Disinfection, sterilization, and antisepsis: An overview

William A. Rutala PhD, MPH, CIC^{a,*}, David J. Weber MD, MPH^{a,b}

^a Division of Infectious Diseases, University of North Carolina School of Medicine, Chapel Hill, NC
^b Department of Hospital Epidemiology, University of North Carolina Hospitals, Chapel Hill, NC

Key Words: Disinfection Sterilization Antisepsis 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 membranes, 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.

Antiseptics are essential to infection prevention as part of a hand hygiene program, as well as other uses, such as surgical hand antisepsis and preoperative skin preparation.

Each year in the United States, there are approximately 53,000,000 outpatient surgical procedures and 46,000,000 inpatient surgical procedures.¹ For example, there are at least 18 million gastrointestinal endoscopies per year.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 infection. Failure to properly disinfect or sterilize medical devices and surgical instruments may lead to transmission via these devices (eg, endoscopes contaminated with carbapenem-resistant *Enterobacteriaceae*).³

Achieving disinfection and sterilization by disinfectants and sterilization practices is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Health care policies must identify whether cleaning, disinfection, or sterilization is indicated based primarily on the items' intended use. This article will capsulize and update other articles on this subject as well as provide updated information regarding newer sterilization, disinfection, and antisepsis technologies and practices.⁴⁻⁷

A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

Fifty years ago, Spaulding⁸ devised a rational approach to disinfection and sterilization of patient care items and equipment. This

E-mail address: brutala@med.unc.edu (W.A. Rutala).

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 and sterilization.⁴⁻¹⁰ 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 or nonintact skin 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 prions, viruses, mycobacteria, and protozoa that challenge the current definitions and expectations of high- and low-level disinfection.¹¹

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, and implants. The items in this category should be purchased as sterile or sterilized by steam sterilization, if possible. If heat-sensitive, the object may be treated with ethylene oxide, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, hydrogen peroxide vapor and ozone, or liquid chemical

^{*} Address correspondence to William A. Rutala, PhD, MPH, CIC, Division of Infectious Diseases, University of North Carolina School of Medicine, 130 Mason Farm Rd, Bioinformatics Bldg, CB #7030, Chapel Hill, NC 27514-7030.

Conflicts of interest: Dr. Rutala is a consultant to PDI and ASP. Dr. Weber is a consultant for PDI and Germitec.

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 h, depending on temperature) Ethylene oxide gas (~15 h), HP gas plasma	Heat-tolerant critical (surgical instru- ments) and semicritical patient care items		
			(28-38 min, NX), HP and ozone (46-70 min, VP4), HP vapor (28-55 min, V-PRO maX)	Heat-sensitive critical and semicritical patient care items		
			Chemical sterilants [‡] : >2% glut (\sim 10 h at	Heat-sensitive critical and semicritical		
			20°C-25°C), 1.12% glut with 1.93% phenol	patient care items that can be		
			(12 h at 25°C), 7.35% HP with 0.23% PA (3 h	immersed		
			at 20°C), 7.5% HP (6 h at 20°C), 1.0% HP			
			with 0.08% PA (8 h at 20°C), \sim 0.2% PA (12 min at 50°C 56°C)			
High-level	Destroys all micro-	Heat-automated	(12 min at 50°C-56°C) Pasteurization (65°C-77°C, 30 min)	Heat-sensitive semicritical items (eg,		
disinfection	organisms except some bacterial spores	Liquid immersion	Chemical sterilants/HLDs [‡] : >2% glut (20-90 min	respiratory therapy equipment)		
			at 20°C-25°C), >2% glut (5 min at 35°C), 0.55%	Heat-sensitive semicritical items (eg,		
			OPA (12 min at 20°C), 1.12% glut with 1.93%	GI endoscopes, bronchoscopes, endo-		
			phenol (20 min at 25°C), 7.35% HP with 0.23%	cavitary probes)		
			PA (15 min at 20°C), 7.5% HP (30 min at 20°C), 1.0% HP with 0.08% PA (25 min at 20°C), 650-			
			675 free chlorine (10 min at 25°C), 2.0% HP			
			(8 min at 20°C), 3.4% glut with 20.1% isopropa-			
			nol (5 min at 25°C)			
Low-level	Destroys vegetative	Liquid contact	EPA-registered hospital disinfectant with no	Noncritical patient care items (eg, blood		
disinfection	bacteria and some fungi and viruses,		tuberculocidal claim (eg, chlorine-based prod- ucts, phenolics, improved HP, HP plus PA,	pressure cuffs) or surfaces (eg, bedside tables) with no visible blood		
	but not mycobac-		quats, quats plus alcohol, or 70%-90% alcohol.	(abies) with no visible blood		
	teria or spores		Exposure time $\geq 1 \text{ min}$			

