141. Shadel BN, Puzniak LA, Gillespie KN, et al. Surveillance for vancomycin-resistant enterococci: type, rates, costs, and implications. *Infect Control Hosp Epidemiol*. 2006;27:1068–1075.
142. Viale P, Tumietto F, Giannella M, et al. Impact of a hospital-wide multifaceted programme for reducing carbapenem-resistant Enterobacteriaceae infections in a large teaching hospital in northern Italy. *Clin Microbiol Infect*. 2015;21:242–247.
143. Munoz-Price LS, Carling P, Cleary T, et al. Control of a two-decade endemic situation with carbapenem-resistant *Acinetobacter baumannii*: electronic dissemination of a bundle of interventions. *Am J Infect Control*. 2014;42:466–471.
144. Huskins WC, Huckabee CM, O'Grady NP, et al. Intervention to reduce transmission of resistant bacteria in intensive care. *N Engl J Med*. 2011;364:1407–1418.
145. Derde LP, Cooper BS, Goossens H, et al. Interventions to reduce colonisation and transmission of antimicrobial-resistant bacteria in intensive care units: an interrupted time series study and cluster randomised trial. *Lancet Infect Dis*. 2014;14:31–39.
146. Harbarth S, Fankhauser C, Schrenzel J, et al. Universal screening for methicillin-resistant *Staphylococcus aureus* at hospital admission and nosocomial infection in surgical patients. *JAMA*. 2008;299:1149–1157.
147. Jain R, Kralovic SM, Evans ME, et al. Veterans Affairs initiative to prevent methicillin-resistant *Staphylococcus aureus* infections. *N Engl J Med*. 2011;364:1419–1430.
148. Schwaber MJ, Carmeli Y. An ongoing national intervention to contain the spread of carbapenem-resistant Enterobacteriaceae. *Clin Infect Dis*. 2014;58:697–703.
149. Septimus EJ, Schweizer ML. Decolonization in prevention of health Care-Associated infections. *Clin Microbiol Rev*. 2016;29:201–222.
150. Frost SA, Alogso MC, Metcalfe L, et al. Chlorhexidine bathing and health care-associated infections among adult intensive care patients: a systematic review and meta-analysis. *Crit Care*. 2016;20:379.
151. Dicks KV, Lofgren E, Lewis SS, et al. A multicenter pragmatic interrupted time series analysis of chlorhexidine gluconate bathing in community Hospital intensive care units. *Infect Control Hosp Epidemiol*. 2016;37:791–797.
152. Borer A, Gilad J, Porat N, et al. Impact of 4% chlorhexidine whole-body washing on multidrug-resistant *Acinetobacter baumannii* skin colonisation among patients in a medical intensive care unit. *J Hosp Infect*. 2007;67:149–155.
153. Chung YK, Kim JS, Lee SS, et al. Effect of daily chlorhexidine bathing on acquisition of carbapenem-resistant *Acinetobacter baumannii* (CRAB) in the medical intensive care unit with CRAB endemicity. *Am J Infect Control*. 2015;43:1171–1177.
154. Palmore TN, Michelin AV, Bordner M, et al. Use of adherence monitors as part of a team approach to control clonal spread of multidrug-resistant *Acinetobacter baumannii* in a research hospital. *Infect Control Hosp Epidemiol*. 2011;32:1166–1172.
155. Snitkin ES, Zelazny AM, Thomas PJ, et al. Tracking a hospital outbreak of carbapenem-resistant *Klebsiella pneumoniae* with whole-genome sequencing. *Sci Transl Med*. 2012;4:148ra16.
156. Calfee D, Jenkins SG. Use of active surveillance cultures to detect asymptomatic colonization with carbapenem-resistant *Klebsiella pneumoniae* in intensive care unit patients. *Infect Control Hosp Epidemiol*. 2008;29:966–968.
157. Waters TM, Daniels MJ, Bazzoli GJ, et al. Effect of Medicare's nonpayment for Hospital-Acquired Conditions: lessons for future policy. *JAMA Intern Med*. 2015;175:347–354.
158. Centers for Disease C, Prevention. FDA approval of an extended period for administering VariZIG for postexposure prophylaxis of varicella. *MMWR Morb Mortal Wkly Rep*. 2012;61:212.
159. Centers for Disease C, Prevention. A new product (VariZIG) for postexposure prophylaxis of varicella available under an investigational new drug application expanded access protocol. *MMWR Morb Mortal Wkly Rep*. 2006;55:209–210.
160. Kaplan JE, Benson C, Holmes KH, et al. Guidelines for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. *MMWR Recomm Rep*. 2009;58(RR–4):1–207, quiz CE1–4.
161. Marin M, Guris D, Chaves SS, et al. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2007;56(RR–4):1–40.
162. Weinstock DM, Boeckh M, Boulad F, et al. Postexposure prophylaxis against varicella-zoster virus infection among recipients of hematopoietic stem cell transplant: unresolved issues. *Infect Control Hosp Epidemiol*. 2004;25:603–608.
163. Weinstock DM, Boeckh M, Sepkowitz KA. Postexposure prophylaxis against varicella zoster virus infection among hematopoietic stem cell transplant recipients. *Biol Blood Marrow Transplant*. 2006;12:1096–1097.
164. Chazan B, Colodner R, Teitler N, et al. Varicella zoster virus in health care workers in northern Israel: seroprevalence and predictive value of history of varicella infection. *Am J Infect Control*. 2008;36:436–438.
165. Wu MF, Yang YW, Lin WY, et al. Varicella zoster virus infection among healthcare workers in Taiwan: seroprevalence and predictive value of history of varicella infection. *J Hosp Infect*. 2012;80:162–167.
166. Johnson JA, Bloch KC, Dang BN. Varicella reinfection in a seropositive physician following occupational exposure to localized zoster. *Clin Infect Dis*. 2011;52:907–909.
167. Advisory Committee on Immunization P, Centers for Disease C, Prevention. Immunization of health-care personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2011;60(RR–7):1–45.
168. Bolyard EA, Tablan OC, Williams WW, et al. Guideline for infection control in healthcare personnel, 1998. Hospital Infection Control Practices Advisory Committee. *Infect Control Hosp Epidemiol*. 1998;19:407–463.
169. Kuehnert MJ, Cardo DM. Infections associated with Health-care personnel: Vaccine-preventable diseases and bloodborne pathogens. *Curr Infect Dis Rep*. 2000;2:475–483.
170. Haiduven DJ, Hench CP, Simpkins SM, et al. Management of varicella-vaccinated patients and employees exposed to varicella in the healthcare setting. *Infect Control Hosp Epidemiol*. 2003;24:538–543.
171. Haiduven DJ, Hench CP, Stevens DA. Postexposure varicella management of nonimmune personnel: an alternative approach. *Infect Control Hosp Epidemiol*. 1994;15:329–334.
172. Rado J, Tako J, Geder L, et al. Herpes zoster house epidemic in steroid-treated patients. *Arch Intern Med*. 1965;116:329–335.
173. Shefer A, Strikas R, Bridges CB. Updated recommendations of the Advisory Committee on Immunization Practices for healthcare personnel vaccination: a necessary foundation for the essential work that remains to build successful programs. *Infect Control Hosp Epidemiol*. 2012;33:71–74.
174. Henderson DK, Dembry L, Fishman NO, et al. SHEA guideline for management of healthcare workers who are infected with hepatitis B virus, hepatitis C virus, and/or human immunodeficiency virus. *Infect Control Hosp Epidemiol*. 2010;31:203–232.
175. Mazurek GH, Jereb J, Vernon A, et al. Updated guidelines for using Interferon Gamma Release Assays to detect *Mycobacterium tuberculosis* infection - United States, 2010. *MMWR Recomm Rep*. 2010;59(RR–5):1–25.
176. Metcalfe JZ, Cattamanchi A, McCulloch CE, et al. Test variability of the QuantiFERON-TB gold in-tube assay in clinical practice. *Am J Respir Crit Care Med*. 2013;187:206–211.
177. McLean HQ, Fiebelkorn AP, Temte JL, et al., Centers for Disease C, Prevention. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: summary recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2013;62(RR–04):1–34.
178. Centers for Disease Control and Prevention. Immunization of health-care personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2011;60(RR–7):1–45.
179. Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, Pediatric Infectious Diseases Society. IDSA, SHEA, and PIDS Joint Policy Statement on Mandatory Immunization of Health Care Personnel According to the ACIP-Recommended Vaccine Schedule; 2013.
180. Vesikari T, Karvonen A, Korhonen T, et al. A randomized, double-blind study of the safety, transmissibility and phenotypic and genotypic stability of cold-adapted influenza virus vaccine. *Pediatr Infect Dis J*. 2006;25:590–595.
181. Milton DK, Fabian MP, Cowling BJ, et al. Influenza virus aerosols in human exhaled breath: particle size, culturability, and effect of surgical masks. *PLoS Pathog*. 2013;9:e1003205.
182. Henderson DK. Management of needlestick injuries: a house officer who has a needlestick. *JAMA*. 2012;307:75–84.
183. Kuhar DT, Henderson DK, Struble KA, et al. Updated US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis. *Infect Control Hosp Epidemiol*. 2013;34:875–892.
184. US Public Health Service. Updated US Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. *MMWR Morb Mortal Wkly Rep*. 2001;50(RR11):1–42.
185. Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Prevention Needlestick Surveillance Group. *N Engl J Med*. 1997;337:1485–1490.
186. Deleted in review.
187. Lautenbach E, Nachamkin I, Hu B, et al. Surveillance cultures for detection of methicillin-resistant *Staphylococcus aureus*: diagnostic yield of anatomic sites and comparison of provider- and patient-collected samples. *Infect Control Hosp Epidemiol*. 2009;30:380–382.
188. Weinstein JW, Tallapragada S, Farrel P, et al. Comparison of rectal and perirectal swabs for detection of colonization with vancomycin-resistant enterococci. *J Clin Microbiol*. 1996;34:210–212.
189. Weintrob AC, Roediger MP, Barber M, et al. Natural history of colonization with gram-negative multidrug-resistant organisms among hospitalized patients. *Infect Control Hosp Epidemiol*. 2010;31:330–337.
190. Marchaim D, Navon-Venezia S, Schwartz D, et al. Surveillance cultures and duration of carriage of multidrug-resistant *Acinetobacter baumannii*. *J Clin Microbiol*. 2007;45:1551–1555.
191. Centers for Disease Control and Prevention. Interim statement regarding potential fetal harm from exposure to dolutegravir—implications for HIV post-exposure prophylaxis (PEP); 2018. https://www.cdc.gov/hiv/pdf/basics/cdc-hiv-dolutegravir-alert.pdf. Accessed June 15, 2018.
192. PEP Quick Guide for Occupational Exposures. Clinician Consultation Center. University of California, San Francisco; updated January 1, 2018. https://nccc.ucsf.edu/clinical-resources/pep-resources/pep-quick-guide/. Accessed January 10, 2019.

299 Disinfection, Sterilization, and Control of Hospital Waste

William A. Rutala and David J. Weber

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 and/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 (e.g., endoscopes contaminated with carbapenem-resistant Enterobacteriaceae [CRE]).[3]

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 unnecessary to sterilize all patient care items, health care policies must identify whether cleaning, disinfection, or sterilization is indicated, based primarily on the items' intended use.

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization.[4–6] Failure to comply with scientifically based guidelines has led to numerous outbreaks.[4] In this chapter, which is an update of previous chapters,[7–13] a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes is presented, based on well-designed studies assessing the efficacy (via laboratory investigations) and effectiveness (via clinical studies) of disinfection and sterilization procedures. In addition, we briefly review the management of medical waste in health care facilities.

DEFINITION OF TERMS

Sterilization is defined as the complete elimination or destruction of all forms of microbial life and is accomplished in health care facilities through either physical or chemical processes. Steam under pressure, dry heat, ethylene oxide (ETO) gas, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, hydrogen peroxide with ozone, and liquid chemicals are the principal sterilizing agents used in health care facilities. Sterilization is intended to convey an absolute meaning, not a relative one. Unfortunately, some health professionals and the technical and commercial literature refer to "disinfection" as "sterilization" and items as "partially sterile." When chemicals are used for the purposes of destroying all forms of microbiologic life, including fungal and bacterial spores, they may be called chemical sterilants. These same germicides used for shorter exposure periods may also be part of the disinfection process (i.e., high-level disinfection).

Disinfection describes a process that eliminates many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial spores. Disinfection is usually accomplished with the use of liquid chemicals or wet pasteurization in health care settings. The efficacy of disinfection is affected by a number of factors, each of which may nullify or limit the efficacy of the process. Some of the factors that affect both disinfection and sterilization efficacy are the prior cleaning of the object; the organic and inorganic load present; the type and level of microbial contamination; the concentration of and time of exposure to the germicide; the nature of the object (e.g., crevices, hinges, and lumens); the presence of biofilms; the temperature and pH during the disinfection process; and in some cases the relative humidity of the sterilization process (e.g., ETO).

By definition, then, disinfection differs from sterilization by its lack of sporicidal property, but this is an oversimplification. A few disinfectants will kill spores with prolonged exposure times (e.g., 3–12 hours) and are called *chemical sterilants.* At similar concentrations but with shorter exposure periods (e.g., 12 minutes for 0.55% ortho-phthalaldehyde [OPA]) these same disinfectants will kill all microorganisms with the exception of large numbers of bacterial spores and are called *high-level disinfectants*. *Low-level disinfectants* may kill most vegetative bacteria, some fungi, and some viruses in a practical period of time (<10 minutes), whereas *intermediate-level disinfectants* may be cidal for mycobacteria, vegetative bacteria, most viruses, and most fungi but do not necessarily kill bacterial spores. The germicides differ markedly among themselves primarily in their antimicrobial spectrum and rapidity of action. Table 299.1 will be discussed later and consulted in this context.

