection, liquid contact	Destroys vegetative bacteria, mycobacteria, most viruses, and most fungi but not bacterial spores	EPA-registered hospital disinfectants with label claiming tuberculocidal activity, such as chlorine-based products and phenolics (at least 60 s)	Noncritical patient-care items (blood-pressure cuff) or surfaces (bedside table), with visible blood
Low-level disinfection, liquid contact	Destroys vegetative bacteria and some fungi and viruses but not mycobacteria or spores	EPA-registered hospital disinfectants with no tuberculocidal claim, such as chlorine-based products, phenolics, and quaternary ammonium compounds (at least 60 s), or 70%–90% alcohol	Noncritical patient-care items (blood-pressure cuff) or surfaces (bedside table), with no visible blood

NOTE. Modified from [13], [14], and [17]. AER, automated endoscope reprocessing; EPA, Environmental Protection Agency; ETO, ethylene oxide; FDA, US Food and Drug Administration; GI, gastrointestinal; glut, glutaraldehyde; HP, hydrogen peroxide; PA, peracetic acid; OPA, ortho-phthalaldehyde.

[a] Consult FDA-cleared package inserts for information about FDA-cleared contact time and temperature; see text for discussion of why one product (2% glut) is used at reduced exposure (20 min at 20°C). Increasing the temperature by using AER will reduce the contact time (e.g., for OPA, 12 min at 20°C, but 5 min at 25°C in AER). Tubing must be completely filled for high-level disinfection and liquid chemical sterilization. Compatibility of material should be investigated when appropriate (e.g., HP and HP with PA will cause functional damage to endoscopes).

Table 2. Summary of advantages and disadvantages of chemical agents used as chemical sterilants or as high-level disinfectants.

Sterilization method	Advantages	Disadvantages
Peracetic acid and hydrogen peroxide	No activation required Odor or irritation not significant	Concerns regarding compatibility with materials (lead, brass, copper, and zinc) and both cosmetic and functional damage Limited clinical use Potential for eye and skin damage
Glutaraldehyde	Numerous published studies of use Relatively inexpensive Excellent compatibility with materials	Respiratory irritation from glutaraldehyde vapor Pungent and irritating odor Relatively slow mycobactericidal activity Coagulates blood and fixes tissue to surfaces Allergic contact dermatitis
Hydrogen peroxide	No activation required May enhance removal of organic material and organisms No disposal issues No odor or irritation issues Does not coagulate blood or fix tissues to surfaces Inactivates *Cryptosporidium* Published studies of use	Concerns regarding compatibility with materials (brass, zinc, copper, and nickel/silver plating) and both cosmetic and functional damage Serious eye damage with contact
Ortho-phthalaldehyde	Fast-acting high-level disinfectant No activation required Odor not significant Claim of excellent compatibility with materials Claim of not coagulating blood or fixing tissues to surfaces	Stains protein gray (e.g., skin, mucous membranes, clothing, and environmental surfaces) Limited clinical use More expensive than glutaraldehyde Eye irritation with contact Slow sporicidal activity Repeated exposure may result in hypersensitivity in some patients with bladder cancer
Peracetic acid	Rapid sterilization cycle time (30–45 min) Low-temperature (50°C–55°C) liquid-immersion sterilization Environmentally friendly by-products (acetic acid, O_2, and H_2O) Fully automated Single-use system eliminates need for concentration testing Standardized cycle 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, and exposure)	Potential incompatibility with materials (e.g., aluminum anodized coating becomes dull) Used for immersible instruments only Biological indicator may not be suitable for routine monitoring Only one scope or a small number of instruments can be processed in a cycle More expensive (endoscope repairs, operating costs, and purchase costs) than high-level disinfection Serious eye and skin damage (concentrated solution) with contact Point-of-use system; no sterile storage

NOTE. Modified from [18]. All products are effective in the presence of organic soil, are relatively easy to use, and have a broad spectrum of antimicrobial activity (bacteria, fungi, viruses, bacterial spores, and mycobacteria). The above characteristics are documented in the literature; contact the manufacturer of the instrument and sterilant for additional information. All products listed have been cleared by the US Food and Drug Administration (FDA) as chemical sterilants, except for ortho-phthalaldehyde, which is an FDA-cleared high-level disinfectant.

in a nonautomated reprocessor, their use should be restricted to reprocessing critical devices that are heat sensitive and incompatible with other sterilization methods.