AER, automated endoscope reprocessor; *EPA*, Environmental Protection Agency; *FDA*, Food and Drug Administration; *GI*, gastrointestinal; *glut*, glutaraldehyde; *HLD*, high-level disinfectant; *HP*, hydrogen peroxide; *NX*, next generation; *OPA*, ortho-phthalaldehyde; *PA*, peracetic acid; *quats*, quaternary ammonium compounds. *Modified from Rutala and Weber^{4–10,46-48} and Kohn et al.⁴⁹

[†]Prions (eg, Creutzfeldt-Jakob disease) exhibit an unusual resistance to conventional chemical and physical decontamination methods and are not readily inactivated by conventional sterilization procedures.⁵⁰

¹Consult the FDA-cleared package insert for information about the cleared contact time and temperature and see reference 5 for discussion regarding why >2% glut products are used at a reduced exposure time (2% glut at 20 min, 20°C). Increasing the temperature using an AER will reduce contact time (eg, OPA 12 min at 20°C but 5 min at 25°C in AER). Exposure temperatures for some HLDs listed above vary from 20°C to 25°C; check FDA-cleared temperature conditions.²⁴ 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 may cause functional damage to endoscopes). Intermediate-level disinfectants destroy vegetative bacteria, mycobacteria, most viruses, and most fungi, but not spores, and may include chlorine-based products, phenolics, and improved HP. Intermediate-level disinfectants are not included in Table 1, as there is no device or surface for which intermediate-level disinfection.

sterilants, if other methods are unsuitable. Tables 1-3 list sterilization processes, high-level disinfectants, and liquid chemical sterilants and the advantages and disadvantages of each. With the exception of 0.2% peracetic acid (12 minutes at 50°C-56°C), the indicated exposure times for liquid chemical sterilants range from 3 to 12 hours. 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, in general, is not sterile. Therefore, because of the inherent limitations of using liquid chemical sterilants in a nonautomated (or automated) reprocessor, their use should be restricted to reprocessing critical devices that are heat-sensitive and incompatible with other sterilization methods.

Sterilization technologies can be relied on to produce sterility only if cleaning—to eliminate organic and inorganic material as well as microbial load—precedes treatment.¹²⁻¹⁴ Other issues sterile reprocessing and operating room professionals must deal with when reprocessing instruments include weight limits for instrument trays, wet packs, packaging, loaned instruments, cleaning monitoring, and water quality.^{14,15}

In May 2015, the Food and Drug Administration (FDA) convened a panel to discuss recent reports and epidemiologic investigations of the

transmission of infections associated with the use of duodenoscopes in endoscopic retrograde cholangiopancreatography procedures.¹⁶ After presentations from industry, professional societies, and invited speakers, the panel made several recommendations, to include reclassifying duodenoscopes based on the Spaulding classification from semicritical to critical to support the shift from high-level disinfection to sterilization. This could be accomplished by shifting from high-level disinfection for duodenoscopes to sterilization and modifying the Spaulding definition of critical items from "objects which enter sterile tissue or the vascular system or through which blood flows should be sterile" to "objects which directly or indirectly (ie, via a mucous membrane such as duodenoscope) enter normally sterile tissue of the vascular system or through which blood flows should be sterile."^{3,17-19} It is noteworthy that in the Spaulding scheme, which identifies how an object should be disinfected or sterilized, he stated that mucous membranes should be intact and that sterilization of semicritical items is desirable.⁸ Implementation of this recommendation requires sterilization technology that achieves a sterility assurance level of 10^{-6} of complex medical instruments such as duodenoscopes. Ideally, this shift would eventually involve not only endoscopes that indirectly enter normally sterile tissue (eg, duodenoscopes, bronchoscopes) but also other semicritical devices (eg, gastrointestinal endoscopes).¹

Semicritical items

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

Summary of advantages and disadvantages of chemical agents used as chemical sterilants or HLDs*