Cleaning, on the other hand, is the removal of visible soil (e.g., organic and inorganic material) and microbial contaminants from objects and surfaces, and it normally is accomplished by manual or mechanical means using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. Also, if the soiled materials become dried or baked onto the instruments, the removal process becomes more difficult and the disinfection or sterilization process less effective or ineffective. Surgical instruments should be pretreated or rinsed to prevent drying of blood and to soften or remove blood from the instruments immediately or as soon as feasible after use. Treating contaminated instruments with alcohol, allowing instruments to soak in water for prolonged periods, or drying increases cleaning difficulty and should be discouraged.[14] *Decontamination* is a procedure that removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

Terms with a suffix "cide" or "cidal" for killing action also are commonly used. For example, a germicide is an agent that can kill microorganisms, particularly pathogenic organisms ("germs"). The term *germicide* includes both antiseptics and disinfectants. *Antiseptics* are germicides applied to living tissue and skin, whereas *disinfectants* are antimicrobials applied only to inanimate objects. Preservatives are agents that inhibit the growth of microorganisms capable of causing biologic deterioration of substances and materials. In general, antiseptics are used only on the skin and not for surface disinfection, and disinfectants are rarely used for skin antisepsis because they may cause injury to skin and other tissues. Other words with the suffix "cide" (e.g., virucide, fungicide, bactericide, sporicide, and tuberculocide) can kill the type of microorganism identified by the prefix. For example, a bactericide is an agent that kills bacteria.[15–18]

RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

About 50 years ago, Earle H. Spaulding[16] 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.[8–13,15–17] Spaulding believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided

TABLE 299.1 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[a]	Destroys all microorganisms, including bacterial spores	High temperature Low temperature Liquid immersion	Steam (approximately 40 min), dry heat (1–6 h depending on temperature) Ethylene oxide gas (approximately 15 h), hydrogen peroxide gas plasma (24–60 min, 100 NX), hydrogen peroxide and ozone (46–60 min, VP4), hydrogen peroxide vapor (28–35 min, V-Pro MAX) Chemical sterilants[b]: >2% glut (approximately 10 h at 20°C–25°C); 1.12% glut with 1.93% phenol (12 h at 25°C); 7.35% HP with 0.23% PA (3 h at 20°C); 7.5% HP (6 h at 20°C); 1.0% HP with 0.08% PA (8 h at 20°C); approximately 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	Destroys all microorganisms except some bacterial spores	Heat automated Liquid immersion	Pasteurization (65°C–77°C, 30 min) Chemical sterilants or high-level disinfectants[b]: >2% glut (20–90 min at 20°C–25°C); >2% glut (5 min at 35°C–37.8°C); 0.55% OPA (12 min at 20°C); 1.12% glut with 1.93% phenol (20 min at 25°C); 7.35% HP with 0.23% 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 30°C); 2.0% HP (8 min at 20°C); 3.4% glut with 20.1% isopropanol (5 min at 25°C)	Heat-sensitive semicritical items (e.g., respiratory therapy equipment) Heat-sensitive semicritical items (e.g., GI endoscopes, bronchoscopes, endocavitary probes)
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 (e.g., chlorine-based products, phenolics, improved hydrogen peroxide, hydrogen peroxide plus peracetic acid, quaternary ammonium compounds ["quats"], quats plus alcohol—exposure times approximately 1 min) or 70–90% alcohol	Noncritical patient care item (blood pressure cuff) or surface (bedside table) with no visible blood

[a]Prions (as in Creutzfeldt-Jakob disease) exhibit an unusual resistance to conventional chemical and physical decontamination methods and are not readily inactivated through conventional sterilization procedures.[238,239]

[b]Consult the FDA cleared package insert for information about the cleared contact time and temperature, and see references 8, 25, and 31 for discussion of why >2% glutaraldehyde products are used at a reduced exposure time (2% glutaraldehyde at 20 min, 20°C). Increasing the temperature through use of an automated endoscope reprocess (AER) will reduce the contact time (e.g., OPA 12 min at 20°C but 5 min at 25°C in AER). Exposure temperatures for some high-level disinfectants listed in the table varies from 20°C to 25°C; check FDA-cleared temperature conditions.[28] Tubing must be completely filled for high-level disinfection and liquid chemical sterilization. Material compatibility should be investigated when appropriate (e.g., 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 hydrogen peroxide). Intermediate-level disinfectants are not included in Table 299.1 because there is no device or surface for which intermediate-level disinfection is specifically recommended over low-level disinfection.

EPA, US Environmental Protection Agency; *FDA,* US 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,[7] Rutala and Weber,[8] Rutala and Weber,[9] Rutala and Weber,[10] Rutala and Weber,[11] Rutala and Weber,[333] and Kohn et al.[334]

into three categories based on the degree of risk of infection involved in the use of the items. Although the scheme remains valid, there are some examples of disinfection studies with viruses, mycobacteria, and protozoa and of disinfectants that challenge the current definitions and expectations of high- and low-level disinfection.[19] The three categories Spaulding described were critical, semicritical, and noncritical.

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. 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, arthroscopes, laparoscopes, and ultrasound probes used in sterile body cavities. Most of the items in this category should be purchased as sterile or be sterilized with steam sterilization if possible. If heat sensitive, the object may be treated with ETO, hydrogen peroxide gas plasma, vaporized hydrogen peroxide vapor, hydrogen peroxide vapor plus ozone, or liquid chemical sterilants if other methods are unsuitable. Tables 299.1, 299.2, and 299.3 summarize sterilization processes and liquid chemical sterilants and the advantages and disadvantages of each. Sterilization technologies can be relied on to produce sterility only if cleaning—to eliminate organic and inorganic material and microbial load—precedes treatment.[20–22] Other issues that 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.[22,23]

Semicritical Items

Semicritical items are those that come in contact with intact mucous membranes or nonintact skin. Respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades and handles,[24,25] esophageal manometry probes, endocavitary probes, nasopharyngoscopes, prostate biopsy probes,[26] infrared coagulation devices,[27] anorectal manometry catheters, cystoscopes, and diaphragm fitting rings are included in this category.[24] These medical devices should be free of all microorganisms, 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 with chemical disinfectants. Glutaraldehyde, hydrogen peroxide, OPA, peracetic acid, hypochorite (via superoxidized water) and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA)[28] and are dependable high-level disinfectants, provided that the factors influencing germicidal procedures are met (see Tables 299.1 and 299.2). When a disinfectant is selected for use with certain patient care items, the chemical compatibility after extended use with the items to be disinfected also must be considered.

TABLE 299.2 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	Material compatibility concerns (lead, brass, copper, zinc), both cosmetic and functional Limited clinical experience Mucous membrane and respiratory health effects[165] 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 (standard)	No activation required May enhance removal of organic matter and organisms No disposal issues No odor or irritation issues Does not coagulate blood or fix tissues to surfaces Inactivates *Cryptosporidium* at 6%–7.5% Use studies published	Material compatibility concerns (brass, zinc, copper, and nickel/silver plating), both cosmetic and functional Serious eye damage with contact
Ortho-phthalaldehyde (OPA)	Fast acting high-level disinfectant No activation required Odor not significant Excellent materials compatibility claimed Does not coagulate blood or fix tissues to surfaces claimed	Stains protein gray (e.g., skin, mucous membranes, clothing, and environmental surfaces) More expensive than glutaraldehyde Eye irritation with contact Slow sporicidal activity Anaphylactic reactions to OPA in bladder cancer patients with repeated exposure to OPA through cystoscopy
Peracetic acid	Standardized cycle (e.g., liquid chemical sterilant processing system using peracetic acid, rinsed with extensively treated potable water) Low temperature (50°C–55°C) liquid immersion sterilization Environmental friendly by-products (acetic acid, O_2, H_2O) Fully automated Single-use system eliminates need for concentration testing May enhance removal of organic material and endotoxin No adverse health effects to operators under normal operating conditions Compatible with many materials and instruments Does not coagulate blood or fix tissues to surfaces Sterilant flows through scope, facilitating salt, protein, and microbe removal Rapidly sporicidal Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)	Potential material incompatibility (e.g., aluminum anodized coating becomes dull) Used for immersible instruments only Biologic indicator may not be suitable for routine monitoring One scope or a small number of instruments can be processed in a cycle More expensive (endoscope repairs, operating costs, purchase costs) than 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 has not been cleared by FDA as sterilization process but for high-level disinfection
Improved hydrogen peroxide (2.0%); high-level disinfectant	No activation required No odor Nonstaining No special venting requirements Manual or automated applications 12-mo shelf life, 14-day reuse 8 min at 20°C high-level disinfectant claim	Material compatibility concerns owing to limited clinical experience Organic material resistance concerns owing to limited data

[a]All products are effective in 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 listed characteristics are documented in the literature; contact the manufacturer of the instrument and high-level disinfectant or chemical sterilant for additional information. All products listed here are FDA cleared as chemical sterilants except OPA, which is an FDA-cleared high-level disinfectant.
AER, Automated endoscope reprocessor; *FDA,* US Food and Drug Administration.
Modified from Rutala and Weber,[7] Rutala and Weber,[8] Rutala and Weber,[9] Rutala and Weber,[10] Rutala and Weber,[11] Rutala and Weber.[333]

The complete elimination of all microorganisms in or on an instrument with the exception of small numbers of bacterial spores is the traditional definition of high-level disinfection. The FDA's definition of high-level disinfection is a sterilant used for a shorter contact time to achieve at least a 6-$\log_{10}$ kill of an appropriate *Mycobacterium* species. Cleaning followed by high-level disinfection should eliminate all pathogens capable of causing infection.

Ideally, semicritical items should be rinsed with sterile water after high-level disinfection to prevent their contamination with organisms that may be present in tap water, such as nontuberculous mycobacteria, *Legionella,* or gram-negative bacilli such as *Pseudomonas.*[29] In circumstances in which rinsing with sterile water rinse is not feasible, a tap water or filtered water (0.2-μ filter) rinse should be followed by an alcohol rinse and forced-air drying.[8,30,31] Forced-air drying markedly reduces bacterial contamination of stored endoscopes, most likely by removing the wet environment favorable for bacterial growth.[30] After rinsing, items should be dried and stored (e.g., packaged or hung) in a manner that protects them from recontamination.

Some items that may come in contact with nonintact skin for a brief period of time (i.e., 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.[8,32] Because hydrotherapy tanks have been associated with spread of infection, some facilities have chosen to disinfect them with recommended levels of chlorine.[8,32]

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,

TABLE 299.3 Summary of Advantages and Disadvantages of Commonly Used Sterilization Methods

STERILIZATION METHOD	ADVANTAGES	DISADVANTAGES
Steam	Nontoxic to patient, staff, environment Cycle easy to control and monitor Rapidly microbicidal Least affected by organic and 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 and health care personnel Leaves no toxic residuals Cycle time is 24–60 min, and no aeration necessary Used for heat- and moisture-sensitive items; process temperature <50°C Simple to operate, install (208-V outlet), and monitor Compatible with most medical devices Requires only 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 (ETO)	Penetrates packaging materials, device lumens Single-dose cartridge and negative-pressure chamber minimize 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, a probable 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
Vaporized hydrogen peroxide	Safe for the environment and health care personnel It leaves no toxic residue; no aeration necessary Cycle time, 28–35 min Used for heat- and moisture-sensitive items (metal and nonmetal devices)	Medical device restrictions based on lumen internal diameter and length; see manufacturer's recommendations (e.g., stainless steel lumen 1 mm in diameter, 125 mm long) 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
Hydrogen peroxide and ozone	Safe for the environment and health care personnel Uses dual sterilants, hydrogen peroxide and ozone No aeration needed owing to absence of toxic by-products Compatible with common medical devices Cycle time, 46–60 min FDA cleared for general instruments and multichannel flexible endoscopes (see manufacturer's instructions)	Endoscope or medical device restrictions based on lumen internal diameter and length (see manufacturer's recommendations) Limited clinical use (no published data on material compatibility, penetrability, organic material resistance) and limited microbicidal efficacy data Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and special container tray

FDA, US Food and Drug Administration; *TWA,* time-weighted average.
Modified from Rutala and Weber,[7] Rutala and Weber,[8] Rutala and Weber,[9] Rutala and Weber,[10] Rutala and Weber,[11] Rutala and Weber.[333]

toys,[33] portable equipment (e.g., wheelchairs, infusion pumps, pulse oximeters, medication carts),[34,35] and floors.[36,37] The five most commonly touched noncritical items in the patient environment have been quantitatively shown to be bed rails, bed surface, supply cart, overbed table, and intravenous pump.[38] 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[39] when they are used as noncritical items and do not contact nonintact skin and/or mucous membranes. However, these items (e.g., bedside tables, bed rails) could potentially contribute to secondary transmission by contaminating hands of health care providers or by contact with medical equipment that will subsequently come in contact with patients.[40] Table 299.4 lists several low-level disinfectants that may be used for noncritical items. Many Environmental Protection Agency (EPA)–registered liquid disinfectants have a 10-minute label claim. However, multiple investigators have demonstrated the effectiveness of these disinfectants against vegetative bacteria (e.g., *Listeria, Escherichia coli, Salmonella,* vancomycin-resistant enterococci [VRE], methicillin-resistant *Staphylococcus aureus* [MRSA]), yeasts (e.g., *Candida*), mycobacteria (e.g., *Mycobacterium tuberculosis*), and viruses (e.g., poliovirus) at exposure times of 30 to 60 seconds.[8,41–45] Accordingly, it is acceptable to disinfect noncritical medical equipment (e.g., blood pressure cuff) and noncritical surfaces (e.g., bedside table) with an EPA-registered disinfectant or disinfectant-detergent at the proper use-dilution and a contact time of approximately 1 minute.[8,46,47] Because the typical drying time for a liquid disinfectant on a surface is 1 to 2 minutes (unless the product contains alcohol [e.g., a 60%–70% alcohol product will dry in about 30 seconds]), one application of the germicide on all hand contact or touchable surfaces to be disinfected is recommended.

Mops (microfiber and cotton-string), reusable cleaning cloths, disposable wipes, and sprays are regularly used to achieve low-level disinfection.[48] Disinfectant cleaning wipes and sprays (e.g., quaternary ammonium compounds ["quats"] and alcohol, chlorine) have been found to be highly effective (>4-$\log_{10}$ reduction) in removing or inactivating epidemiologically important pathogens.[49,50] Hospital laundering practices may not be sufficient to remove microbial contaminants of reusable cleaning towels.[51,52] Microfiber mops have demonstrated superior microbial removal compared with cotton string mops when used with detergent cleaner (95% vs. 68%, respectively). Use of a disinfectant did significantly improve microbial removal when a cotton string mop was used when compared with the detergent cleaner (95% vs. 68%, respectively).[53] Mops (especially cotton-string mops) are commonly not kept adequately cleaned and disinfected, and if the water-disinfectant mixture is not changed regularly (e.g., after every three to four rooms, no longer than 60-minute intervals), the mopping procedure may actually spread heavy microbial contamination throughout the health care facility.[54] In one study, standard laundering provided acceptable decontamination of heavily contaminated mopheads, but chemical disinfection with a phenolic was less effective.[54] The frequent laundering of cotton-string mops (e.g., daily) is therefore recommended.