Semicritical items. Semicritical items are those that come in contact with mucous membranes or nonintact skin. Respiratory-therapy and anesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, anorectal manometry catheters, and diaphragm-fitting rings are included in this category. These medical devices should be free of all microorganisms (i.e., mycobacteria, fungi, viruses, and bacteria), although small numbers of bacterial spores may be present. In general, intact mucous membranes, such as those of the lungs or the gastrointestinal tract, are resistant to infection by common bacterial spores but are susceptible to other organisms, such as bacteria, mycobacteria, and viruses. The minimum requirement for semicritical items is high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde (OPA), peracetic acid with hydrogen peroxide, and chlorine have been cleared by the US Food and Drug Administration (FDA) [19] and are dependable high-level disinfectants when guidelines for effective germicidal procedures are followed (tables 1 and 2). The exposure time for most high-level disinfectants varies from 10 to 45 min, at 20°C–25°C. Outbreaks of infection continue to occur when ineffective disinfectants, including iodophor, alcohol, and overdiluted glutaraldehyde [5], are used for so-called high-level

disinfection. When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected must also be considered. For example, compatibility testing by Olympus America of 7.5% hydrogen peroxide showed cosmetic and functional changes in the tested endoscopes (Olympus America, personal communication). Similarly, Olympus America does not endorse the use of products containing hydrogen peroxide with peracetic acid, because of cosmetic and functional damage (Olympus America, personal communication).

Semicritical items that will have contact with the mucous membranes of the respiratory or gastrointestinal tract should be rinsed with sterile water, filtered water, or tap water, followed by an alcohol rinse [14, 20, 21]. An alcohol rinse and forced-air drying markedly reduces the likelihood of contamination of the instrument (e.g., endoscopes), most likely by eliminating the wet environment favorable to bacterial growth [21]. After rinsing, items should be dried and then stored in a manner that protects them from damage or contamination. 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 (e.g., rectal probes or anoscopes) or vagina (e.g., vaginal probes) [14].

Noncritical items. Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical." Examples of noncritical items are bedpans, blood-pressure cuffs, crutches, bed rails, linens, bedside tables, patient furniture, and floors. In contrast to critical and some semicritical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. There is virtually no documented risk of transmitting infectious agents to patients via noncritical items [22] when they are used as noncritical items and do not contact nonintact skin and/or mucous membranes. However, these items (e.g., bedside tables or bed rails) could potentially contribute to secondary transmission, by contaminating the hands of health care workers or by contact with medical equipment that will subsequently come in contact with patients [23]. Table 1 lists several low-level disinfectants that may be used for noncritical items. The exposure times for these disinfectants are 60 s or longer.

CURRENT ISSUES IN DISINFECTION AND STERILIZATION

Reprocessing of endoscopes. Physicians use endoscopes to diagnose and treat numerous medical disorders. Although endoscopes are a valuable diagnostic and therapeutic tool in modern medicine and although the incidence of infection associated with their use has been reported to be very low (~1 in 1.8 million procedures) [24], more health care–associated outbreaks of infection have been linked to contaminated endoscopes than to any other medical device [3–5]. To prevent the spread of health care–associated infection, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, and nasopharyngoscopes) must be properly cleaned and, at a minimum, subjected to high-level disinfection after each use. High-level disinfection can be expected to destroy all microorganisms, although a few bacterial spores may survive when high numbers of spores are present.

Recommendations for the cleaning and disinfection of endoscopic equipment have been published and should be strictly followed [14, 20]. Unfortunately, audits have shown that personnel do not adhere to guidelines on reprocessing [25–27] and that outbreaks of infection continue to occur [28, 29]. To ensure that the personnel responsible for reprocessing are properly trained, initial and annual competency testing should be required for each individual who is involved in reprocessing endoscopic instruments [14, 20, 21, 30].