Sterilization method	Advantages	Disadvantages		
PA/HP	• 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		
Glut	Numerous use studies published	 Respiratory irritation from glut vapor 		
	Relatively inexpensive	• Pungent and irritating odor		
	• Excellent material compatibility	 Relatively slow mycobactericidal activity (unless other dis- infectants added, eg, phenolics, alcohol) Coagulates blood and fixes tissue to surfaces 		
		Allergic contact dermatitis		
		ACGIH recommends limiting employee exposure to ceiling concentration of 0.05 ppm		
HP (standard)	 No activation required 	 Material compatibility concerns (brass, zinc, copper, and 		
	 May enhance removal of organic matter and organisms 	nickel/silver plating), both cosmetic and functional		
	 No disposal issues 	 Serious eye damage with contact 		
	 No odor or irritation issues 			
	Does not coagulate blood or fix tissues to surfaces			
	Inactivates Cryptosporidium at 6%-7.5%			
	Use studies published			
OPA	• Fast-acting HLD	• Stains protein gray (eg, skin, mucous membranes, clothing,		
	No activation required	environmental surfaces)		
	 Odor not significant Excellent materials compatibility claimed 	 More expensive than glut Eye irritation with contact 		
	 Does not coagulate blood or fix tissues to surfaces (claimed) 	Slow sporicidal activity		
	Relatively rapid mycobactericidal activity	Anaphylactic reactions to OPA in bladder cancer patients		
	- Relatively rupid mycobactericidal activity	with repeated exposure to OPA through cystoscopy		
PA	• Standardized cycle (eg, liquid chemical sterilant processing system using	Potential material incompatibility (eg, aluminum anodized		
	PA, rinsed with extensively treated potable water)	coating becomes dull)		
	• Low-temperature (50°C-55°C) liquid immersion sterilization	• Used for immersible instruments only		
	• Environmentally friendly by-products (acetic acid, O ₂ , H ₂ O)	• Biological indicator may not be suitable for routine		
	Fully automated	monitoring		
	 Single-use system eliminates need for concentration testing May enhance removal of organic material and endotoxin 	 One scope or a small number of instruments can be processed in a cycle 		
	 No adverse health effects to operators under normal operating condi- tions 	 More expensive (endoscope repairs, operating costs, purchase costs) than high-level disinfection 		
	 Compatible with many materials and instruments 	 Serious eye and skin damage (concentrated solution) with 		
	Does not coagulate blood or fix tissues to surfaces	contact		
	Sterilant flows through scope, facilitating salt, protein, and microbe removal	 Point-of-use system, no sterile storage AER using 0.2% PA not FDA cleared as sterilization process 		
	• Rapidly sporicidal	but as HLD		
	 Provides procedure standardization (constant dilution, perfusion of channel, temperature, exposure) 			
Improved HP (2.0%), HLD	 No activation required No odor 	 Material compatibility concerns because of limited clinical experience 		
	Nonstaining	Organic material resistance concerns because of limited dat		
	No special venting requirements			
	Manual or automated applications			
	• 12-month shelf life, 14-day reuse			
	• 8 min at 20°C HLD claimed			

NOTE. 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 HLD/chemical sterilant for additional information. All products listed above are FDA cleared as chemical sterilants, except OPA and 2% accelerated HP, which are FDA-cleared HLDs.

ACGIH, American Conference of Governmental Industrial Hygienists; AER, automated endoscope reprocessor; FDA, Food and Drug Administration; glut, glutaraldehyde; HLD, highlevel disinfectant; HP, hydrogen peroxide; OPA, ortho-phthalaldehyde; PA, peracetic acid.

*Modified from Rutala and Weber.^{4-10,46}

anesthesia equipment, some endoscopes, laryngoscope blades and handles,^{20,21} esophageal manometry probes, endocavitary probes, nasopharyngoscopes, prostate biopsy probes,²² infrared coagulation devices,²³ anorectal manometry catheters, cystoscopes, and diaphragm fitting rings are included in this category.²⁰ These medical devices should be free of all microorganisms, although small numbers of bacterial spores may be present. FDA's definition of high-level disinfection is a sterilant used for a shorter contact time to achieve at least a 6 log₁₀ kill of an appropriate *Mycobacterium* species. Cleaning followed by high-level disinfection should eliminate all pathogens capable of causing infection.

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, hypochlorite (via superoxidized water), and peracetic acid with hydrogen peroxide are cleared by the FDA²⁴ and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (Tables 1 and 2). The exposure time for most high-level disinfectant varies from 8 to 45 minutes at 20°C-25°C. When a disinfectant is selected for use with certain patient care items, the chemical compatibility after extended use with the items to be disinfected must also be considered. The reprocessing of semicritical items such as endoscopes, laryngoscopes, and