Hospital cleanliness continues to attract patient attention, and in the United States it is still primarily assessed via visual appearance, which is not a reliable indicator of surface cleanliness.[55] Three other methods have been offered for monitoring patient room hygiene: adenosine triphosphate (ATP) bioluminescence[56,57]; fluorescent markers[58–60]; and microbiologic sampling. Studies have demonstrated suboptimal cleaning through use of aerobic colony counts, ATP bioluminescence, and fluorescent markers.[56,60] ATP bioluminescence and fluorescent markers are preferred to aerobic plate counts because they provide an immediate assessment of cleaning effectiveness. When the four major

TABLE 299.4 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 Used to disinfect small surfaces such as rubber stoppers on medication vials No toxic residue	Not sporicidal Affected by organic matter Slow acting against nonenveloped viruses (e.g., norovirus) No detergent or cleaning properties Not EPA registered Damages some instruments (e.g., hardens rubber, deteriorates glue) Flammable (large amounts require special storage) Evaporates rapidly, making contact-time compliance difficult Not recommended for use on large surfaces Outbreaks ascribed to contaminated alcohol[134]
Sodium hypochlorite	Bactericidal, tuberculocidal, fungicidal, virucidal Sporicidal Fast acting Inexpensive (in dilutable form) Not flammable Unaffected by water hardness Reduces biofilms on surfaces Relatively stable (e.g., 50% reduction in chlorine concentration in 30 days)[79] Used as the disinfectant in water treatment EPA registered	Reaction hazard with acids and ammonias Leaves salt residue Corrosive to metals (some ready-to-use products may be formulated with corrosion inhibitors) Unstable active (some ready-to-use products may be formulated with stabilizers to achieve longer shelf life) Affected by organic matter Discolors or stains fabrics Potential hazard is production of trihalomethane Odor (some ready-to-use products may be formulated with odor inhibitors); irritating at high concentrations
Improved hydrogen peroxide	Bactericidal, tuberculocidal, fungicidal, virucidal Fast efficacy Easy compliance with wet-contact times Safe for workers (lowest EPA toxicity category, IV) Benign for the environment Surface compatible Nonstaining EPA registered Not flammable	More expensive than most other disinfecting actives Not sporicidal at low concentrations
Iodophors	Bactericidal, mycobactericidal, virucidal Not flammable Used for disinfecting blood culture bottles	Not sporicidal Shown to degrade silicone catheters Requires prolonged contact to kill fungi Stains surfaces Used mainly as an antiseptic rather than disinfectant
Phenolics	Bactericidal, tuberculocidal, fungicidal, virucidal Inexpensive (in dilutable form) Nonstaining Not flammable EPA registered	Not sporicidal Absorbed by porous materials and can irritate tissue Depigmentation of skin caused by certain phenolics Hyperbilirubinemia in infants when phenolic not prepared as recommended
Quaternary ammonium compounds[a] (e.g., didecyl dimethyl ammonium bromide, dioctyl dimethyl ammonium bromide)	Bactericidal, fungicidal, virucidal against enveloped viruses (e.g., HIV) Good cleaning agents EPA registered Surface compatible Persistent antimicrobial activity when undisturbed Inexpensive (in dilutable form)	Not sporicidal In general, not tuberculocidal and not virucidal against nonenveloped viruses High water hardness and cotton or gauze can make less microbicidal A few reports documented asthma as result of exposure to benzalkonium chloride Affected by organic matter Absorption by cotton, some wipes Multiple outbreaks ascribed to contaminated benzalkonium chloride[134]
Peracetic acid and hydrogen peroxide	Bactericidal, fungicidal, virucidal and sporicidal (e.g., *Clostridioides difficile* [formerly *Clostridium difficile*]) Active in the presence of organic material Environmental friendly by-products (acetic acid, O_2, H_2O) EPA registered Surface compatible	Lack of stability Potential for material incompatibility (e.g., brass, copper) More expensive than most other disinfecting actives Odor may be irritating Can cause mucous membrane and respiratory health effects

[a]If low-level disinfectant is prepared on-site (not ready-to-use product), document correct concentration at a routine frequency.
EPA, Environmental Protection Agency; *HIV,* human immunodeficiency virus.
Modified from Rutala and Weber,[9] *Rutala and Weber.*[46]

hospital cleaning validation methods (i.e., visual, microbiologic, ATP, and fluorescence) were compared, the fluorescent marker was the most useful tool in determining how thoroughly a surface was cleaned, and mimicked the microbiologic data better than ATP (<500 relative light units). There was no statistical correlation between ATP levels and standard aerobic plate counts.[61]

DISINFECTION OF HEALTH CARE EQUIPMENT AND SURFACES

Disinfectants are used alone or in combinations in the health care setting. These include alcohols, chlorine and chlorine compounds, formaldehyde, glutaraldehyde, OPA, standard and improved (or accelerated) hydrogen peroxide, hydrogen peroxide plus peracetic acid, iodophors, peracetic acid, phenolics, quats, and quats and alcohol. Key considerations for selecting the optimal disinfectant include kill claims; treatment time or contact time; safety; and ease of use.[46] With some exceptions (e.g., ethanol or bleach), commercial formulations based on these chemicals are considered unique products and must be registered with the EPA or cleared by the FDA. In most instances, a given product is designed for a specific purpose and is to be used in a certain manner. Therefore the label should be read carefully to ensure that the right product is selected for the intended use and applied in an efficient manner. In addition, caution must be exercised to avoid hazards with use of cleaners and disinfectants on electronic medical equipment. Problems associated

with inappropriate use of liquids on electronic medical equipment have included equipment fires, equipment malfunctions, and health care worker burns.

Disinfectants are not interchangeable, and an overview of the performance characteristics of each is provided in the following sections so the user has sufficient information to select an appropriate disinfectant for any item and use it in the most efficient way. It should be recognized that excessive costs and infection risks may be attributed to incorrect concentrations and inappropriate disinfectants.[62] Finally, occupational diseases among cleaning personnel have been associated with the use of several disinfectants such as formaldehyde, glutaraldehyde, and chlorine, and precautions (e.g., gloves, proper ventilation) should be used to minimize exposure.[63,64] Asthma and reactive airway disease may occur in sensitized individuals exposed to any airborne chemical including germicides. Clinically important asthma may occur at levels below ceiling levels regulated by the Occupational Health and Safety Administration (OSHA) or recommended by the National Institute for Occupational Safety and Health (NIOSH). The preferred method of control is to eliminate the chemical (by means of engineering controls or substitution) or relocate the worker.

Chemical Disinfectants

Alcohol

In the health care setting, "alcohol" refers to two water-soluble chemical compounds whose germicidal characteristics are generally underrated: ethyl alcohol and isopropyl alcohol.[65] These alcohols are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and virucidal but do not destroy bacterial spores. Their cidal activity drops sharply when diluted below 50% concentration, and the optimum bactericidal concentration is in the range of 60% to 90% solutions in water (volume/volume).[66,67]

Alcohols are not recommended for sterilizing medical and surgical materials, principally because of their lack of sporicidal action and their inability to penetrate protein-rich materials. Fatal postoperative wound infections with *Clostridium* have occurred when alcohols were used to sterilize surgical instruments contaminated with bacterial spores.[68] Alcohols have been used effectively to disinfect oral and rectal thermometers, computers,[69] hospital pagers, scissors, cardiopulmonary resuscitation (CPR) manikins, applanation tonometers,[70] external surfaces of equipment (e.g., ventilators), and stethoscopes.[8] Alcohol towelettes have been used for years to disinfect small surfaces such as rubber stoppers of multiple-dose medication vials or vaccine bottles.

Alcohols are flammable and consequently must be stored in a cool, well-ventilated area. Large volumes of alcohol products need to be stored in rooms meeting special fire department regulations. They also evaporate rapidly, and this makes extended exposure time difficult to achieve unless the items are immersed.

Chlorine and Chlorine Compounds

Hypochlorites are the most widely used of the chlorine disinfectants and are available in a liquid (e.g., sodium hypochlorite) or solid (e.g., calcium hypochlorite) form. The most prevalent chlorine products in the United States are aqueous solutions of 5.25% to 6.15% sodium hypochlorite, which usually are called household bleach. They have a broad spectrum of antimicrobial activity (i.e., bactericidal, virucidal, fungicidal, mycobactericidal, sporicidal), do not leave toxic residues, are unaffected by water hardness, are inexpensive and fast acting,[70,71] remove dried or fixed organisms and biofilms from surfaces,[72] and have a low incidence of serious toxicity.[73,74] Sodium hypochlorite at the concentration used in domestic bleach (5.25%–6.15%) may produce ocular irritation or oropharyngeal, esophageal, and gastric burns,[63,75,76] but the frequency is rare.[77] Other disadvantages of hypochlorites include corrosiveness to metals at high concentrations (>500 ppm), inactivation by organic matter, discoloring or "bleaching" of fabrics, release of toxic chlorine gas when mixed with ammonia or acid (e.g., household cleaning agents),[78] and relative stability.[79]

Reports have examined the microbicidal activity of a new disinfectant, "superoxidized water." The concept of electrolyzing saline to create a disinfectant or antiseptics is appealing because the basic materials of saline and electricity are inexpensive and the end product (i.e., water) is not damaging to the environment. The main products of this water are hypochlorous acid (e.g., at a concentration of about 144 mg/L) and chlorine. This is also known as electrolyzed water, and as with any germicide, the antimicrobial activity of superoxidized water is strongly affected by the concentration of the active ingredient (available free chlorine).[80] The free available chlorine concentrations of different superoxidized solutions reported in the literature range from 7 to 180 ppm.[80] Data have shown that freshly generated superoxidized water is rapidly effective (<2 minutes) in achieving a 5-$\log_{10}$ reduction of pathogenic microorganisms (i.e., *M. tuberculosis, Mycobacterium chelonae,* poliovirus, human immunodeficiency virus [HIV], MRSA, *E. coli, Candida albicans, Enterococcus faecalis, Pseudomonas aeruginosa*) in the absence of organic loading. However, the biocidal activity of this disinfectant was substantially reduced in the presence of organic material (5% horse serum).[81,82]

Hypochlorites are widely used in health care facilities in a variety of settings.[71] Inorganic chlorine solution is used for disinfecting tonometer heads[83] and for disinfection of noncritical surfaces and equipment. A 1:10 to 1:100 dilution of 5.25% to 6.15% sodium hypochlorite (i.e., household bleach)[8] or an EPA-registered tuberculocidal disinfectant[8] has been recommended for decontaminating blood spills. For small spills of blood (i.e., drops of blood) on noncritical surfaces, the area can be disinfected with a 1:100 dilution of 5.25% to 6.15% sodium hypochlorite or an EPA-registered tuberculocidal disinfectant. Because hypochlorites and other germicides are substantially inactivated in the presence of blood,[84,85] large spills of blood require that the surface be cleaned before an EPA-registered disinfectant or a 1:10 (final concentration) solution of household bleach is applied. If there is a possibility of a sharps injury, there should be an initial decontamination, followed by cleaning and terminal disinfection (1:10 final concentration).[85] Extreme care should always be employed to prevent percutaneous injury. At least 500 ppm available chlorine for 10 minutes is recommended for decontamination of CPR training manikins.[8] Other uses in health care include as an irrigating agent in endodontic treatment and for disinfecting laundry, dental appliances, hydrotherapy tanks,[32] regulated medical waste before disposal,[71] applanation tonometers,[70] and the water distribution system in hemodialysis centers and hemodialysis machines.[8] Disinfection with a 1:10 dilution of concentrated sodium hypochlorite (i.e., bleach) has been shown to be effective in reducing environmental contamination in patient rooms and in reducing *Clostridioides difficile* (formerly *Clostridium difficile*) infection rates in hospital units where there is a high endemic *C. difficile* infection rate or in an outbreak setting.[86] At the University of North Carolina (UNC) Hospitals, we use a sporicidal solution (1:10 dilution of household bleach or approximately 5000 ppm chlorine) in all *C. difficile*–infected patient rooms for routine daily and terminal cleaning. This is done by means of one application of the sporicide, covering all hand contact surfaces to allow sufficient wetness for an approximately 1-minute contact time.

Chlorine has long been favored as the preferred disinfectant in water treatment. Hyperchlorination of a *Legionella*-contaminated hospital water system[32] resulted in a dramatic decrease (30% to 1.5%) in the isolation of *Legionella pneumophila* from water outlets and a cessation of health care–associated legionnaires' disease in the affected unit.[87,88] Chloramine T and hypochlorites have been used in disinfecting hydrotherapy equipment.[71]

Hypochlorite solutions in tap water at a pH greater than 8 stored at room temperature (20°C) in closed, opaque plastic containers may lose up to 40% to 50% of their free available chlorine level over a period of 1 month. Thus, if a user wished to have a solution containing 500 ppm of available chlorine at day 30, a solution containing 1000 ppm of chlorine should be prepared at time 0. There is no decomposition of sodium hypochlorite solution after 30 days when stored in a closed brown bottle.[79]

Glutaraldehyde

Glutaraldehyde is a saturated dialdehyde that has gained wide acceptance as a high-level disinfectant and chemical sterilant.[89–93] Aqueous solutions of glutaraldehyde are acidic and generally in this state are not sporicidal. Only when the solution is "activated" (made alkaline) by use of alkalinizing agents to pH 7.5 to 8.5 does the solution become sporicidal. Once activated, these solutions have a shelf-life of minimally 14 days

because of the polymerization of the glutaraldehyde molecules at alkaline pH levels. This polymerization blocks the active sites (aldehyde groups) of the glutaraldehyde molecules that are responsible for its biocidal activity.

Novel glutaraldehyde formulations (e.g., glutaraldehyde-phenol-sodium phenate, potentiated acid glutaraldehyde, stabilized alkaline glutaraldehyde) produced in the past 50 years have overcome the problem of rapid loss of activity (e.g., current use life, 28–30 days) while generally maintaining excellent microbicidal activity.[90,91] However, it should be recognized that antimicrobial activity is dependent not only on age but also on use conditions such as dilution and organic stress. The use of glutaraldehyde-based solutions in health care facilities is common because of their advantages, including excellent biocidal properties; activity in the presence of organic matter (20% bovine serum); and noncorrosive action when used on endoscopic equipment, thermometers, or rubber or plastic equipment. The advantages, disadvantages, and characteristics of glutaraldehyde are listed in Table 299.2.