In general, endoscope disinfection or sterilization with a liquid chemical sterilant or high-level disinfectant involves the following 5 steps, which should be performed after leak testing: (1) clean: mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and an enzymatic cleaner; (2) disinfect: immerse endoscope in high-level disinfectant (or chemical sterilant), perfuse disinfectant (which eliminates air pockets and ensures contact of the germicide with the internal channels) into all accessible channels, such as the suction/biopsy channel and the air/water channel, and expose endoscope for the time recommended for specific products; (3) rinse: rinse the endoscope and all channels with sterile water, filtered water (commonly used with automated endoscope reprocessors), or tap water; (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 (e.g., hung vertically).

Unfortunately, there is poor compliance with the recommendations for reprocessing endoscopes. In addition, in rare instances, the scientific literature and recommendations from professional organizations regarding the use of disinfectants and sterilants may differ from claims on the manufacturer's label. One example is the contact time used to achieve high-level disinfection with 2% glutaraldehyde. On the basis of FDA requirements (the FDA regulates liquid sterilants and high-level disinfectants used on critical and semicritical medical devices), manufacturers test the efficacy of their germicide formulations under worst-case conditions (i.e., minimum recommended concentration of the active ingredient) and in the presence of organic soil (typically, 5% serum). The soil represents the or-

ganic loading to which the device is exposed during actual use and that would remain on the device in the absence of cleaning. These stringent test conditions are designed to provide a margin of safety, by assuring that the contact conditions for the germicide provide complete elimination of the test bacteria (e.g., 10^5–10^6 cfu *M. tuberculosis* in organic soil and dried on a scope) if inoculated into the most difficult areas for the disinfectant to penetrate and in the absence of cleaning. However, the scientific data demonstrate that *M. tuberculosis* levels can be reduced by at least 8 $\log_{10}$ cfu with cleaning (reduction of 4 $\log_{10}$ cfu) followed by chemical disinfection for 20 min at 20°C (reduction of 4–6 $\log_{10}$ cfu) [14, 15, 19, 20, 31]. Because of these data, professional organizations (at least 14 worldwide) that have endorsed an endoscope-reprocessing guideline recommend contact with 2% glutaraldehyde for 20 min (or <20 min outside the United States) at 20°C to achieve high-level disinfection, which differs from the recommendation given on the manufacturer's label [20, 32–34].

It is important to emphasize that the FDA tests do not include cleaning, a critical component of the disinfection process. When cleaning has been included in the test methodology, contact with 2% glutaraldehyde for 20 min has been demonstrated to be effective in eliminating all vegetative bacteria.

Inactivation of Creutzfeldt-Jakob disease (CJD) agent. CJD is a degenerative neurologic disorder in humans, with an incidence in the United States of ~1 case/million population/year [35]. CJD is thought to be caused by a proteinaceous infectious agent, or prion. CJD is related to other human transmissible spongiform encephalopathies (TSEs), such as kuru (now eradicated), Gertsmann-Straussler-Sheinker syndrome (1 case/40 million population/year), and fatal insomnia syndrome (<1 case/40 million population/year). The agents of CJD and other TSEs exhibit an unusual resistance to conventional chemical and physical decontamination methods. Because the CJD agent is not readily inactivated by conventional disinfection and sterilization procedures and because of the invariably fatal outcome of CJD, the procedures for disinfection and sterilization of the CJD prion have been both conservative and controversial for many years.

The current recommendations consider inactivation data but also use epidemiological studies of prion transmission, infectivity of human tissues, and efficacy of removing proteins by cleaning. On the basis of scientific data, only critical devices (e.g., surgical instruments) and semicritical devices contaminated with high-risk tissue (i.e., brain, spinal cord, or eye tissue) from high-risk patients (e.g., known or suspected infection with CJD or other prion disease) require special prion reprocessing. When high-risk tissues, high-risk patients, and critical or semicritical medical devices are involved, one of the following methods should be used: cleaning of the device and sterilization using a combination of sodium hydroxide and autoclaving [36] (e.g., immerse in 1N NaOH for 1 h, remove and rinse in water, and then transfer to an open pan for autoclaving for 1 h [at 121°C in a gravity displacement sterilizer or at 134°C in a porous or prevacuum sterilizer]); autoclaving for 18 min at 134°C in a prevacuum sterilizer; or autoclaving for 1 h at 132°C in a gravity displacement sterilizer) [14, 37]. The temperature should not exceed 134°C, because the effectiveness of autoclaving may decline as the temperature is increased (e.g., to 136°C or 138°C) [38]. Prion-contaminated medical devices that are impossible or difficult to clean should be discarded. Flash sterilization (i.e., steam sterilization of an unwrapped item for 3 min at 132°C) should not be used for reprocessing. To minimize environmental contamination, noncritical environmental surfaces should be covered with plastic-backed paper; when contaminated with high-risk tissues, the paper should be properly discarded. Noncritical environmental surfaces (e.g., laboratory surfaces) contaminated with high-risk tissues should be cleaned and then spot decontaminated with a 1:10 dilution of hypochlorite solution [37].