Sterilization method	Advantages	Disadvantages			
Steam	Nontoxic to patient, staff, environment	Deleterious to heat-sensitive instruments			
	Cycle easy to control and monitor	 Microsurgical instruments damaged by repeated exposure 			
	Rapidly microbicidal	May leave instruments wet, causing them to rust			
	Least affected by organic/inorganic soils among sterilization pro- cesses listed	Potential for burns			
	Rapid cycle time				
	 Penetrates medical packing, device lumens 				
HP gas plasma	 Safe for the environment and health care personnel 	 Cellulose (paper), linens, and liquids cannot be processed 			
	Leaves no toxic residuals	 Endoscope and other medical device restrictions based on lumen internal diameter and length (eg, single- and dual-channel device with stainless ster 			
	 Cycle time 28-38 min and no aeration necessary 				
	 Used for heat- and moisture-sensitive items since process tem- perature <50°C 	lumen that is ≥1.0 mm in internal diameter and ≤150 mm in length; see manufacturer's recommendations)			
	• Simple to operate, install (208-V outlet), and monitor	Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and			
	Compatible with most medical devices	special container tray			
	Requires only electrical outlet	• HP may be toxic at levels greater than 1 ppm TWA			
	• Microbicidal efficacy data	Organic matter reduces microbicidal activity			
100% ETO	Penetrates packaging materials, device lumens	Requires aeration time to remove ETO residue			
	• Single-dose cartridge and negative-pressure chamber minimize	• ETO is toxic, a probable carcinogen, and flammable			
	the potential for gas leak and ETO exposure • Simple to operate and monitor	 ETO emissions regulated by states, but catalytic cell removes 99.9% of ETO and converts it to CO₂ and H₂O 			
	Compatible with most medical materials	• ETO cartridges should be stored in flammable liquid storage cabinet			
		• Lengthy cycle/aeration time			
		Organic matter reduces microbicidal activity			
Vaporized HP	 Safe for environment and health care personnel Leaves no toxic residue, no aeration necessary 	 Medical device restrictions based on lumen internal diameter and length (eg single-channel device with stainless steel lumen that is ≥0.7 mm in internal 			
	Cycle time 28-55 min	diameter and ≤500 mm in length; see manufacturer's recommendations)			
	Used for heat- and moisture-sensitive items (metal and non-	• Not used for liquid, linens, powders, or any cellulose materials			
	metal devices)	 Requires synthetic packaging (polypropylene) 			
		Limited materials compatibility data			
		Limited clinical use data			
		 Limited comparative microbicidal efficacy data 			
		Organic matter reduces microbicidal activity			
HP and ozone	 Safe for environment and health care personnel 	• Endoscope and other medical device restrictions based on lumen internal			
	Uses dual sterilants, HP and ozone	diameter and length (eg, single- and dual-channel device with stainless stee			
	 No aeration needed because of no toxic by-products 	lumen that is ≥0.7 mm in internal diameter and ≤500 mm in length; see			
	Compatible with common medical devices	manufacturer's recommendations)			
	• Cycle time 46-70 min	Limited clinical use data			
	• FDA cleared for general instruments and multichannel flexible	Limited materials compatibility data			
	endoscopes (see manufacturer's instructions)	Limited microbicidal efficacy data			
		 Requires synthetic packaging (polypropylene wraps, polyolefin pouches) an special container tray 			
		• Organic matter reduces microhicidal activity			

• Organic matter reduces microbicidal activity

ETO, ethylene oxide; *FDA*, Food and Drug Administration; *HP*, hydrogen peroxide; *TWA*, time-weighted average. *Modified from Rutala and Weber.^{4-10,46-48}

nasopharyngoscopes is discussed in detail in another article in this journal.²⁵

Since 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.²⁶ Before new equipment (especially semicritical equipment, as the margin of safety is less than that for sterilization)³ is used for patient care on more than one 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. At University of North Carolina Hospitals, to ensure patient-safe instruments, all staff who reprocess semicritical instruments (eg, instruments that contact a mucous membrane, including vaginal probes, endoscopes, prostate probes) are required to attend a 3-hour class on high-level disinfection of these instruments. The class includes the rationale for and importance of highlevel disinfection and a discussion of high-level disinfectants and exposure times, reprocessing steps, monitoring minimum effective concentration, personal protective equipment, and the reprocessing environment (establishing "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 reprocessing standards and policies. Results of infection control rounds should be provided to unit managers, and deficiencies in reprocessing should be corrected (immediately, if patient safety issue, such as no brushing of channels) and corrective measures documented to infection control within 2 weeks.

Some items that may come in contact with nonintact skin for a brief period of time (eg, hydrotherapy tanks, ultrasound probes on intact skin [includes central line puncture site]) are usually considered noncritical surfaces and are disinfected with low- or intermediate-level disinfectants.^{5,27,28} Since hydrotherapy tanks have been associated with spread of infection, some facilities have chosen to disinfect them with recommended levels of chlorine.^{5,27}

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, bedside tables, patient furniture, toys,²⁹ portable equipment (eg, wheelchairs, infusion pumps, pulse oximeters, medication carts),^{30,31} and floors.^{32,33}

Summary of advantages and disadvantages of disinfectants used as low-level disinfectants*