The in vitro inactivation of microorganisms by glutaraldehydes has been extensively investigated and reviewed.[92] Several investigators showed that ≥2% aqueous solutions of glutaraldehyde, buffered to pH 7.5 to 8.5 with sodium bicarbonate, were effective in killing vegetative bacteria in <2 minutes; *M. tuberculosis,* fungi, and viruses in <10 minutes; and spores of *Bacillus* and *Clostridium* species in 3 hours.[70,92,93] Spores of *Clostridioides difficile* are more rapidly killed by 2% glutaraldehyde than are spores of species of *Clostridium* and *Bacillus*;[94,95] this includes the hypervirulent binary toxin strains of *C. difficile* spores (WA Rutala, unpublished data, 2017). There have been reports of microorganisms with relative resistance to glutaraldehyde, including some mycobacteria (*M. chelonae, Mycobacterium avium-intracellulare, Mycobacterium xenopi*),[96–98] *Methylobacterium mesophilicum,*[99] *Trichosporon,* fungal ascospores (e.g., *Microascus cinereus*, *Chaetomium globosum*), and *Cryptosporidium.*[100] *M. chelonae* persisted in a 0.2% glutaraldehyde solution used to store porcine prosthetic heart valves.[101] In a large outbreak of *Mycobacterium massiliense* infections in Brazil after videolaparoscopic equipment was used for different elective cosmetic procedures (e.g., liposuction), the organism was highly tolerant to 2% glutaraldehyde.[102] Porins may have a role in the resistance of mycobacteria to glutaraldehyde and OPA.[103]

Dilution of glutaraldehyde during use commonly occurs, and studies have shown a glutaraldehyde concentration decline after a few days of use in an automatic endoscope washer.[104] This occurs because instruments are not thoroughly dried and water is carried in with the instrument, which increases the solution's volume and dilutes its effective concentration. This emphasizes the need to ensure that semicritical equipment is disinfected with an acceptable concentration of glutaraldehyde. Data suggest that 1.0% to 1.5% glutaraldehyde is the minimum effective concentration (MEC) for >2% glutaraldehyde solutions when used as a high-level disinfectant.[104–106] Chemical test strips or liquid chemical monitors are available for determining whether an effective concentration of glutaraldehyde is present despite repeated use and dilution. The frequency of testing should be based on how frequently the solutions are used (e.g., used daily, test daily; used weekly, test before use), or the manufacturer's recommendation should be followed. The strips should not be used to extend the use life beyond the expiration date. Data suggest that the chemicals in the test strip deteriorate with time,[107] and a manufacturer's expiration date should be placed on the bottles. The bottle of test strips should be dated when opened and used for the period of time indicated on the bottle (e.g., 120 days). The results of test strip monitoring should be documented. The glutaraldehyde test kits have been preliminarily evaluated for accuracy and range,[107] but the reliability has been questioned.[108] The concentration should be considered unacceptable or unsafe when the test indicates a dilution below the product's MEC (generally to 1.0%–1.5% glutaraldehyde or lower) by the indicator not changing color.

Glutaraldehyde is used most commonly as a high-level disinfectant for medical equipment such as endoscopes, endocavitary probes, spirometry tubing, dialyzers, transducers, anesthesia and respiratory therapy equipment, hemodialysis proportioning, and dialysate delivery systems.[8] Glutaraldehyde is noncorrosive to metal and does not damage lensed instruments, rubber, or plastics. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 20°C to 25°C range from 20 to 90 minutes depending on the product. However, multiple scientific studies and professional organizations support the efficacy of >2% glutaraldehyde for 20 minutes at 20°C.[8,31,109] Minimally, one should follow this latter recommendation. Glutaraldehyde should not be used for cleaning noncritical surfaces, because it is too toxic and expensive.

Colitis believed to be due to glutaraldehyde exposure from residual disinfecting solution in the endoscope solution channels has been reported and is preventable through careful endoscope rinsing.[63] One study found that residual glutaraldehyde levels were higher and more variable after manual disinfection (<0.2–159.5 mg/L) than after automatic disinfection (0.2–6.3 mg/L).[110] Similarly, keratopathy and corneal decompensation were caused by ophthalmic instruments that were inadequately rinsed after soaking in 2% glutaraldehyde.[111]

Glutaraldehyde exposure should be monitored to ensure a safe work environment. In the absence of an OSHA permissible exposure limit (PEL), if the glutaraldehyde level is higher than the American Conference of Governmental Industrial Hygienists (ACGIH) ceiling limit of 0.05 ppm, it would be prudent to take corrective action and repeat monitoring.[112]

Hydrogen Peroxide

The literature contains several accounts of the properties, germicidal effectiveness, and potential uses for stabilized hydrogen peroxide in the health care setting. Reports ascribing good germicidal activity to hydrogen peroxide have been published and attest to its bactericidal, virucidal, sporicidal, and fungicidal properties.[113–116] Some other studies have shown limited bactericidal and virucidal activity of standard 3% hydrogen peroxide.[45,70] The advantages, disadvantages, and characteristics of hydrogen peroxide are listed in Tables 299.2 and 299.4. As with other chemical sterilants, dilution of the hydrogen peroxide must be monitored through regular testing of the MEC (i.e., 7.5%–6.0%). Compatibility testing by Olympus America of 7.5% hydrogen peroxide found both cosmetic changes (e.g., discoloration of black anodized metal finishes)[117] and functional changes with the tested endoscopes (Olympus, written communication, October 15, 1999).

Commercially available 3% hydrogen peroxide is a stable and effective disinfectant when used on some inanimate surfaces. It has been used in concentrations from 3% to 6% for the disinfection of soft contact lenses (e.g., 3% for 2–3 hours),[113,118] tonometer biprisms, ventilators, fabrics,[119] and endoscopes.[120] Hydrogen peroxide was effective in spot-disinfecting fabrics in patients' rooms.[119] Corneal damage from a hydrogen peroxide–soaked tonometer tip that was not properly rinsed has been reported.[121]

Improved Hydrogen Peroxide

An improved hydrogen peroxide–based technology has been introduced into health care for disinfection of noncritical environmental surfaces and patient equipment[122–124] and high-level disinfection of semicritical equipment such as endoscopes.[122,125–127] Improved hydrogen peroxide contains very low levels of anionic and/or nonionic surfactants in an acidic product that act with hydrogen peroxide to produce microbicidal activity. This combination of ingredients speeds the antimicrobial activity of hydrogen peroxide and cleaning efficiency.[122,125] Improved hydrogen peroxide is considered safe for humans and equipment, and benign for the environment. Improved hydrogen peroxide has the lowest EPA toxicity category (i.e., category IV) based on its oral, inhalation, and dermal toxicity, which means it is practically nontoxic and not an irritant.[122,127,128] It is prepared and marketed by several companies in various concentrations (e.g., 0.5%–2%), and different companies may use different terminology for these products, such as "accelerated" or "activated." Lower concentrations (i.e., 0.5%, 1.4%) are designed for the low-level disinfection of noncritical environmental surfaces and patient care objects; higher concentrations (i.e., 2.0%) can be used as high-level disinfectants for semicritical medical devices (e.g., endoscopes).

When a study compared the bactericidal activity of two improved hydrogen peroxide products versus standard 0.5%, 1.4%, and 3% hydrogen peroxide formulations, the improved hydrogen peroxide–based environmental surface disinfectants proved to be more effective (>6-$\log_{10}$ reduction) and fast-acting (30–60 seconds) microbicides in the presence

of a soil load (to simulate the presence of body fluids) than commercially available hydrogen peroxide. Only 30- to 60-second contact times were studied because longer contact times (e.g., 10 minutes) are not achievable in clinical practice.[45] In 2017, Boyce and colleagues compared a quat disinfectant and an improved hydrogen peroxide and found the improved hydrogen peroxide reduced surface contamination and reduced a composite colonization or infection outcome.[129] Another study demonstrated that 1.4% activated hydrogen peroxide is very effective in reducing microbial contamination of hospital privacy curtains. In fact, the activated hydrogen peroxide completely eliminated contamination with MRSA and VRE and resulted in a 98.5% reduction in microbes (only *Bacillus* sp. was recoverable).[130] Thus, at UNC Hospitals, privacy curtains are being disinfected at the grab area by means of spraying the grab area of the curtain three times with activated hydrogen peroxide at discharge cleaning.

Iodophors

Iodine solutions or tinctures have long been used by health professionals, primarily as antiseptics on skin or tissue. The FDA has not cleared any liquid chemical sterilant or high-level disinfectant with iodophors as the main active ingredient. However, iodophors have been used both as antiseptics and as disinfectants. An iodophor is a combination of iodine and a solubilizing agent or carrier; the resulting complex provides a sustained-release reservoir of iodine and releases small amounts of free iodine in aqueous solution. The best known and most widely used iodophor is povidone-iodine, a compound of polyvinylpyrrolidone with iodine. This product and other iodophors retain the germicidal efficacy of iodine but, unlike iodine, are generally nonstaining and are relatively free of toxicity and irritancy.[131]

There are several reports that document intrinsic microbial contamination of antiseptic formulations of povidone-iodine and poloxamer-iodine.[132–134] It was found that "free" iodine (I_2) contributes to the bactericidal activity of iodophors and that dilutions of iodophors demonstrate more rapid bactericidal action than does a full-strength povidone-iodine solution. Therefore iodophors must be diluted according to the manufacturers' directions in order to achieve antimicrobial activity.

Published reports on the in vitro antimicrobial efficacy of iodophors demonstrate that iodophors are bactericidal, mycobactericidal, and virucidal but may require prolonged contact times to kill certain fungi and bacterial spores.[16,135–138]

Besides their use as an antiseptic, iodophors have been used for the disinfection of blood culture bottles and medical equipment such as hydrotherapy tanks and thermometers. Antiseptic iodophors are not suitable for use as hard-surface disinfectants because of concentration differences. Iodophors formulated as antiseptics contain less free iodine than those formulated as disinfectants.[139]

Ortho-phthalaldehyde

OPA is a high-level disinfectant that received FDA clearance in October 1999. The solution contains at least 0.55% 1,2-benzenedicarboxaldehyde or OPA, and it has supplanted glutaraldehyde as the most commonly used "aldehyde" for high-level disinfection in the United States. OPA solution is a clear, pale-blue liquid with a pH of 7.5. The advantages, disadvantages, and characteristics of OPA are listed in Table 299.2.

In vitro studies have demonstrated excellent microbicidal activity,[70,140–144] including superior mycobactericidal activity (5-$\log_{10}$ reduction in 5 minutes) compared with glutaraldehyde. Walsh and colleagues also found OPA effective (>5-$\log_{10}$ reduction) against a wide range of microorganisms, including glutaraldehyde-resistant mycobacteria and *Bacillus atrophaeus* spores.[142]

OPA has several potential advantages compared with glutaraldehyde. It has excellent stability over a wide pH range (pH 3–9), is not a known irritant to the eyes and nasal passages, does not require exposure monitoring, has a barely perceptible odor, and requires no activation. OPA, like glutaraldehyde, has excellent material compatibility. A potential disadvantage of OPA is that it stains proteins gray (including unprotected skin) and thus must be handled with caution.[117] However, skin staining would indicate improper handling and indicates a need for additional training and/or personal protective equipment (PPE) (gloves, eye and mouth protection, fluid-resistant gowns). OPA residues remaining on inadequately water-rinsed transesophageal echocardiography probes may leave stains on the patient's mouth. Meticulous cleaning, use of the correct OPA exposure time (e.g., 12 minutes), and copious rinsing of the probe with water should eliminate this problem. Because OPA has been associated with several episodes of anaphylaxis after cystoscopy,[145] the manufacturer has modified its instructions for use of OPA and contraindicates the use of OPA as a disinfectant for reprocessing all urologic instruments for patients with a history of bladder cancer. PPE should be worn for handling of contaminated instruments, equipment, and chemicals.[146] In addition, equipment must be thoroughly rinsed to prevent discoloration of a patient's skin or mucous membrane. The MEC of OPA is 0.3%, and that concentration is monitored with test strips designed specifically for the OPA solution. Monitoring of OPA exposure level revealed that the concentration during the disinfection process was significantly higher in the manual group (median, 1.43 ppb) than in the automatic group (median, 0.35 ppb). These findings corroborate other findings that show that it is desirable to introduce automatic endoscope reprocessors to decrease disinfectant exposure levels among scope-reprocessing technicians.[147]

Peracetic Acid

Peracetic, or peroxyacetic acid, is characterized by a very rapid action against all microorganisms. Special advantages of peracetic acid include its lack of harmful decomposition products (i.e., acetic acid, water, oxygen, hydrogen peroxide); it enhances removal of organic material[148] and leaves no residue. It remains effective in the presence of organic matter and is sporicidal even at low temperatures. Peracetic acid can corrode copper, brass, bronze, plain steel, and galvanized iron, but these effects can be reduced with additives and pH modifications. The advantages, disadvantages, and characteristics of peracetic acid are listed in Table 299.2.

Peracetic acid will inactivate gram-positive and gram-negative bacteria, fungi, and yeasts in less than 5 minutes at less than 100 ppm. In the presence of organic matter, 200 to 500 ppm is required. For viruses the dosage range is wide (12–2250 ppm), with poliovirus inactivated in yeast extract in 15 minutes with 1500 to 2250 ppm. A processing system using peracetic acid at a temperature of 50°C to 56°C can be used for processing heat-sensitive semicritical and critical devices that are compatible with the peracetic acid and processing system and that cannot be sterilized by other legally marketed traditional sterilization methods validated for that type of device (e.g., steam, hydrogen peroxide gas plasma, vaporized hydrogen peroxide). After processing, the devices should be used immediately or stored in a manner similar to that of a high-level disinfected endoscope.[149,150] The sterilant, 35% peracetic acid, is diluted to 0.2% with tap water that has been filtered and exposed to ultraviolet (UV) light. Some data demonstrate the effectiveness of the liquid chemical sterilant processing system for reprocessing duodenoscopes.[151] Simulated-use trials with the earlier version of this processing system have demonstrated excellent microbicidal activity,[70,149,152–154] and three clinical trials have demonstrated both excellent microbial killing and no clinical failures leading to infection.[155–157] Three clusters of infection with use of the earlier version of the peracetic acid automated endoscope reprocessor were linked to inadequately processed bronchoscopes when inappropriate channel connectors were used with the system.[158] These clusters highlight the importance of training, proper model-specific endoscope connector systems, and quality control procedures to ensure compliance with endoscope manufacturer's recommendations and professional organization guidelines. An alternative high-level disinfectant available in the United Kingdom contains 0.35% peracetic acid. Although this product is rapidly effective against a broad range of microorganisms,[159,160] it tarnishes the metal of endoscopes and is unstable, resulting in only a 24-hour use life.[160]

Peracetic Acid With Hydrogen Peroxide

Three chemical sterilants that contain peracetic acid plus hydrogen peroxide (e.g., 0.08% peracetic acid plus 1.0% hydrogen peroxide, 0.23% peracetic acid plus 7.35% hydrogen peroxide) have been cleared by the FDA. The advantages, disadvantages, and characteristics of peracetic acid with hydrogen peroxide are listed in Table 299.2.

