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Disinfection and sterilization: An overview

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All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. The level of disinfection or sterilization is dependent on the intended use of the object: critical (items that contact sterile tissue such as surgical instruments), semicritical (items that contact mucous membrane such as endoscopes), and noncritical (devices that contact only intact skin such as stethoscopes) items require sterilization, high-level disinfection, and low-level disinfection, respectively. Cleaning must always precede high-level disinfection and sterilization.

All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic microbes leading to infection. Failure to properly disinfect or sterilize equipment may lead to transmission via contaminated medical and surgical devices (eg, *Mycobacterium tuberculosis*-contaminated bronchoscopes). This paper will capsulize other papers on this subject as well as provide updated information of newer sterilization (eg, hydrogen peroxide vapor, ozone) and disinfection (eg, improved hydrogen peroxide) technologies.[1-4]

A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

Over 45 years ago, Earle H. Spaulding[5] 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.[1,6-8] 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 high-level disinfection), and noncritical (comes in contact with intact skin and requires low-level disinfection). These categories and the methods to achieve sterilization, high-level disinfection, and low-level disinfection are summarized in Table 1. 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.[9]

Critical items

Critical items are so called because of the high risk of infection if such an item is contaminated with any microorganism, including bacterial spores. Thus, it is critical that objects that enter sterile tissue or the vascular system be sterile 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 be sterilized by steam sterilization if possible. If heat sensitive, the object may be treated with ethylene oxide, hydrogen peroxide gas plasma, ozone, or vaporized hydrogen peroxide or by liquid chemical sterilants if other methods are unsuitable. Tables 1 to 3 list sterilization processes and liquid chemical sterilants. With the exception of 0.2%

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

Process	Level of microbial inactivation	Method	Examples (with processing times)	Health care application (examples)
Sterilization	Destroys all microorganisms, including bacterial spores	High temperature Low temperature Liquid immersion	Steam (~40 min), dry heat (1-6 hr depending on temperature) Ethylene oxide gas (~15 hr), hydrogen peroxide gas plasma (28-52 min), ozone (~4 hr), hydrogen peroxide vapor (55 min) Chemical sterilants†: >2% glut (~10 hr); 1.12% glut with 1.93% phenol (12 hr); 7.35% HP with 0.23% PA (3 hr); 8.3% HP with 7.0% PA (5 hr); 7.5% HP (6 hr); 1.0% HP with 0.08% PA (8 hr); ≥0.2% PA (12 min at 50°C-56°C)	Heat-tolerant critical (surgical instruments) and semicritical patient care items Heat-sensitive critical and semicritical patient care items Heat-sensitive critical and semicritical patient care items that can be immersed
High-level disinfection (HLD)	Destroys all micro-organisms except high numbers of bacterial spores	Heat automated Liquid immersion	Pasteurization (65°C-77°C, 30 min) Chemical sterilants/HLDs†: >2% glut (20-45 min); 0.55% OPA (12 min); 1.12% glut with 1.93% phenol (20 min); 7.35% HP with 0.23% PA (15 min); 7.5% HP (30 min); 1.0% HP with 0.08% PA (25 min); 400-450 ppm chlorine (10 min); 2.0% HP (8 min); 3.4% glut with 26% isopropanol (10 min)	Heat-sensitive semicritical items (eg, respiratory therapy equipment) Heat-sensitive semicritical items (eg, GI endoscopes, bronchoscopes, endocavitary probes)
Intermediate-level disinfection	Destroys vegetative bacteria, mycobacteria, most viruses, most fungi but not bacterial spores	Liquid contact	EPA-registered hospital disinfectant with label claim regarding tuberculocidal activity (eg, chlorine-based products, phenolics, improved hydrogen peroxide exposure times at least 1 min)	Noncritical patient care item (blood pressure cuff) or surface with visible blood
Low-level disinfection	Destroys vegetative bacteria, some fungi and viruses but not mycobacteria or spores	Liquid contact	EPA-registered hospital disinfectant with no tuberculocidal claim (eg, chlorine-based products, phenolics, improved hydrogen peroxide, quaternary ammonium compounds-exposure times at least 1 min) or 70%-90% alcohol	Noncritical patient care item (blood pressure cuff) or surface (bedside table) with no visible blood