Emerging pathogens, antibiotic-resistant bacteria, and bioterrorism agents. Emerging pathogens are of growing concern to the general public and infection-control professionals. Relevant pathogens include *Cryptosporidium parvum, Helicobacter pylori, Escherichia coli* O157:H7, HIV, hepatitis C virus, rotavirus, multidrug-resistant *M. tuberculosis,* human papillomavirus, and nontuberculosis mycobacteria (e.g., *Mycobacterium chelonae*). Similarly, recent publications have highlighted concern about the potential for biological terrorism [39]. The CDC has categorized several agents as "high priority" because they can be easily disseminated or transmitted by person-to-person contact, can cause high mortality, and are likely to cause public panic and social disruption [40]. These agents include *Bacillus anthracis* (anthrax), *Yersinia pestis* (plague), variola major (smallpox), *Francisella tularensis* (tularemia), filoviruses (Ebola and Marburg [hemorrhagic fever]), and arenaviruses (Lassa [Lassa fever] and Junin [Argentine hemorrhagic fever]) and related viruses [40].

With rare exceptions (e.g., human papillomavirus), the susceptibility of each of these pathogens to chemical disinfectants or sterilants has been studied, and all of these pathogens (or surrogate microbes, such as feline calicivirus for Norwalk virus, vaccinia for variola [41], and *Bacillus atrophaeus* [formerly *Bacillus subtilis*] for *B. anthracis*) have been found to be susceptible to currently available chemical disinfectants or sterilants [42]. Standard sterilization and disinfection procedures for patient-care equipment (as recommended in this article) are adequate for sterilization or disinfection of instruments or devices contaminated with blood or other body fluids from persons infected with bloodborne pathogens, emerging pathogens, or bioterrorism agents, with the exception of prions (see previous section). No changes in procedures for cleaning, disinfecting,

Table 3. Summary of advantages and disadvantages of commonly used sterilization technologies.

Sterilization method	Advantages	Disadvantages
Steam	Nontoxic to patient, staff, and environment Cycle is easy to control and monitor Rapidly microbicidal Least affected by organic/inorganic soils, among sterilization processes listed Rapid cycle time Penetrates medical packing and device lumens	Deleterious for heat-sensitive instruments Microsurgical instruments damaged by repeated exposure May leave instruments wet, causing them to rust Potential for burns
Hydrogen peroxide gas plasma	Safe for the environment Leaves no toxic residuals Cycle time is 45–73 min, and no aeration is necessary Used for heat- and moisture-sensitive items, because process temperature is <50°C Equipment is simple to operate, install (208 V outlet), and monitor Compatible with most medical devices Equipment requires electrical outlet only	Cellulose (paper), linens, and liquids cannot be processed Sterilization chamber is small (~3.5–7.3 ft^3) Endoscope or medical-device restrictions based on lumen internal diameter and length (see manufacturer's recommendations) Requires synthetic packaging (polypropylene wraps or polyolefin pouches) or special container tray Hydrogen peroxide may be toxic at levels >1 ppm TWA
100% ETO	Penetrates packaging materials and device lumens Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure Equipment is simple to operate and monitor Compatible with most medical materials	Requires aeration time to remove ETO residue Sterilization chamber is small (~4–8.8 ft^3) ETO is toxic, a carcinogen, and flammable ETO emission regulated by states, but catalytic cell removes 99.9% of ETO and converts it to CO_2 and H_2O ETO cartridges should be stored in flammable liquid–storage cabinet Lengthy cycle and aeration time
ETO mixture[a]	Penetrates medical packaging and many plastics Compatible with most medical materials Cycle is easy to control and monitor	Some states (e.g., CA, NY, and MI) require ETO-emission reduction of 90%–99.9% CFC (inert gas that eliminates explosion hazard) banned in 1995 Potential hazards to staff and patients Lengthy cycle and aeration time ETO is toxic, a carcinogen, and flammable
Peracetic acid	Rapid cycle time (30–45 min) Low-temperature (50°C–55°C) liquid-immersion sterilization Environmentally friendly by-products Sterilant flows through endoscope, which facilitates salt, protein, and microbe removal	Point-of-use system; no sterile storage Biological indicator may not be suitable for routine monitoring Used for immersible instruments only Some incompatibility with materials (e.g., aluminum anodized coating becomes dull) Only 1 scope or a small number of instruments processed in a cycle Potential for serious eye and skin damage (concentrated solution) with contact Must use connector between system and scope to ensure infusion of sterilant to all channels