The bactericidal and sporicidal properties of peracetic acid plus hydrogen peroxide have been demonstrated.[161,162] Manufacturer's data demonstrated that this combination of peracetic acid plus hydrogen peroxide inactivated all microorganisms with the exception of bacterial spores within 20 minutes. The 0.08% peracetic acid plus 1.0% hydrogen peroxide product was effective in inactivating a glutaraldehyde-resistant *Mycobacterium*.[163]

The combination of peracetic acid and hydrogen peroxide has been used for disinfecting hemodialyzers[164] and environmental surfaces.[165] This disinfectant product was associated with mucous membrane and respiratory health effects when used by hospital staff for surface disinfection.[165] A study used a peracetic acid and hydrogen peroxide solution for all daily, discharge, and common area cleaning and found a significant decrease in hospital-onset *C. difficile* rates.[166] The percentage of dialysis centers using a peracetic acid with hydrogen peroxide–based disinfectant for reprocessing dialyzers increased from 5% in 1983 to 72% in 1997.[167]

Phenolics

Phenol has occupied a prominent place in the field of hospital disinfection since its initial use as a germicide by Lister in his pioneering work on antiseptic surgery. In the past 40 years, however, work has been concentrated on the numerous phenol derivatives or phenolics and their antimicrobial properties. Phenol derivatives originate when a functional group (e.g., alkyl, phenyl, benzyl, halogen) replaces one of the hydrogen atoms on the aromatic ring. Two phenol derivatives commonly found as constituents of hospital disinfectants are ortho-phenylphenol and ortho-benzyl-para-chlorophenol.

Published reports on the antimicrobial efficacy of commonly used phenolics showed that they were bactericidal, fungicidal, virucidal, and tuberculocidal.[16,70,85,135,168–172]

Many phenolic germicides are EPA registered as disinfectants for use on environmental surfaces (e.g., bedside tables, bed rails, laboratory surfaces) and noncritical medical devices. Phenolics are not FDA cleared as high-level disinfectants for use with semicritical items.

The use of phenolics in nurseries has been questioned because of the occurrence of hyperbilirubinemia in infants placed in bassinets where phenolic detergents were used.[173] In addition, Doan and coworkers demonstrated bilirubin level increases in phenolic-exposed infants compared with nonphenolic-exposed infants when the phenolic was prepared according to the manufacturers' recommended dilution.[174] If phenolics (or other disinfectants) are used to clean nursery floors, they must be diluted according to the recommendation on the product label. Phenolics (and other disinfectants) should not be used to clean infant bassinets and incubators while occupied. If phenolics are used to terminally clean infant bassinets and incubators, the surfaces should be rinsed thoroughly with water and dried before the infant bassinets and incubators are reused.[8,175]

Quaternary Ammonium Compounds

The quaternary ammonium compounds are widely used as surface disinfectants. There have been some reports of health care–associated infections associated with contaminated quaternary ammonium compounds used to disinfect semicritical or critical patient care equipment such as cystoscopes or cardiac catheters.[176,177] As with several other disinfectants (e.g., phenolics, iodophors), gram-negative bacteria have been found to survive or grow in them.[134]

Results from manufacturers' data sheets and from published scientific literature indicate that the quaternaries sold as hospital disinfectants are generally fungicidal, bactericidal, and virucidal against lipophilic (enveloped) viruses; they are not sporicidal and generally not tuberculocidal or virucidal against hydrophilic (nonenveloped) viruses.[a] Best and colleagues and Rutala and colleagues demonstrated the poor mycobactericidal activities of quaternary ammonium compounds.[41,135]

The quats are commonly used in ordinary environmental sanitation of noncritical environmental surfaces such as floors, bed rails, bedside tables, and furniture. EPA-registered quaternary ammonium compounds are appropriate to use when disinfecting medical equipment that comes into contact with intact skin (e.g., blood pressure cuffs). Several factors can affect the use of quats, including the types of wipes and towels used[182] and the concentration of quat delivered by automated disinfectant dispensers (approximately 70% disinfectant solution had quat concentrations below 50% of expected concentration).[183] Microfiber wipes, cotton towels, and one of two types of disposable wipes soaked in a quat disinfectant revealed significant binding of the disinfectant (≤50% of the original quat in parts per million—for example, from 800 ppm to 400 ppm or less).[183] Quats are commonly combined with alcohol, which significantly improves their speed of action and antimicrobial spectrum. Disinfectant wipes with alcohol and quaternary ammonium compounds are effective in killing health care pathogens and are commonly used for surface disinfection.[70] For example, studies showed that quats alone are not effective against *Candida auris*, whereas quats combined with alcohol have excellent activity against *C. auris*.[62,184]

Pasteurization

Pasteurization is not a sterilization process; its purpose is to destroy all pathogenic microorganisms with the exception of bacterial spores. The time-temperature relation for hot-water pasteurization is generally greater than 70°C (158°F) for 30 minutes. The water temperature and time should be monitored as part of a quality assurance program.[185] Pasteurization of respiratory therapy[186,187] and anesthesia[188] equipment is a recognized alternative to chemical disinfection.

Ultraviolet Light

UV light has been recognized as an effective method for killing microorganisms. It has been suggested for use in health care for several purposes, including air disinfection, room decontamination (see "'No Touch' Methods for Room Decontamination"), surface disinfection, biofilm disinfection,[189] and ultrasound probe disinfection.[190] Contaminated ultrasound probes can potentially transmit pathogens. When the probe is in contact with only the patient's skin, there is a low risk of infection, and low-level disinfection is recommended.

STERILIZATION

Most medical and surgical devices used in health care facilities are made of materials that are heat stable and thus are sterilized by heat, primarily steam sterilization. However, since 1950, there has been an increase in medical devices and instruments made of materials (e.g., plastics) that require low-temperature sterilization. ETO gas has been used since the 1950s for heat- and moisture-sensitive medical devices. Within the past 25 years, a number of new, low-temperature sterilization systems (e.g., hydrogen peroxide gas plasma, vaporized hydrogen peroxide, hydrogen peroxide plus ozone) have been developed and are being used to sterilize medical devices. This section reviews sterilization technologies used in health care and makes recommendations for their optimum performance in the processing of medical devices.[8]

Sterilization destroys all microorganisms on the surface of an article or in a fluid to prevent disease transmission associated with the use of that item. Although the use of inadequately sterilized critical items represents a high risk of transmitting pathogens, documented transmission of pathogens associated with an inadequately sterilized critical item is exceedingly rare.[191–193] This is likely due to the wide margin of safety associated with the sterilization processes used in health care facilities. The concept of what constitutes "sterile" is measured as a probability of sterility for each item to be sterilized. This probability is commonly referred to as the sterility assurance level (SAL) of the product and is defined as the probability of a single viable microorganism occurring on a product after sterilization. SAL is normally expressed as 10^{-n}. For example, if the probability of a spore surviving were 1 in 1 million, the SAL would be 10^{-6}.[194,195] Dual SALs (e.g., 10^{-3} SAL for blood culture tubes, drainage bags; 10^{-6} SAL for scalpels, implants) have been used in the United States for many years and the choice of a 10^{-6} SAL was strictly arbitrary and not associated with any adverse outcomes (e.g., patient infections).[194]

Medical devices that have contact with sterile body tissues or fluids are considered critical items. These items should be sterile when used because any microbial contamination could result in disease transmission. Such items include surgical instruments, biopsy forceps, and implanted

[a]References 16, 41, 42, 135, 168, 178–181.

medical devices. If these items are heat resistant, the recommended sterilization process is steam sterilization, because it has the largest margin of safety owing to its reliability, consistency, and lethality and is least affected by organic and inorganic soils. However, reprocessing heat- and moisture-sensitive items requires use of a low-temperature sterilization technology (e.g., ETO, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, hydrogen peroxide plus ozone).[196] A summary of the advantages and disadvantages of commonly used sterilization technologies is presented in Table 299.3.

Health care facilities must have a quality assurance process in place to ensure the adequacy of staff training, competency testing (at employment and at least annually), compliance with evidence-based guidelines and/or manufacturer's instructions for use, appropriate and adequate space, and appropriate process monitoring (e.g., cleaning monitors) with documentation.[197] All areas that reprocess semicritical or critical patient care equipment should be audited to ensure that they comply with evidence-based guidelines and/or manufacturer's instruction for use, and if deficiencies are identified, they should be corrected.[198] If noncompliance with evidence-based guidelines occurs during reprocessing of critical and semicritical equipment, a patient risk assessment using a 14-step protocol can guide an institution in determining if and how patients should be notified of the potential adverse event.[199]

Steam Sterilization

Of all the methods available for sterilization, moist heat in the form of saturated steam under pressure is the most widely used and the most dependable. Steam sterilization is nontoxic, inexpensive,[200] rapidly microbicidal, sporicidal, and rapidly heats and penetrates fabrics (see Table 299.3).[201] Like all sterilization processes, steam sterilization has some deleterious effects on some materials, including corrosion and combustion of lubricants associated with dental handpieces,[202] reduction in ability to transmit light associated with laryngoscopes,[203] and increased hardening time (5- to 6-fold) with plaster cast.[204]

The basic principle of steam sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time. Thus, there are four parameters of steam sterilization: steam, pressure, temperature, and time. The ideal steam for sterilization is dry saturated steam and entrained water (dryness fraction ≥97%).[205] Pressure serves as a means to obtain the high temperatures necessary to quickly kill microorganisms. Specific temperatures must be obtained to ensure the microbicidal activity. The two common steam sterilizing temperatures are 121°C (250°F) and 132°C (270°F). These temperatures (and other high temperatures) must be maintained for a minimal time to kill microorganisms. Recognized minimum exposure periods for sterilization of wrapped health care supplies are 30 minutes at 121°C (250°F) in a gravity displacement sterilizer or 4 minutes at 132°C (270°F) in a prevacuum sterilizer. At constant temperatures, sterilization times vary depending on the type of item (e.g., metal versus rubber, plastic, items with lumens), whether the item is wrapped or unwrapped, and the sterilizer type.

The two basic types of steam sterilizers (autoclaves) are the gravity displacement autoclave and the high-speed prevacuum sterilizer. In the former, steam is admitted at the top or the sides of the sterilizing chamber and, because the steam is lighter than air, forces air out the bottom of the chamber through the drain vent. Gravity displacement autoclaves are primarily used to process laboratory media, water, pharmaceutical products, regulated medical waste, and nonporous articles whose surfaces have direct steam contact. With gravity displacement sterilizers the penetration time into porous items is prolonged because of incomplete air elimination. High-speed prevacuum sterilizers are similar to gravity displacement sterilizers except that they are fitted with a vacuum pump (or ejector) to ensure air removal from the sterilizing chamber and load before the steam is admitted. The advantage of using a vacuum pump is that there is nearly instantaneous steam penetration even into porous loads.

Like other sterilization systems, the steam cycle is monitored with physical, chemical, and biologic monitors.[8] Steam sterilizers usually are monitored with a printout (or graphically) that shows temperature, the time at the temperature, and pressure. Typically, chemical indicators are affixed to the outside and incorporated into the pack to monitor the temperature or time and temperature. The effectiveness of steam sterilization is monitored with a biologic indicator containing spores of *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*). Positive spore test results are a relatively rare event and can be attributed to operator error, inadequate steam delivery,[206] or equipment malfunction.

Portable steam sterilizers are used in outpatient, dental, and rural clinics. These sterilizers are designed for small instruments, such as hypodermic syringes and needles and dental instruments. The ability of the sterilizer to reach physical parameters necessary to achieve sterilization should be monitored with physical, chemical, and biologic indicators.[8]

Steam sterilization should be used whenever possible on all critical and semicritical items that are heat and moisture resistant (e.g., respiratory therapy and anesthesia equipment), even when not essential to prevent pathogen transmission. Steam sterilizers also are used in health care facilities to decontaminate microbiologic waste[207] and sharps containers, but additional exposure time is required in the gravity displacement sterilizer for these items.

Immediate-Use Steam Sterilization

"Flash" steam sterilization was originally defined by Underwood and Perkins as sterilization of an unwrapped object at 132°C for 3 minutes at 27 to 28 pounds of pressure in a gravity displacement sterilizer.[208] It was intended for instruments (e.g., dropped instruments) when there is insufficient time to sterilize an item by means of the preferred package method. The term "flash" arose out of the abbreviated time of exposure of the unwrapped instrument. "Flash sterilization" is an antiquated term that does not fully describe the various steam sterilization cycles now used to process items not intended to be stored for later use. "Immediate use" is defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. This implies that the sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. The same critical reprocessing steps (such as cleaning, decontamination, rinsing, and aseptic transfer from the sterilizer to the point of use) must be followed. Immediate-use steam sterilization (IUSS) should not be used for convenience, as an alternative to purchasing sufficient instrument sets, or as a time saver.[209,210] Some hospitals have reduced or eliminated the need for IUSS by means of various practices such as a multidisciplinary collaboration to analyze the reason for each IUSS event.[211,212]

Ethylene Oxide "Gas" Sterilization

ETO is a colorless gas that is flammable and explosive. The four essential parameters (operational ranges) are gas concentration (450–1200 mg/L); temperature (37 °C–63°C); relative humidity (40%–80%; water molecules carry ETO to reactive sites); and exposure time (1–6 hours). These influence the effectiveness of ETO sterilization.[213–215] Within certain limitations, an increase in gas concentration and temperature may shorten the time necessary for achieving sterilization.

The main disadvantages associated with ETO are the lengthy cycle time and its potential hazards to patients and staff; the main advantages are that it is highly penetrating and can sterilize occluded locations in medical items and can sterilize heat- or moisture-sensitive medical equipment without deleterious effects on the material used in the medical devices (see Table 299.3).[214] Acute exposure to ETO may result in irritation (e.g., to skin, eyes, gastrointestinal or respiratory tract) and central nervous system depression.[63] Chronic inhalation has been linked to the formation of cataracts, cognitive impairment, neurologic dysfunction, and disabling polyneuropathies.[63] Occupational exposure in health care facilities has been linked to hematologic changes and an increased risk of spontaneous abortions and various cancers.[63] ETO should be considered a probable human carcinogen.[216]

The use of ETO evolved when few alternatives existed for sterilizing heat- and moisture-sensitive medical devices; now there are several low-temperature sterilization technologies (see Table 299.3). However, favorable properties account for its continued use.[217] Two ETO gas mixtures replaced ETO-chlorofluorocarbon (CFC) mixtures for large-capacity, tank-supplied sterilizers. The ETO–carbon dioxide (CO_2)

mixture consists of 8.5% ETO and 91.5% CO_2. This mixture has limited use in US health care facilities but is sometimes used in hospitals in India and China. It is less expensive than ETO-hydrochlorofluorocarbons (HCFCs), but a disadvantage is the need for pressure vessels rated for steam sterilization, because higher pressures (28-psi gauge) are required. The other mixture, which is a drop-in CFC replacement, is ETO mixed with HCFC. HCFCs are approximately 50-fold less damaging to the earth's ozone layer than are CFCs. The EPA began regulations of HCFC in the year 2015 and will terminate production in the year 2030. An alternative to the pressurized mixed-gas ETO systems is 100% ETO. In part because of the aforementioned events, the 100% ETO sterilizers using unit-dose cartridges are the system for ETO use in US health care facilities.