EPA, Environmental Protection Agency; *FDA*, Food and Drug Administration; *GI*, gastrointestinal; *glut*, glutaraldehyde; *HP*, hydrogen peroxide; *OPA*, ortho-phthalaldehyde; *PA*, peracetic acid; *ppm*, parts per million.
*Modified from Rutala and Weber,[4] Rutala and Weber,[7] and Kohn et al.[15]
†Consult the FDA cleared package insert for information about the cleared contact time and temperature, and see reference Rutala and Weber[1] for discussion of why one product is used at a reduced exposure time (2% glutaraldehyde at 20 min, 20°C). Increasing the temperature using an automated endoscope reprocess (AER) will reduce the contact time (eg, OPA 12 min at 20°C but 5 min at 25°C in AER). Exposure temperatures for some high-level disinfectants above varies from 20°C to 25°C; check FDA-cleared temperature conditions.[10] Tubing must be completely filled for high-level disinfection and liquid chemical sterilization. Material compatibility should be investigated when appropriate (eg, HP and HP with PA will cause functional damage to endoscopes).

peracetic acid (12 minutes at 50°C-56°C), the indicated exposure times for liquid chemical sterilants range from 3 to 12 hours.[10] Liquid chemical sterilants can be relied on to produce sterility only if cleaning, which eliminates organic and inorganic material, precedes treatment and if proper guidelines as to concentration, contact time, temperature, and pH are met. Another limitation to sterilization of devices with liquid chemical sterilants is that the devices cannot be wrapped during processing in a liquid chemical sterilant; thus, it is impossible to maintain sterility following processing and during storage. Furthermore, devices may require rinsing following exposure to the liquid chemical sterilant with water that generally is not sterile. Therefore, because of the inherent limitations of using liquid chemical sterilants 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, gastrointestinal endoscopes, bronchoscopes, laryngoscopes, esophageal manometry probes, anorectal manometry catheters, endocavitary probes, prostate biopsy probes, 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, bacteria), although small numbers of bacterial spores may be present. Intact mucous membranes, such as those of the lungs or the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, peracetic acid with hydrogen peroxide, and chlorine are cleared by the Food and Drug Administration[10] and are dependable high-level disinfectants provided that the factors influencing germicidal procedures are met (Tables 1 and 2). The exposure time for most high-level disinfectants varies from 8 to 45 minutes at 20°C to 25°C. The reprocessing of semicritical items, such as endoscopes, laryngoscopes, and nasopharyngoscopes are discussed in detail in another paper in this Special Issue (Rutala/Weber).

Because semicritical equipment has been associated with reprocessing errors that result in patient lookback and patient notifications, it is essential that control measures be instituted to prevent patient exposures.[11] Before new equipment (especially semicritical equipment as the margin of safety is less than that for sterilization)[12] is used for patient care on more than 1 patient, reprocessing procedures for that equipment should be developed. Staff should receive training on the safe use and reprocessing of the equipment and be competency tested. Infection control rounds or audits should be conducted annually in all clinical areas that reprocess critical and semicritical devices to ensure adherence to the reprocessing standards and policies. Results of

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/hydrogen peroxide	• No activation required • Odor or irritation not significant	• Material compatibility concerns (lead, brass, copper, zinc) both cosmetic and functional • Limited clinical experience • 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
Hydrogen peroxide	• 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* • Use studies published	• Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional • Serious eye damage with contact
Ortho-phthalaldehyde	• 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	• Stains protein gray (eg, skin, mucous membranes, clothing, and environmental surfaces) • Limited clinical experience • 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 cytsoscopy
Peracetic acid	• Rapid sterilization cycle time (30-45 min) • 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 • 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, exposure)	• Potential material incompatibility (eg, aluminum anodized coating becomes dull) • Used for immersible instruments only • One scope or a small number of instruments can be processed in a cycle • More expensive (endoscope repairs, operating costs, purchase costs) than high-level disinfection • 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 • Antimicrobial claims not independently verified • Organic material resistance concerns because of limited data