NOTE. Modified from [46]. CFC, chlorofluorocarbon; ETO, ethylene oxide; HCFC, hydrochlorofluorocarbon; TWA, time-weighted average.

[a] 8.6% ETO and 91.4% HCFC; 10% ETO and 90% HCFC; or 8.5% ETO and 91.5% CO_2.

or sterilizing need to be made [14, 15]. In addition, there are no data to show that antibiotic-resistant bacteria (e.g., methicillin-resistant *Staphylococcus aureus,* vancomycin-resistant *Enterococcus faecium,* and multidrug-resistant *M. tuberculosis*) are less sensitive to liquid chemical germicides than are antibiotic-sensitive bacteria at currently used germicide contact conditions and concentrations [15, 43, 44].

Advances in disinfection and sterilization methods. In the past several years, new methods of disinfection and sterilization have been introduced in health care settings. OPA is a chemical sterilant that received FDA clearance in October 1999. It contains 0.55% 1,2-benzenedicarboxaldehyde. In vitro studies have demonstrated excellent microbicidal activity [14, 15]. For example, Gregory et al. [45] demonstrated that OPA has shown superior mycobactericidal activity (reduction of 5 $\log_{10}$ in 5 min), when compared with glutaraldehyde. The advantages, disadvantages, and characteristics of OPA are listed in table 2 [15].

The FDA recently cleared a liquid high-level disinfectant (superoxidized water) that contains 650–675 ppm free chlorine and a new sterilization system using ozone. Because there are limited data in the scientific literature for assessing the antimicrobial activity or material compatibility of these processes, they have not yet been integrated into clinical practice in the United States [14].

Several methods are used to sterilize patient-care items in health care, including steam sterilization, ETO, hydrogen peroxide gas plasma, and a peracetic acid–immersion system. The advantages and disadvantages of these systems are listed in table 3 [14].

New sterilization technology based on plasma was patented in 1987 and has been marketed in the United States since 1993. Gas plasmas have been referred to as the fourth state of matter (i.e., liquid, solid, gas, and gas plasma). Gas plasmas are generated in an enclosed chamber in a deep vacuum, by using radio frequency or microwave energy to excite the gas molecules and produce charged particles, many of which are in the form of free radicals. This process has the ability to inactivate a broad spectrum of microorganisms, including resistant bacterial spores. Studies have been conducted against vegetative bacteria (including mycobacteria), yeasts, fungi, viruses, and bacterial spores [14]. The effectiveness of all sterilization processes can be altered by lumen length, lumen diameter, inorganic salts, and organic materials [14].

CONCLUSION

When properly used, disinfection and sterilization can ensure the safe use of invasive and noninvasive medical devices. The method of disinfection and sterilization depends on the intended use of the medical device: critical items (those that contact sterile tissue) must be sterilized prior to use; semicritical items (those that contact mucous membranes or nonintact skin) must undergo high-level disinfection; and noncritical items (those that contact intact skin) should undergo low-level disinfection. Cleaning should always precede high-level disinfection and sterilization. Current disinfection and sterilization guidelines must be strictly followed.

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