The excellent microbicidal activity of ETO has been demonstrated in several studies[20,154,217–220] and summarized in published reports.[221] ETO inactivates all microorganisms, although bacterial spores (especially *B. atrophaeus*) are more resistant than other microorganisms. For this reason, *B. atrophaeus* is the recommended biologic indicator organism.

As with all sterilization processes, the effectiveness of ETO sterilization can be altered by lumen length, lumen diameter, inorganic salts, and organic materials.[20,154,218–220,222] For example, although ETO is not used commonly for reprocessing endoscopes,[223] several studies have shown failure of ETO in inactivating contaminating spores in endoscope channels [224] or lumen test units.[20,154,219,220] Residual ETO levels averaging 66.2 ppm have been found even after the standard degassing time.[120] Failure of ETO also has been observed when dental handpieces were contaminated with *Streptococcus mutans* and exposed to ETO.[225] It is recommended that dental handpieces be steam sterilized.

ETO is used in health care facilities to sterilize critical items (and sometimes semicritical items) that are moisture or heat sensitive and cannot be sterilized with steam sterilization.

Hydrogen Peroxide Gas Plasma

New low-temperature sterilization technology based on hydrogen peroxide and plasma was patented in 1987 and marketed in the United States in 1993. Gas plasmas have been referred to as the fourth state of matter (i.e., liquids, solids, gases, and gas plasmas). Gas plasmas are generated in an enclosed chamber under deep vacuum using radiofrequency or microwave energy to excite the gas (i.e., hydrogen peroxide) molecules and produce charged particles, many of which are in the form of free radicals (e.g., hydroxyl and hydroperoxyl). This system works by diffusing hydrogen peroxide into the chamber and then "exciting" the hydrogen peroxide into a plasma state. The combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes instruments without leaving toxic residues. The biologic indicator used with this system is *G. stearothermophilus* spores.

This process has the ability to inactivate a broad range of microorganisms, including resistant bacterial spores. Studies have been conducted against vegetative bacteria (including mycobacteria), yeasts, fungi, viruses, and bacterial spores.[20,154,219,226–232] Like all low-temperature sterilization processes, the effectiveness can be altered by lumen length, lumen diameter, inorganic salts, and organic materials.[20,154,222,226–228]

Materials and devices that cannot tolerate high temperatures and humidity, such as some plastics, electrical devices, and corrosion-susceptible metal alloys, can be sterilized with hydrogen peroxide gas plasma. This method has been compatible with most (>95%) medical devices and materials tested.[233,234]

Vaporized Hydrogen Peroxide

Another low-temperature sterilization system used in health care facilities to sterilize reusable metal and nonmetal devices is vaporized hydrogen peroxide.[235] The system is compatible with a wide range of medical instruments and materials (e.g., polypropylene, brass, polyethylene). There are no toxic by-products; only water vapor and oxygen are produced. The system is not intended to process liquids, linens, powders, or any cellulose materials. The system can sterilize instruments with diffusion-restricted spaces (e.g., scissors) and medical devices with a single stainless steel lumen based on lumen internal diameter and length (e.g., an inside diameter of 1 mm or larger and a length of 125 mm or shorter; see manufacturer's recommendations). Thus, gastrointestinal endoscopes and bronchoscopes cannot be sterilized in this system at the current time. Although this system has not been comparatively evaluated with other sterilization processes, vaporized hydrogen peroxide has been shown to be effective in killing spores, viruses, mycobacteria, fungi, and bacteria.[235] Table 299.3 lists the advantages and disadvantages of this and other processes.

Hydrogen Peroxide Plus Ozone

A new low-temperature sterilizer is marketed as a combination of hydrogen peroxide plus ozone. This sterilizer is primarily a hydrogen peroxide sterilizer similar to the vaporized hydrogen peroxide and hydrogen peroxide gas plasma sterilizers discussed earlier. The sterilizer uses ozone to lower the hydrogen peroxide concentration.[236] In July 2016, the sterilizer was cleared by the FDA for colonoscopes, gastroscopes, and other multichannel flexible endoscopes of up to four channels having internal lumens of ≥1.45 mm in inner diameter and ≤3.5 meters in length.[236,237] Although this system has not been comparatively evaluated with other sterilization processes, vaporized hydrogen peroxide has been shown to be effective in killing spores, viruses, mycobacteria, fungi, and bacteria.[236] Table 299.3 lists the advantages and disadvantages of this and other sterilization processes.

Current Issues in Sterilization

Inactivation of Creutzfeldt-Jakob Disease Agent

Creutzfeldt-Jakob disease (CJD) is a degenerative neurologic disorder of humans with an incidence in the United States of approximately 1 case per million population per year.[238,239] CJD is thought to be caused by a proteinaceous infectious agent or prion. CJD is related to other human transmissible spongiform encephalopathies (TSEs), which include kuru (incidence rate of zero; now eradicated), Gerstmann-Sträussler-Scheinker (GSS) syndrome (1 case per 40 million), and fatal insomnia syndrome (FFI) (<1 case per 40 million). The agents of CJD and other TSEs exhibit an unusual resistance to conventional chemical and physical decontamination methods. A new practical diagnostic test for detecting the pathogenetic prion protein in spinal fluid has been reported and is called the real-time quaking-induced conversion test.[240] Because the CJD agent is not readily inactivated with 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.[238,239,241–243]

The current recommendations consider inactivation data but also use epidemiologic studies of prion transmission, infectivity of human tissues, and efficacy of removing proteins by cleaning.[238,239,241,242] On the basis of scientific data, only critical (e.g., surgical instruments) and semicritical devices contaminated with high-risk tissue (i.e., brain, spinal cord, and eye tissue) from high-risk patients (e.g., known or suspected infection with CJD or other prion disease) require special prion reprocessing. A moist environment after contamination reduces the attachment of both protein and prion amyloid to the stainless steel surface, so moist conditions should be maintained.[244] After the device is clean, it should be sterilized by means of either autoclaving (i.e., steam sterilization) or a combination of sodium hydroxide and autoclaving using one of the following options: (1) autoclave at 134°C for 18 minutes in a prevacuum sterilizer; (2) autoclave at 132°C for 1 hour in a gravity displacement sterilizer; (3) immerse in 1N NaOH for 1 hour, remove and rinse in water, then transfer to an open pan and autoclave [121°C gravity displacement or 134°C porous or prevacuum sterilizer] for 1 hour; or (4) immerse in 1N NaOH for 1 hour and heat in a gravity displacement sterilizer at 121°C for 30 minutes, then clean and subject to routine sterilization.[238,239,243,245] Some data suggest that the temperature should not exceed 134°C because the effectiveness of autoclaving may decline as the temperature is increased (e.g., 136°C, 138°C).[246] Prion-contaminated medical devices that are impossible or difficult to clean should be discarded. To minimize environmental contamination, noncritical environmental surfaces should be covered with plastic-backed paper, and 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 solutions.[238,245]

DISINFECTION

High-Level Disinfection of Semicritical Items

Semicritical items are those that come in contact with intact mucous membranes or nonintact skin. Respiratory therapy and anesthesia equipment, gastrointestinal endoscopes, bronchoscopes, laryngoscopes, transesophageal echocardiogram probes, tonometers, endocavitary probes, prostate biopsy probes, cystoscopes, hysteroscopes, infrared coagulation devices, and diaphragm fitting rings are included in this category. These medical devices should be free of all microorganisms (i.e., mycobacteria, fungi, viruses, bacteria), although small numbers of bacterial spores may be present.[3,24,247]

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.[199] Before new equipment (especially semicritical equipment, for which the margin of safety is less than that for sterilization)[248] 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 should be competency tested. At UNC Hospitals, to ensure patient-safe instruments, all staff members who reprocess semicritical instruments (e.g., instruments that come into contact with a mucous membrane, such as vaginal probes, endoscopes, prostate probes) are required to attend a 3-hour class on high-level disinfection of semicritical instruments. This includes health care providers reprocessing instruments in outpatient care facilities.[249] The class includes the rationale for and importance of high-level disinfection, discussion of high-level disinfectants and exposure times, reprocessing steps, monitoring for MEC, use of PPE, and the reprocessing environment (e.g., establish "dirty-to-clean" flow). Infection-control rounds or audits should be conducted annually in all clinical areas in which critical and semicritical devices are reprocessed, in order to ensure adherence to the reprocessing guidelines, manufacturers' instructions for use, and institutional policies.[198]

Current Issues With High-Level Disinfection of Semicritical Items

Reprocessing Endoscopes: A Shift From Disinfection to Sterilization

Physicians use endoscopes to diagnose and treat numerous medical disorders. Although endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with use has been reported as low, more health care–associated outbreaks have been linked to contaminated endoscopes than to any other medical device. In fact, over the past few years alone there have been more than 25 outbreaks of multidrug-resistant organisms (MDROs; e.g., CRE) in major hospitals in the United States and the world that have killed dozens of patients and caused morbidity in hundreds more.[6] These outbreaks have been linked primarily to contaminated duodenoscopes that are used to diagnose and treat disease of the liver, bile ducts, and pancreas. However, other gastrointestinal endoscopes (e.g., colonoscopes, gastroscopes) and bronchoscopes have been associated with about 100 more outbreaks causing additional death and illness.[4] The key concern raised by these outbreaks is whether current endoscope reprocessing guidelines are adequate to ensure a patient-safe endoscope (i.e., one devoid of potential pathogens) or whether the features of endoscopes—their long, narrow channels; right-angle turns; components that are difficult to clean and disinfect; heavy microbial contamination; and biofilm development (and required removal)[14]—make it impossible to achieve high-level disinfection of these instruments.[250] Because gastrointestinal endoscopes and bronchoscopes come into contact with intact mucous membranes but frequently have contact with nonintact mucous membranes and sterile tissue, there is a risk of patient-to-patient transmission of potential pathogens, with a subsequent risk of infection. The critical need and rationale for this transition from disinfection to sterilization for endoscopes have been discussed in various peer-reviewed publications including *JAMA, American Journal of Infection Control,* and *Infection Control and Hospital Epidemiology*.[3,248,251]

Recommendations for the cleaning and disinfection of endoscopic equipment have been published and should be strictly followed.[8,31] Unfortunately, audits have shown that personnel do not adhere to guidelines on reprocessing,[5] and outbreaks of infection continue to occur.[6] To ensure that reprocessing personnel are properly trained, initial and annual competency testing should be conducted for each individual who is involved in reprocessing endoscopic instruments.

In general, endoscope disinfection or sterilization with a liquid chemical sterilant or high-level disinfectant involves five steps 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) and perfuse (eliminates air pockets and ensures contact of the germicide with the internal channels) disinfectant into all accessible channels such as the suction/biopsy channel and air/water channel, and expose for a time recommended for specific products; (3) rinse—rinse the endoscope and all channels with sterile water, filtered water (commonly used with 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).[8]

Inactivation of Human Papilloma Virus

Human papilloma virus (HPV) is an extremely common sexually acquired pathogen and is considered the cause of cervical cancer. A 2014 paper demonstrated that the FDA-cleared high-level disinfectants (i.e., glutaraldehyde, OPA) tested did not inactivate HPV, a nonenveloped virus.[252] These findings are inconsistent with many papers in the peer-reviewed literature that demonstrate that high-level disinfectants such as OPA and glutaraldehyde inactivate nonenveloped viruses such as hepatitis A virus, polio, adenovirus, and norovirus.[8] Because the high-level disinfectants are commonly used to disinfect endocavitary probes (e.g., vaginal probes, rectal probes) and this equipment and associated surfaces are contaminated,[253] there is an urgency to corroborate these data. At present, hospitals should continue to use the FDA-cleared high-level disinfectants consistent with the manufacturers' instructions until the data can be corroborated. Studies are being done to validate these findings. Data have demonstrated the activity of a hydrogen peroxide mist device to inactivate HPV.[254]

Immersion Versus Perfusion of Channel Scopes Such as Cystoscopes

In the United States, it is estimated that over 4 million cystoscopies are performed each year. Cystoscopy is a diagnostic procedure in which the examiner uses a specially designed endoscope to examine the bladder, lower urinary tract, and prostate gland or to collect urine samples, perform biopsies, or remove small stones. A flexible or rigid scope can be used to carry out the procedure. Because the endoscope and other channeled scopes (e.g., hysteroscopes, some nasopharyngoscopes) come into contact with the patient's mucous membranes, such instruments are considered semicritical devices that must at a minimum undergo high-level disinfection.