Disinfectant active	Advantages	Disadvantages
Alcohol	 Bactericidal, tuberculocidal, fungicidal, virucidal Fast-acting Noncorrosive Nonstaining 	 Not sporicidal Microbicidal activity affected by organic matter Slow-acting against nonenveloped viruses (eg, norovirus) No detergent or cleaning properties
	 Used to disinfect small surfaces (eg, rubber stoppers on medication vials) No toxic residue 	 Not EPA registered Damages some instruments (eg, hardens rubber, deteriorates glue) Flammable (large amounts require special storage) Evaporates rapidly, making contact time compliance difficult
a d'anna hann a chda a'r a		 Not recommended for use on large surfaces Outbreaks ascribed to contaminated alcohol⁵¹
odium hypochlorite (chlorine)	 Bactericidal, tuberculocidal, fungicidal, virucidal Sporicidal (in high concentrations) Fast-acting 	 Reaction hazard with acids and ammonias Leaves salt residue Corrosive to metals (some ready-to-use products may be
	 Inexpensive (in dilutable form) Not flammable Unaffected by water hardness 	 formulated with corrosion inhibitors) Unstable active (some ready-to-use products may be formulated with stabilizers to achieve longer shelf life)
	 Reduces biofilms on surfaces Relatively stable (eg, 50% reduction in chlorine concentration in 30 d⁵² 	Microbicidal activity affected by organic matter Discolors/stains fabrics
	• Used as the disinfectant in water treatment • EPA registered	 Potential hazard is production of trihalomethane May cause skin and eye irritation Odor (some ready-to-use products may be formulated with odor inhibitors) Irritating at high concentrations
nproved (or acceler- ated) HP	 Bactericidal, tuberculocidal, fungicidal, virucidal Fast efficacy Easy compliance with wet treatment times Safe for workers (lowest EPA toxicity category of IV) Benign for the environment Nonstaining EPA registered Not flammable 	 More expensive than most other disinfecting actives Not sporicidal at low concentrations Some material compatibility issues
dophors	 Not flammable Not flammable Used for disinfecting blood culture bottles 	 Not sporicidal Shown to degrade silicone catheters Require prolonged contact to kill fungi Stain surfaces
henolics	 Bactericidal, tuberculocidal, fungicidal, virucidal Inexpensive (in dilutable form) 	 Used mainly as antiseptics rather than disinfectants Not sporicidal Absorbed by porous materials and irritate tissue
	 Nonstaining Not flammable EPA registered 	 Depigmentation of skin caused by certain phenolics Hyperbilirubinemia in infants when phenolics not prepare as recommended
uats (eg, didecyldime- thylammonium bro- mide, dioctyldimethy-	 Bactericidal, fungicidal, virucidal against enveloped viruses (eg, HIV) Good cleaning agents 	 Not sporicidal In general, not tuberculocidal or virucidal against nonenve oped viruses
lammonium bromide)	 EPA registered Surface compatible Nonstaining Persistent antimicrobial activity when undisturbed Inexpensive (in dilutable form) 	 High water hardness can make less microbicidal A few reports documented asthma as a result of exposure to benzalkonium chloride Microbicidal activity affected by organic matter Absorption by cotton may diminish microbicidal activity Multiple outbreaks ascribed to contaminated benzalkoniun chloridal
Alcohol and quat	 Bactericidal, tuberculocidal, fungicidal, virucidal (enveloped and many nonenveloped viruses, eg, adenovirus, rotavirus, enterovirus, rhinovirus) Fast-acting Surface compatible Nonstaining Persistent antimicrobial activity when undisturbed 	chloride ⁵¹ • Not sporicidal • Evaporate more rapidly than water-based disinfectants
PA/HP	 EPA registered Eparegistered Active in the presence of organic material Environmentally friendly by-products (acetic acid, O₂, H₂O) EPA registered Surface compatible 	 Lack of stability Potential for material incompatibility (eg, brass, copper) More expensive than most other disinfecting actives Odor may be irritating Can cause mucous membrane and respiratory health effect

NOTE. If low-level disinfectant is prepared on site (not ready to use), document correct concentration at a routine frequency, as the concentration delivered by automated disinfectant dispensers varies.

C difficile, *Clostridium difficile*; *EPA*, Environmental Protection Agency; *HP*, hydrogen peroxide; *PA*, peracetic acid; *quat*, quaternary ammonium compound. *Modified from Rutala and Weber.^{4-10,46-52}

Antimicrobial spectrum and characteristics of hand hygiene antiseptic agents*

Group	Gram-positive bacteria	Gram-negative bacteria	Mycobacteria	Fungi	Viruses	Speed of action	Comments
Alcohols	+++	+++	+++	+++	+++	Fast	Optimum concentration 60%- 95%, no persistent activity
Chlorhexidine (2%-4% aqueous)	+++	++	+	+	+++	Intermediate	Persistent activity, rare allergic reactions, not compatible with some anionic and nonionic detergents, ototoxicity
Iodine compounds	+++	+++	+++	++	+++	Intermediate	Cause skin burns, usually too irritating for hand hygiene
Iodophors	+++	+++	+	++	++	Intermediate	Less irritating than iodine
Phenol derivative (eg, PCMX)	+++	+	+	+	+	Intermediate	Not compatible with nonionic detergents, ecologic concerns
Triclosan	+++	++	+	-	+++	Intermediate	
Quats (eg, benzethonium chloride, cetrimide)	+	++	-	-	+	Slow	Not compatible with anionic detergents

NOTE. +++ = excellent, ++ = good, + = fair, - = no activity or not sufficient activity.