AER, Automated endoscope reprocessor; *FDA*, Food and Drug Administration; *HLD*, high-level disinfectants; *OPA*, ortho-phthalaldehyde.
NOTE. Modified from Rutala and Weber,[1] Rutala and Weber,[3] Rutala and Weber,[4] Rutala and Weber,[16] and Rutala and Weber.[17]
*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 above characteristics are documented in the literature; contact the manufacturer of the instrument and sterilant for additional information. All products listed above are FDA-cleared as chemical sterilants except OPA, which is an FDA-cleared, high-level disinfectant.

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 2 weeks.

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[13] when they are used as noncritical items and do not contact nonintact skin and/or mucous membranes. However, these items (eg, bedside tables, bed rails) could potentially contribute to secondary transmission by contaminating hands of health care workers or by contact with medical equipment that will subsequently come in contact with patients.[14] Table 1 lists several low-level disinfectants that may be used for noncritical items. The exposure time for low-level disinfection of noncritical items is at least 1 minute.

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

Sterilization method	Advantages	Disadvantages
Steam	• Nontoxic to patient, staff, environment • Cycle easy to control and monitor • Rapidly microbicidal • Least affected by organic/inorganic soils among sterilization processes listed • Rapid cycle time • Penetrates medical packing, 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 ≥28 minutes and no aeration necessary • Used for heat- and moisture-sensitive items since process temperature <50°C • Simple to operate, install (208 V outlet), and monitor • Compatible with most medical devices • Only requires electrical outlet	• Cellulose (paper), linens, and liquids cannot be processed • Endoscope or medical device restrictions based on lumen internal diameter and length (see manufacturer's recommendations) • Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and special container tray • Hydrogen peroxide may be toxic at levels greater than 1 ppm TWA
100% Ethylene oxide	• Penetrates packaging materials, device lumens • Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure • Simple to operate and monitor • Compatible with most medical materials	• Requires aeration time to remove ETO residue • ETO is toxic, carcinogenic, 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/aeration time
ETO mixtures 8.6% ETO/91.4% HCFC 10% ETO/90% HCFC 8.5% ETO/91.5% CO_2	• Penetrates medical packaging and many plastics • Compatible with most medical materials • Cycle easy to control and monitor	• Some states (eg, CA, NY, 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/aeration time • ETO is toxic, carcinogenic, and flammable
Vaporized hydrogen peroxide	• Safe for the environment and health care worker • It leaves no toxic residue; no aeration necessary • Fast cycle time, 55 min • Used for heat and moisture sensitive items (metal and nonmetal devices)	• Medical devices restrictions based on lumen internal diameter and length; see manufacturer's recommendations, eg, stainless steel lumen 1-mm diameter, 125-mm length • Not used for liquid, linens, powders, or any cellulose materials • Requires synthetic packaging (polypropylene) • Limited materials compatibility data • Limited clinical use and comparative microbicidal efficacy data
Ozone	• Used for moisture and heat-sensitive items • Ozone generated from oxygen and water (nontoxic) • No aeration needed because of no toxic by-products • FDA cleared for metal and plastic instruments including some instruments with lumens	• Limited clinical use (no published data on material compatibility/penetrability/organic material resistance) and limited microbicidal efficacy data

CFC, Chlorofluorocarbon; *ETO*, ethylene oxide; *FDA*, Food and Drug Administration; *HCFC*, hydrochlorofluorocarbon; *TWA*, time-weighted average.
NOTE. Modified from Rutala and Weber,[3] Rutala and Weber,[4] Rutala and Weber,[17] and Rutala and Weber.[18]

CONCLUSION

When properly used, disinfection and sterilization can ensure the safe use of invasive and noninvasive medical devices. Cleaning should always precede high-level disinfection and sterilization. Strict adherence to current disinfection and sterilization guidelines is essential to prevent patient infections and exposures to infectious agents.

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