A study evaluated the disinfection of cystoscopes, and the results demonstrated that disinfection (i.e., a reduction in bacterial load of greater than 7-$\log_{10}$ colony-forming units [CFUs]) did not occur unless the channel was actively perfused with the glutaraldehyde disinfectant. Failure to perfuse the channel led to only minimal, if any, reduction in bacterial contamination. However, complete inactivation of 10^8 CFUs of both VRE and CRE was achieved when the channel was actively perfused. It appears that no high-level disinfectant entered the channel unless it was actively perfused, because the level of microbial contamination was not reduced with immersion.[255] This occurs because the air pressure in the channel is stronger than the fluid pressure at the fluid-air interface. Recommendations are provided for high-level disinfection of cystoscopes and include actively perfusing the device while it is immersed in the high-level disinfectant.[255] Unfortunately, some cystoscope reprocessing recommendations published in the literature are incorrect. For example, authors recommended complete immersion of the cystoscope into the high-level disinfectant but did not mention perfusion of the high-level disinfectant into the channel.[256]

Ultrasound Probe Disinfection With Vaporized Hydrogen Peroxide

Although the most common method of performing high-level disinfection of contaminated endocavitary probes is by immersion in an FDA-cleared high-level disinfectant (e.g., glutaraldehyde), an alternative procedure for disinfecting the endocavitary and surface probes is a proprietary hydrogen peroxide vapor system, which uses 35% hydrogen peroxide at 56°C with the probe reaching no more than 40°C (i.e., Trophon). The efficacy of this technology, which has been cleared by the FDA for high-level disinfection, has been described in recent publications.[257,258] The results demonstrated complete inactivation (>6-$\log_{10}$ reduction) of VRE and a carbapenem-resistant *Klebsiella pneumoniae* strain, in both the presence and the absence of 5% fetal calf serum (FCS). The Trophon EPR system showed good, but not complete, inactivation of *Mycobacterium terrae* (5.2-$\log_{10}$ reduction for *M. terrae* with FCS, 4.6-$\log_{10}$ reduction for *M. terrae* without FCS) and *C. difficile* spores.[257] Another study showed a 4-$\log_{10}$ reduction of virus titer with various test methods and murine norovirus, adenovirus, and parvovirus.[258]

Low-Level Disinfection of Noncritical Environmental Surfaces and Patient Care Equipment

Over the past decade, excellent evidence in the scientific literature has indicated that contaminated environmental surfaces and noncritical patient care items play an important role in the transmission of several key health care–associated pathogens including MRSA, VRE, *Acinetobacter,* norovirus, and *C. difficile*.[34,40,259–263] All these pathogens have been demonstrated to persist in the environment for days (in some cases months), frequently contaminate the environmental surfaces in rooms of colonized or infected patients,[264] transiently colonize the hands of health care personnel,[265] can be transmitted by health care personnel, and have caused outbreaks in which environmental transmission was deemed to play a role. Important to note, a study by Stiefel and colleagues demonstrated that contact with the environment was just as likely to contaminate the hands of health care providers as was direct contact with the patient.[265] Furthermore, admission to a room in which the previous patient had been colonized or infected with MRSA, VRE, *Acinetobacter,* or *C. difficile* was shown to be a risk factor for the newly admitted patient to develop colonization or infection.[59,266]

Adequacy of Room Cleaning and Disinfection With Chemical Germicides

It has long been recommended in the United States that environmental surfaces in patient rooms be cleaned and disinfected on a regular basis (e.g., daily, three times per week), when surfaces are visibly soiled, and after patient discharge (terminal cleaning).[8] In the past 10 years there have been several studies that have affected the implementation and effectiveness of cleaning of hospital room surfaces.[263] A randomized trial demonstrated that daily disinfection in rooms of patients with *C. difficile* and MRSA reduced acquisition of MRSA and *C. difficile* on hands after contact with surfaces and reduced contamination of hands of health care providers caring for the patients.[267] In 2015 a study demonstrated that use of a daily disinfectant cleaner instead of a daily cleaner reduced hospital-acquired infection (HAI) rates.[268] These studies and others[86] support the use of hospital disinfectants, which are generally EPA registered. Unfortunately, studies have demonstrated that adequate environment cleaning is frequently lacking.[269] For example, Carling and coworkers assessed the thoroughness of terminal cleaning in the patient's immediate environment in 23 acute-care hospitals (1119 patient rooms) by using a transparent, easily cleaned, stable solution that fluoresces when exposed to hand-held UV light.[60] The overall thoroughness of cleaning, expressed as a percent of surfaces evaluated, was 49% (range for all hospitals, 35%–81%). A 2017 study of hospitals that implemented a program to improve the thoroughness of disinfection of near-patient surfaces found that thoroughness of cleaning scores improved from 61% to >80% and that the increase could be maintained over time by means of repeated cycles of assessment paired with repeated feedback and education sessions.[270] An ATP detection device combined with educational feedback for environmental service workers also resulted in significant improvement in cleaning efficacy of the hospital room environment.[271] Preliminary results suggest that a novel chemical additive that colorizes chlorine-based disinfectants to visualize surface coverage improves sites of application, which may improve cleaning by environmental services personnel and may reduce microbial contamination of surfaces.[272]

Improving Room Cleaning and Disinfection, and Demonstrating the Effectiveness of Surface Decontamination in Reducing Health Care–Associated Infections

Investigators have reported that intervention programs aimed at environmental service workers resulted in significant improvement in cleaning practices.[60] Such interventions have generally included multiple activities: improved education, monitoring of the thoroughness of cleaning (e.g., through use of ATP assays or fluorescent dyes) with feedback regarding performance given to the environmental service workers,[270] and/or use of cleaning checklists. We have found that assignment of cleaning responsibility (e.g., medical equipment to be cleaned by nursing; environmental surfaces to be cleaned by environmental service) is also important to ensure that all objects and surfaces are decontaminated, especially the surfaces of medical equipment (e.g., cardiac monitors). Improved environmental cleaning has been demonstrated to reduce the environmental contamination with VRE,[273,274] MRSA,[274] and *C. difficile.*[275] Important to note, no study has reported proper cleaning of more than 85% of objects in the postintervention period. Furthermore, all studies have focused on improvement in only a limited number of "high-risk" objects. Therefore a concern regarding published studies is that they have demonstrated improved cleaning of only this limited number of "high-risk" objects (or "targeted" objects) rather than an improvement in the overall thoroughness of room decontamination.

"No-Touch" Methods for Room Decontamination

As noted earlier, multiple studies have demonstrated that environmental surfaces and objects in rooms are frequently not properly cleaned and that these surfaces may be important in transmission of health care–associated pathogens. Furthermore, whereas interventions aimed at improving cleaning thoroughness have demonstrated effectiveness, many surfaces remain inadequately cleaned and therefore potentially contaminated. For this reason, several manufacturers have developed room disinfection units that can effectively decontaminate environmental surfaces and objects and/or inoculated test surfaces.[276–296] The two systems that have been studied comprehensively and are discussed here are UV light and hydrogen peroxide.[259,297,298] These technologies supplement, but do not replace, standard cleaning and disinfection because surfaces must be physically cleaned of dirt and debris.

Ultraviolet Light for Room Decontamination

UV irradiation has been used for the control of pathogenic microorganisms in a variety of applications, such as control of legionellosis, and for disinfection of air, surfaces, and instruments.[297,299] At certain wavelengths, UV light will break the molecular bonds in DNA, thereby destroying the organism. UV-C has a characteristic wavelength of 200 to 270 nm (e.g., 254 nm), which lies in the germicidal active portion of the electromagnetic spectrum of 200 to 320 nm. Another UV device uses pulsed xenon radiation, which produces UV light in the 200- to 320-nm range. The efficacy of UV irradiation is a function of many different parameters such as organic load, distance from the UV device, pathogen, dose, exposure time, lamp placement, direct or indirect line of sight from the device, room size and shape, and air movement patterns. Studies have systematically investigated how these parameters affect the effectiveness of UV irradiation.[300,301]

Weber and colleagues summarized multiple studies that assessed the effectiveness of UV devices to inactivate microbes inoculated onto test surfaces that were then placed in a typical room.[300] The most commonly tested organisms were epidemiologically important health care–associated pathogens and included MRSA, VRE, *C. difficile*, and *Acinetobacter* spp. In general, the studies showed that >3-$\log_{10}$ vegetative bacteria can be killed in 5 to 25 minutes by UV-C and that UV-C

requires more time and energy to kill spore-forming organisms—for example, *C. difficile* spores.[276–284]

Hydrogen Peroxide Systems for Room Decontamination

Several systems that produce hydrogen peroxide (e.g., hydrogen peroxide vapor, aerosolized dry mist hydrogen peroxide) have been studied for their ability to decontaminate environmental surfaces, objects in hospital rooms, and unused medical supplies.[302] Hydrogen peroxide vapor has been used increasingly for the decontamination of rooms in health care settings.[281,285–294] These investigators found that hydrogen peroxide systems are a highly effective method for eradicating various pathogens (e.g., MRSA, *M. tuberculosis, Serratia, C. difficile* spores, *Clostridium botulinum* spores) from rooms, furniture, and equipment.

Comparison of Ultraviolet Irradiation Versus Hydrogen Peroxide for Room Decontamination

The UV-C device studied and the systems that use hydrogen peroxide have their own advantages and disadvantages,[303] and there is now ample evidence that these "no-touch" systems can reduce environmental contamination with health care–associated pathogens. However, each specific system should be studied and its efficacy demonstrated before being introduced into health care facilities. The main advantage of both types of units is their ability to achieve substantial reductions in vegetative bacteria. As noted earlier, manual cleaning has been demonstrated to be suboptimal because many environmental surfaces are not cleaned. Another advantage is their ability to substantially reduce *C. difficile,* given that low-level disinfectants (such as quaternary ammonium compounds) have only limited or no measurable activity against spore-forming bacteria.[303] Both systems are residual free and they decontaminate all exposed surfaces and equipment in the room.

The major disadvantages of both decontamination systems are the substantial capital equipment costs; the need to remove personnel and patients from the room, thus limiting their use to terminal room disinfection (must prevent or minimize exposure to UV light and hydrogen peroxide); the staff time needed to transport the system to rooms to be decontaminated and monitor its use; the need to physically clean the room of dust and debris; and the sensitivity to use parameters. There are several important differences between the two systems. The UV-C system offers faster decontamination, which reduces the downtime of the room before another patient can be admitted. The hydrogen peroxide systems have been demonstrated to be more effective in eliminating spore-forming organisms. Whether this improved sporicidal activity is clinically important is unclear; studies have demonstrated that although environmental contamination is common in the rooms of patients with *C. difficile* infection, the level of contamination is relatively low (also true for MRSA and VRE).

In the past 5 years, multiple trials have assessed the efficacy of UV light and hydrogen peroxide room decontamination units for reducing HAIs. Currently, six clinical trials have demonstrated a reduction of HAIs with the use of hydrogen peroxide systems, and seven clinical trials have demonstrated a reduction in HAIs with UV light.[259,298] However, 11 of these studies used a before-after design, which is more likely subject to bias than crossover studies or randomized clinical trials. Two studies used a stronger epidemiologic design—a prospective cohort study[304] or a randomized clinical trial.[279] Specifically, the later study in nine hospitals was a prospective, multicenter, cluster-randomized, crossover trial that evaluated three strategies for enhanced room disinfection: quat plus UV-C; bleach alone, and bleach plus UV-C. The study showed that enhanced room decontamination strategies (i.e., bleach and/or UV-C decontamination) decreased the clinical incidence of acquisition of target MDROs (i.e., MRSA, VRE, *C. difficile*) by approximately 10% to 30% ($P = .036$). Comparing the best strategy with the worst strategy (i.e., quat vs. quat plus UV) revealed that a reduction of 94% in epidemiologically important pathogens (i.e., 60.8 vs. 3.4) led to a 35% decrease in colonization or infection (2.3% vs. 1.5%). These data demonstrate that a decrease in room contamination was associated with a decrease in patient colonization or infection. To our knowledge, this was the first study that quantitatively described the entire pathway whereby improved disinfection decreased microbial contamination, which in turn reduced patient colonization or infection.[279,305]

Based on these data, hospitals should use a "no-touch" device for terminal room decontamination after discharge of patients on contact precautions. However, the multitude of commercially available devices makes choosing a device difficult. UV devices may vary because of differences in UV wavelength, dose, ability to measure dose, and cost. Similarly, hydrogen peroxide devices may differ with regard to concentration, method of injecting hydrogen peroxide into the room, dissemination of the hydrogen peroxide in the room, and cost. For these reasons, infection preventionists should review the peer-reviewed literature and choose for purchase only devices with demonstrated bactericidal capability as assessed by carrier test method and/or ability to disinfect actual rooms. Ultimately, one should choose only "no-touch" devices that have demonstrated the ability to reduce HAIs.[259,298]

Continuous Room Decontamination

Even after cleaning and disinfection, surfaces can rapidly become recontaminated. Thus, hands of health care providers can become colonized by touching contaminated environmental surfaces and patient care equipment, and inadequate hand hygiene or inappropriate glove use can then result in the transfer of health care pathogens from patient to patient. Because routine cleaning of room surfaces by environmental services is frequently inadequate, continuous room decontamination methods are being evaluated. These include visible light disinfection (high-intensity narrow-spectrum light)[306]; low-concentration hydrogen peroxide; persistent disinfectants[69,146,307,308]; and self-disinfection surfaces (e.g., copper).[309] These methods are under active investigation but to date have not been assessed for their ability to reduce HAIs.[309]

Surface Disinfection: Treatment Time (Wipes/Sprays) Versus Contact Time (Liquids)

Another current issue in disinfection is the correct interpretation, based on testing methodology, of the contact time (wet time) for liquid disinfectants used for surface disinfection versus the treatment time (undisturbed time, duration of wet time not relevant) for wipes and sprays used in surface disinfection. The issue of "contact time" and "treatment time" is complex because it is based on different EPA test methods used for liquid disinfectants versus a disinfectant "towelette" or "spray," respectively. The registration test for liquid disinfectants is the Association of Official Analytical Chemists (AOAC) use-dilution test, and the contact time should be the "wet" time. This simulates the contact time in the test tube with the inoculated carrier. The registration tests for a disinfectant wipe and the spray are the EPA disinfectant towelette test and germicidal spray test, respectively, and the label should be interpreted as the "treatment time." For the wipe, the "treatment time" is the kill time and is equal to the combination of the physical removal and inactivation caused by the disinfectant regardless of the surface appearance (e.g., wet vs. dry). For the spray, the "treatment time" is the kill time or the time for complete inactivation of the test bacteria caused by the disinfectant regardless of the surface appearance (e.g., wet or dry). So if a product is a liquid disinfectant (e.g., dilutable quaternary ammonium compound) and the label indicates an EPA registration label based on the use-dilution test of 2 minutes, then the treated surface should remain wet for 2 minutes. In contrast, if a disinfectant wipe or a spray has an EPA registration time of 2 minutes, then the surface (i.e., wiped or sprayed) should be allowed to remain undisturbed for the EPA registration time of 2 minutes (i.e., duration of wet time is not relevant). Infection preventionists, environmental service workers, nurses, regulators (e.g., state and federal), and accrediting agencies (e.g., The Joint Commission) surveying health care facilities should be aware of the different requirements for EPA registration of surface disinfectants registered by the Use Dilution Method (liquids have a contact time and wet time) and those tested by the towelette and spray tests (wipes have a treatment time and no wet time).[47]

OSHA Bloodborne Pathogen Standard

In December 1991, OSHA promulgated a standard entitled "Occupational Exposure to Bloodborne Pathogens" to eliminate or minimize occupational exposure to bloodborne pathogens.[310] One component of this

requirement is that all equipment and environmental and working surfaces be cleaned and decontaminated with an appropriate disinfectant after contact with blood or other potentially infectious materials. In February 1997, OSHA amended its policy that allowed the use of EPA-registered tuberculocidal disinfectants and/or diluted bleach solution and expanded it to include EPA-registered disinfectants that are labeled as effective against HIV and hepatitis B virus (HBV). These disinfectants would be considered as appropriate disinfectants "provided such surfaces have not become contaminated with agent(s) or volumes of or concentrations of agent(s) for which higher level disinfection is recommended."[311] When bloodborne pathogens other than HBV or HIV are of concern, OSHA continues to require the use of EPA-registered tuberculocidal disinfectants or hypochlorite solution (diluted 1:10 or 1:100 with water).[311] Studies have demonstrated that in the presence of large blood spills, a 1:10 final dilution of EPA-registered hypochlorite solution initially should be used to inactivate bloodborne viruses[85,312] in order to minimize risk of disease to health care workers from percutaneous injury during the cleanup process.