PCMX, para-chloro-meta-xylenol; quats, guaternary ammonium compounds.

*Modified from Boyce JM, Pittet D. Heathcare Infection Control Practices Advisory Committee.⁴⁵

The 5 most commonly touched noncritical items in the patient environment have been quantitatively shown to be bed rails, bed surfaces, supply carts, overbed tables, and intravenous pumps.³⁴ 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 items³⁵ when they are used as noncritical items and do not contact nonintact skin, mucous membranes, or sterile tissue. However, these items (eg, bedside tables, bed rails) could potentially contribute to secondary transmission by contaminating hands of health care providers or by contacting medical equipment that will subsequently come in contact with patients.³⁶ Tables 1 and 4 list several low-level disinfectants that may be used for noncritical items. Table 4 lists the advantages and disadvantages of the low-level disinfectants that are used on noncritical patient care items (eg, blood pressure cuffs) and noncritical environmental surfaces. The exposure time for low-level disinfection of noncritical items is at least 1 minute.

Many Environmental Protection Agency-registered liquid disinfectants have a 10-minute label claim. However, multiple investigators have demonstrated the effectiveness of these disinfectants against vegetative bacteria (eg, Listeria, Escherichia coli, Salmonella, vancomycin-resistant enterococci, methicillin-resistant Staphylococcus aureus), yeasts (eg, Candida), mycobacteria (eg, Mycobacterium tuberculosis), and viruses (eg, poliovirus) at exposure times of 30-60 seconds.^{5,37-42} Thus, it is acceptable from a microbial inactivation perspective to disinfect noncritical medical equipment (eg, blood pressure cuffs) and noncritical surfaces (eg, bedside tables) with an Environmental Protection Agency-registered disinfectant or disinfectant/detergent at the proper use dilution and a contact time of ≥ 1 minute.^{5,43,44} Since the typical drying time for a liquid disinfectant or disinfectant towelette on a surface is 1-4 minutes⁴² and microbial inactivation occurs in 30-60 seconds,^{40,42} one application of the disinfectant with a contact time of ≥ 1 minute on all hand contact or touchable noncritical surfaces is recommended.

ANTISEPSIS

Antiseptics are used in health care to reduce the level of microorganisms on the skin to a level unlikely to allow transfer from providers to patients (eg, cross-transmission via hands) or be the nidus of infection (eg, skin preparation prior to insertion of an intravascular device). Table 5 summarizes the antimicrobial spectrum of the antiseptics most commonly used in health care.⁴⁵ Bacterial spores are not listed, as they

are not susceptible to available antiseptics and can only be removed mechanically by hand hygiene with soap and water or scrubbing. The most commonly used antiseptics in health care are chlorhexidine (CHG) (alone or in combination with alcohol), alcohol (alone or in combination with CHG or iodophor), and iodophor (alone or in combination with alcohol). Antiseptics are used for microbial reduction on skin in the following ways: hand hygiene, preoperative showers, preoperative skin preparation, skin preparation prior to insertion of catheters, and routine daily bathing of patients. Regarding this issue, Boyce reviewed several important topics associated with the use of antiseptics to include: current issues in hand hygiene; daily CHG treatment in the intensive care unit; prevention of infection during intravascular access, and best products for skin antisepsis for preoperative bathing, surgical site preparation, and surgical hand scrubs. Antiseptics (10% povidoneiodine) have also been used to decontaminate bone, with minimum sacrifice of cell viability, after dropping a bone graft on the operating room floor.^{53,54}

CONCLUSIONS

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.

References

- Fields R. Outpatient surgeries outnumber inpatient surgeries at 53M procedures a year. Available from: https://www.beckersasc.com/news-analysis/outpatient-surgeries-outnumber-inpatient-surgeries-at-53m-procedures-a-year.html. Accessed January 2019.
- Peery AF, Dellon ES, Lund JC, Crockett SD, McGowan CE, Bulsiewicz WJ, et al. Burden of gastrointestinal disease in the United States: 2012 update. Gastroenterology 2012;143:1179-87.
- Rutala WA, Weber DJ. Outbreaks of carbapenem-resistant Enterobacteriaceae infections associated with duodenoscopes: what can we do to prevent infections? Am [Infect Control 2016;44(Suppl):47-51.
- Rutala WA, Weber DJ. Disinfection and sterilization: an overview. Am J Infect Control 2013;41(Suppl):2-5.
- Rutala WA, Weber DJ; Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008 Centers for Disease Control and Prevention. Available from: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf. Accessed January 2019.
- Rutala WA, Weber DJ. Disinfection, sterilization, and antisepsis: an overview. Am J Infect Control 2016;44(Suppl):1-6.

- Rutala WA, Weber DJ. Disinfection, sterilization, and control of hospital waste. In: Bennett JE, Dolan R, Blaser MJ, editors. Principles and practice of infectious diseases. Philadelphia (PA): Elsevier. In press.
- Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence C, Block SS, eds. Disinfection, sterilization, and preservation. Philadelphia (PA): Lea & Febiger; 1968:517-31.
- Simmons BP. CDC guidelines for the prevention and control of nosocomial infections. Guideline for hospital environmental control. Am J Infect Control 1983;11:97-120.
- Rutala WA. APIC guideline for selection and use of disinfectants. 1994, 1995, and 1996 APIC Guidelines Committee. Association for Professionals in Infection Control and Epidemiology, Inc. Am J Infect Control 1996;24:313-42.
- McDonnell G, Burke P. Disinfection: is it time to reconsider Spaulding? J Hosp Infect 2011;78:163-70.
- Alfa MJ, DeGagne P, Olson N, Puchalski T. Comparison of ion plasma, vaporized hydrogen peroxide, and 100% ethylene oxide sterilizers to the 12/88 ethylene oxide gas sterilizer. Infect Control Hosp Epidemiol 1996;17:92-100.
- Rutala WA, Gergen MF, Weber DJ. Efficacy of a washer-disinfector in eliminating healthcare-associated pathogens from surgical instruments. Infect Control Hosp Epidemiol 2014;35:883-5.
- Alfa MJ. Monitoring and improving the effectiveness of cleaning medical and surgical devices. Am J Infect Control 2013;41(Suppl):56-9.
- Seavey R. High-level disinfection, sterilization, and antisepsis: current issues in reprocessing medical and surgical instruments. Am J Infect Control 2013;41 (Suppl):111-7.
- Food and Drug Administration. Infections associated with reprocessed duodenoscopes. Available from: https://www.fda.gov/medicaldevices/productsandmedicalprocedures/reprocessingofreusablemedicaldevices/ucm454630.htm#meeting. Accessed January 2019.
- Rutala WA, Kanamori H, Gergen MF, Sickbert-Bennett EE, Weber DJ. What's new in reprocessing endoscopes: are we going to ensure "the needs of the patient come first" by shifting from disinfection to sterilization? Am J Infect Control 2019;47 (Suppl):A62-6.
- Rutala WA, Weber DJ. ERCP scopes: what can we do to prevent infections? Infect Control Hosp Epidemiol 2015;36:643-8.
- Rutala WA, Weber DJ. Gastrointestinal endoscopes: a need to shift from disinfection to sterilization? JAMA 2014;312:1405-6.
- Rutala WA, Weber DJ. Reprocessing semicritical items: current issues and new technologies. Am | Infect Control 2016;44(Suppl):53-62.
- Rutala WA, Weber DJ. New developments in reprocessing semicritical items. Am J Infect Control 2013;41(Suppl):60-6.
- Rutala WA, Gergen MF, Weber DJ. Disinfection of a probe used in ultrasoundguided prostate biopsy. Infect Control Hosp Epidemiol 2007;28:916-9.
- 23. Rutala WA, Gergen MF, Weber DJ. Disinfection of an infrared coagulation device used to treat hemorrhoids. Am J Infect Control 2012;40:78-9.
- 24. Food and Drug Administration. FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices. Available from: https://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofreusablemedicaldevices/ucm437347.htm. Accessed January 2019.
- Rutala WA, Weber DJ. Reprocessing semicritical items: outbreaks and current issues. Am J Infect Control 2019;47(Suppl):A79-89.
- Rutala WA, Weber DJ. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. Infect Control Hosp Epidemiol 2007;28:146-55.
- 27. Sehulster L, Chinn RY. Centers for Disease Control and Prevention. Healthcare Infection Control Practices Advisory Committee. Guidelines for environmental infection control in health-care facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR Recomm Rep 2003;52:1-42.
- Thompson J, Garrett JH Jr. Transducer disinfection for assessment and insertion of peripheral and central catheters. Available from: https://www.avainfo.org/page/ UltrasoundDisinfect. Accessed January 21, 2019.
- **29.** Kanamori H, Rutala WA, Weber DJ. The role of patient care items as a fomite in healthcare-associated outbreaks and infection prevention. Clin Infect Dis 2017;65:1412-9.
- **30.** John A, Alhmidi H, Cadnum JL, Jencson AL, Donskey CJ. Contaminated portable equipment is a potential vector for dissemination of pathogens in the intensive care unit. Infect Control Hosp Epidemiol 2017;38:1247-9.

- Suwantarat N, Supple LA, Cadnum JL, Sankar T, Donskey CJ. Quantitative assessment on interactions between hospitalized patients and portable medical equipment and other fomites. Am J Infect Control 2017;45:1276-8.
- **32.** Deshpande A, Cadnum JL, Fertelli D, Sitzlar B, Thota P, Mana TS, et al. Are hospital floors an underappreciated reservoir for transmission of health care–associated pathogens. Am J Infect Control 2017;45:336-8.
- 33. Koganti S, Alhmidi H, Tomas ME, Cadnum JL, Jencson A, Donskey CJ. Evaluation of hospital floors as a potential source of pathogen dissemination using a nonpathogenic virus as a surrogate marker. Infect Control Hosp Epidemiol 2016;37:1374-7.
- Huslage K, Rutala WA, Sickbert-Bennett E, Weber DJ. A quantitative approach to defining "high-touch" surfaces in hospitals. Infect Control Hosp Epidemiol 2010;31:850-3.
- 35. Weber DJ, Rutala WA. Environmental issues and nosocomial infections. In: Wenzel RP, ed. Prevention and control of nosocomial infections, 3rd ed Baltimore (MD): Williams and Wilkins; 1997:491-514.
- 36. Weber DJ, Rutala WA, Miller MB, Huslage K, Sickbert-Bennett E. Role of hospital surfaces in the transmission of emerging health care–associated pathogens: norovirus, *Clostridium difficile*, and *Acinetobacter* species. Am J Infect Control 2010;38 (Suppl):25-33.
- Best M, Sattar SA, Springthorpe VS, Kennedy ME. Efficacies of selected disinfectants against Mycobacterium tuberculosis. J Clin Microbiol 1990;28:2234-9.
- Best M, Kennedy ME, Coates F. Efficacy of a variety of disinfectants against *Listeria* spp. Appl Environ Microbiol 1990;56:377-80.
- Best M, Springthorpe VS, Sattar SA. Feasibility of a combined carrier test for disinfectants: studies with a mixture of five types of microorganisms. Am J Infect Control 1994;22:152-62.
- Rutala WA, Barbee SL, Aguiar NC, Sobsey MD, Weber DJ. Antimicrobial activity of home disinfectants and natural products against potential human pathogens. Infect Control Hosp Epidemiol 2000;21:33-8.
- Rutala WA, Gergen MF, Weber DJ. Efficacy of improved hydrogen peroxide against important healthcare-associated pathogens. Infect Control Hosp Epidemiol 2012;33:1159-61.
- 42. West AM, Teska PJ, Oliver HF. There is no additional bactericidal efficacy of Environmental Protection Agency–registered disinfectant towelettes after surface drying or beyond label contact time. Am J Infect Control 2019;47:27-32.
- Rutala WA, Weber DJ. Selection of the ideal disinfectant. Infect Control Hosp Epidemiol 2014;35:855-65.
- Rutala WA, Weber DJ. Surface disinfection: treatment time (wipes/sprays) versus contact time (liquids). Infect Control Hosp Epidemiol 2018;39:329-31.
- 45. Boyce JM, Pittet D. Healthcare Infection Control Practices Advisory Committee. Society for Healthcare Epidemiology of America. Association for Professionals in Infection Control. Infectious Diseases Society of America. Hand Hygiene Task Force. Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Infect Control Hosp Epidemiol 2002;23(Suppl):3-40.
- 46. Rutala WA, Weber DJ. Cleaning, disinfection and sterilization. In: Grota P, ed. APIC text of infection control and epidemiology, 4th ed Washington (DC): Association for Professionals in Infection Control and Epidemiology; 2014:1-15.
- Rutala WA, Weber DJ. Disinfection and sterilization in health care facilities: an overview and current issues. Infect Dis Clin North Am 2016;30:609-37.
- Rutala WA, Weber DJ. Disinfection and sterilization in health care facilities: what clinicians need to know. Clin Infect Dis 2004;39:702-9.
- Kohn WG, Collins AS, Cleveland JL, Harte JA, Eklund KJ, Malvitz DM. Centers for Disease Control and Prevention. Guidelines for infection control in dental healthcare settings—2003. MMWR Recomm Rep 2003;52:1-61.
- Rutala WA, Weber DJ. Guideline for disinfection and sterilization of prion-contaminated medical instruments. Infect Control Hosp Epidemiol 2010;31:107-17.
- Weber DJ, Rutala WA, Sickbert-Bennett EE. Outbreaks associated with contaminated antiseptics and disinfectants. Antimicrob Agents Chemother 2007;51:4217-24.
- Rutala WA, Cole EC, Thomann CA, Weber DJ. Stability and bactericidal activity of chlorine solutions. Infect Control Hosp Epidemiol 1998;19:323-7.
- Bruce B, Sheibani-Rad S, Appleyard D, Calfee RP, Reinert SE, Chapin KC, et al. Are dropped osteoarticular bone fragments safely reimplantable in vivo? J Bone Joint Surg Am 2011;93:430-8.
- Bauer J, Liu RW, Kean TJ, Dennis JE, Petersilige W, Gilmore A. A comparison of five treatment protocols for contaminated bone grafts in reference to sterility and cell viability. J Bone Joint Surg Am 2011;93:439-44.