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, C. difficile,* severe acute respiratory syndrome (SARS) coronavirus, *Helicobacter pylori, E. coli* O157:H7, HIV, hepatitis C virus, rotavirus, multidrug-resistant *M. tuberculosis*, HPV, Middle East respiratory syndrome (MERS) coronavirus, hemorrhagic fever viruses (Lassa and Ebola), highly pathogenic avian influenza viruses (e.g., H5N1, H7N9), *C. auris,* norovirus, and nontuberculosis mycobacteria (e.g., *M. chelonae*).[313] Similarly, publications have highlighted the concern about the potential for biologic terrorism.[314] The Centers for Disease Control and Prevention (CDC) has categorized several agents as "high priority" because they can be easily disseminated or transmitted person to person, cause high mortality, and are likely to cause public panic and social disruption.[315] These agents include *Bacillus anthracis* (anthrax), *Yersinia pestis* (plague), variola major (smallpox), *Francisella tularensis* (tularemia), filoviruses (Ebola hemorrhagic fever, Marburg hemorrhagic fever), arenaviruses (Lassa [Lassa fever], Junin [Argentine hemorrhagic fever]), and related viruses.[315] *C. auris* is an emerging multidrug-resistant yeast that can cause invasive infections. *C. auris* can persist on surfaces in health care environments, and the CDC's interim disinfection recommendation for *C. auris* patient rooms is a hospital-grade disinfectant effective against *C. difficile* spores.[316] Studies have demonstrated that *C. auris* is inactivated (>4-$\log_{10}$ reduction in 1 minute) by numerous disinfectants (e.g., chlorine, accelerated hydrogen peroxide, quat-alcohol).[184,317]

With rare exceptions, 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 norovirus, vaccinia for variola,[136] and *B. atrophaeus* [formerly *Bacillus subtilis*] for *B. anthracis*) are susceptible to currently available chemical disinfectants or sterilants.[94,229,318] Standard sterilization and high-level disinfection procedures for patient care equipment (as recommended in this chapter) are adequate to sterilize or disinfect instruments or devices contaminated with blood or other body fluids from persons infected with bloodborne pathogens, emerging pathogens, and bioterrorism agents, with the exception of prions (see CJD above). No changes in procedures for cleaning, disinfecting, or sterilizing need to be made.[8]

In addition, there are no data to show that antibiotic-resistant bacteria (MRSA, VRE, multidrug- resistant *M. tuberculosis*) or CRE are less sensitive to the liquid chemical germicides than antibiotic-sensitive bacteria at currently used germicide contact conditions and concentrations.[319–321]

CONTROL OF HOSPITAL WASTE

Health care facilities that generate medical, chemical, or radiologic waste have a moral and legal obligation to dispose of these wastes in a manner that poses minimal potential hazard to the environment or public health. The proper disposal of these wastes requires a dynamic waste management plan that conforms to federal, state, and local regulations and provides adequate personnel and financial resources to ensure implementation.

Medical waste disposal has been as a major problem in the United States for the past 40 years. The problem has developed as a result of medical waste washing ashore in some coastal states in 1987 and 1988 and the perceived threat of acquiring HIV infection via this waste. This has led to restrictive rules governing the disposal of medical waste in many states and an increase in the volume of waste defined as regulated medical waste. Coincidentally, with an increase in volume of regulated medical waste (formerly called "infectious waste"), the options for medical waste treatment and disposal are diminishing because of space and environmental concerns. This section reviews some of the principles associated with medical waste management; more detailed descriptions of collection, storage, processing, transporting, treatment, and public health implications of medical waste may be found elsewhere.[322–329]

Despite the attention given to medical waste by the public, the media, and all levels of government, the terms "hospital waste," "medical waste," "regulated medical waste," and "infectious waste" are often used as synonymous. Hospital waste refers to all waste, biologic or nonbiologic, that is discarded and not intended for further use. Medical waste refers to materials generated as a result of patient diagnosis, immunization, or treatment, such as soiled dressings or intravenous tubing. Infectious waste refers to that portion of medical waste that could potentially transmit an infectious disease. Congress and the EPA used the term "regulated medical waste" rather than "infectious waste" in the Medical Waste Tracking Act (MWTA) of 1988 in deference to the remote possibility of disease transmission associated with this waste. Thus, "medical waste" is a subset of "hospital waste," and "regulated medical waste" (which is synonymous with "infectious waste" from a regulatory perspective) is a subset of "medical waste."[323,327]

As stated, regulated medical waste (or infectious waste) is capable of producing an infectious disease. This definition requires a consideration of the factors necessary for disease induction that include dose, host susceptibility, presence of a pathogen, virulence of a pathogen, and the most commonly absent factor, a portal of entry. For waste to be infectious, therefore, it must contain pathogens with sufficient virulence and quantity that exposure to the waste by a susceptible host could result in an infectious disease. Because there are no tests that allow infectious waste to be identified objectively, responsible agencies (such as the CDC, the EPA, or state agencies) define waste as infectious when it is suspected to contain pathogens in sufficient number to cause disease. Not only does this subjective definition result in conflicting opinions from the CDC, the EPA, and state agencies regarding what constitutes infectious waste and how it should be treated, but it also gives undue emphasis to the mere presence of pathogens.

Guidelines produced by the CDC have designated five types of hospital waste as regulated medical waste (i.e., microbiology laboratory waste, pathology and anatomy waste, contaminated animal carcasses, blood, and sharps).[32] The EPA guidelines (not regulations) from 1986 consider the same types of waste as infectious or regulated medical waste but also designate communicable disease isolation waste.[328] In the MWTA, the EPA modified its position on "communicable disease isolation waste" by including only certain "highly" communicable disease waste such as waste associated with Biosafety Level 4 organisms (e.g., Marburg, Ebola, and Lassa viruses) as regulated medical waste (Table 299.5).[328] In a systematic random survey of all US hospitals conducted in July 1987 and January 1988, the overall compliance rates with the CDC and EPA recommendations were 82% and 75%, respectively. Not only were the majority of hospitals in compliance, but the hospitals frequently treated other hospital waste as infectious, including contaminated laboratory waste (87%), surgery waste (78%), dialysis waste (69%), items contacting secretions (63%), intensive care unit waste (37%), and emergency room waste (41%).[323]

A key component in evaluating the impact of a medical waste management program is the quantity of waste produced per patient. Hospitalized patients generate about 15 pounds of hospital waste per day. The amount of hospital waste generated by US hospitals is approximately 6700 tons per day. US hospitals designate approximately 15%

TABLE 299.5 Types of Medical Waste Designated as Infectious (or Regulated Medical Waste) and Disposal and Treatment Methods Recommended by the CDC and EPA[a]

	CDC		EPA		MWTA
SOURCE OR TYPE OF MEDICAL WASTE	**REGULATED MEDICAL WASTE METHODS**	**DISPOSAL AND TREATMENT**	**INFECTIOUS WASTE METHODS**	**DISPOSAL AND TREATMENT**	**REGULATED MEDICAL WASTE[b]**
Microbiologic (e.g., stocks and cultures of infectious agents)	Yes[c]	S, I	Yes	S, I, TI, C	Yes
Blood and blood products	Yes	S, I, Sew	Yes	S, I, Sew, C	Yes
Pathologic (e.g., tissue, organs)	Yes	I	Yes	I, SW, CB	Yes
Sharps (e.g., needles)	Yes	S, I	Yes	S, I	Yes[d]
Communicable disease isolation	No	—	Yes	S, I	Yes[d]
Contaminated animal carcasses, body parts, and bedding	Yes	S, I (carcasses)	Yes	I, SW (not bedding)	Yes
Contaminated laboratory wastes	No	—	Optional[e]	If considered IW, use S or I	No
Surgery and autopsy wastes	No	—	Optional	If considered IW, use S or I	No
Dialysis unit	No	—	Optional	If considered IW, use S or I	No
Contaminated equipment	No	—	Optional	If considered IW, use S or I	No

[a]The Joint Commission requires that there be a hazardous waste system designed and operated in accordance with applicable law and regulations.
[b]The Act went into effect on June 22, 1989 and expired June 22, 1991. It affected only four states (New Jersey, New York, Connecticut, and Rhode Island). The Act required both treatment (any method, technique, or process designed to change the biologic character or composition of medical waste so as to eliminate or reduce its potential for causing disease) and destruction (waste is ruined, torn apart, or mutilated so that it is no longer generally recognizable as medical waste).
[c]The CDC guidelines specify "microbiology laboratory waste" as an infectious waste. This term includes stocks and cultures of etiologic agents and microbiology laboratory waste contaminated with etiologic agents (e.g., centrifuge tubes, pipettes, tissue culture bottles).
[d]MWTA specified used and unused sharps. The Act regulated wastes from persons with highly communicable diseases such as class 4 etiologic agents (e.g., Marburg, Ebola, Lassa).
[e]Optional infectious waste: EPA states that the decision to handle these wastes as infectious should be made by a responsible, authorized person or committee at the individual facility.
C, Chemical disinfection for liquids only; *CB,* cremation or burial by mortician; *CDC,* Centers for Disease Control and Prevention[32]; *EPA,* Environmental Protection Agency[328]; *I,* incineration; *IW,* infectious waste; *MWTA,* Medical Waste Tracking Act[329]; *S,* steam sterilization; *Sew,* sanitary sewer (EPA requires secondary treatment); *SW,* steam sterilization with incineration or grinding; *TI,* thermal inactivation.
Modified from Rutala WA, Mayhall CG, Society of Hospital Epidemiology of America[327]; and Rutala and Weber.[9]

of the total hospital waste by weight as infectious (about 1000 tons of infectious waste per day).[323] Not surprisingly, the percentage of medical waste treated as infectious increases with the number and types of medical waste classified as infectious. For example, about 6% of hospital waste would be treated as infectious waste if the CDC guidelines are followed, but 45% of hospital waste could be considered infectious waste under the MWTA.[323,330]

The vast majority of US hospitals designate and treat microbiologic, pathologic, isolation, blood, and sharp waste as infectious.[323] In the late 1980s, treatment of infectious waste by US hospitals was most commonly accomplished by means of incineration (range, 64%–93% depending on type of waste), but emission regulations that limit air pollutants have reduced the number of incinerators and use of incineration for medical waste. For example, in September 1997 there were an estimated 2373 medical waste incinerators in the United States, but based on the EPA's 2010 inventory there were 54 infectious waste incinerators at that time.[331] Autoclaves or steam sterilizers have become the primary nonincineration technology used by hospital to process their regulated medical waste (except pathology waste) (E. Krisiunas, written communication, 2008). Several other nonincineration alternatives have been proposed for treating regulated medical waste (e.g., mechanical and chemical disinfection, microwave decontamination). Nonregulated medical waste is generally discarded in a properly sited and operated sanitary landfill because this is a safe and inexpensive disposal method (e.g., landfill disposal, $0.02–$0.05 per pound for nonregulated medical waste versus contract incineration [i.e., off-site], $0.20–$0.60 per pound for regulated medical waste).

The conflicting information in state and federal regulations is related to the paucity of microbiologic and epidemiologic evidence that medical waste represents a threat to public health. First, with the exception of "sharps" such as needles, which have caused disease only in an occupational setting, there is no scientific evidence that medical waste has caused disease in the hospital or the community. Second, data demonstrate that household waste contains on average of 100 times as many microorganisms with pathogenic potential for humans than medical waste.[327] Third, detailed reports of the beach washups found that the vast majority of waste on beaches was debris (about 99%) such as wood, plastic, and paper, not medical waste. EPA documents acknowledge that much of the medical waste that washed ashore in the summer of 1988 was syringe related (65%) and came from home health care and illegal drug use. Fourth, studies have shown that most US hospitals are in compliance with the CDC infectious waste guidelines. Fifth, although the principal purpose of the MWTA was to reduce medical waste on beaches, it has not demonstrated its intended benefit. The relative number of syringes on the beaches in the MWTA states was significantly greater during implementation of the Act (17.23%) than before the Act went into effect (3.2%).[330] If regulatory controls were based on epidemiologic, microbiologic, and environmental data, only two types of medical waste would require special handling and treatment—sharps and microbiologic waste.

Federal medical waste regulations have been promulgated by the Department of Transportation (DOT) and OSHA. The DOT regulation involves the transport of infectious substances and medical waste and went into effect January 1996.[332] The OSHA Bloodborne Pathogen Standard requires labeling to designate waste that poses a health threat in the workplace. The OSHA definition of regulated waste is not intended to designate waste that must be treated. Generators that apply the OSHA definition of regulated waste (rather than state regulations) to designate infectious waste for treatment by incineration or other means may unintentionally incur additional expenses.[310]

CONCLUSION

When properly used, disinfection and sterilization can ensure the safe use of invasive and noninvasive medical devices. However, current disinfection and sterilization guidelines must be strictly followed.

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Key References

The complete reference list is available online at Expert Consult.

8. Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities; 2008. https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf. Accessed January 2018.
9. Rutala WA, Weber DJ. Disinfection, sterilization and control of hospital waste. In: Bennett JE, Dolan R, Blaser MJ, eds. *Principles and Practice of Infectious Diseases*. 8th ed. Philadelphia: Elsevier Saunders; 2015:3294–3309.
10. Rutala WA, Weber DJ. Disinfection, sterilization, and antisepsis: an overview. *Am J Infect Control*. 2016;44:e1–e6.
11. Rutala WA, Weber DJ. Disinfection and sterilization in health care facilities: an overview and current issues. *Infect Dis Clin North Am*. 2016;30:609–637.
12. Rutala WA, Weber DJ. Selection and use of disinfectants in healthcare. In: Mayhall CG, ed. *Hospital Epidemiology and Infection Control*. 4th ed. Philadelphia PA: Wolters Kluwer/Lippincott Williams & Wilkins; 2012.
13. Rutala WA, Weber DJ. Disinfection and sterilization in healthcare facilities. In: Lauterbach E, Malani PN, Woeltje KF, et al, eds. *SHEA Practical Healthcare Epidemiology*. 4th ed. Cambridge, UK: Cambridge University Press; 2018.
16. Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence C, Block SS, eds. *Disinfection, Sterilization, and Preservation*. Philadelphia: Lea & Febiger; 1968:517–531.
20. Alfa MJ, DeGagne P, Olson N, et al. 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.
24. Rutala WA, Weber DJ. Reprocessing semicritical items: current issues and new technologies. *Am J Infect Control*. 2016;44:e53–e62.
28. Food and Drug Administration. FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices, March 2015. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347htm.
31. Petersen B, Cohen J, Hambrick RD, et al. Multi-society guideline on reprocessing flexible gastrointestinal endoscopes, 2016. *Gastrointest Endosc*. 2017;85:282–294.
32. 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.
40. Weber DJ, Rutala WA, Miller MB, et al. 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:S25–S33.
44. Rutala WA, Barbee SL, Aguiar NC, et al. Antimicrobial activity of home disinfectants and natural products against potential human pathogens. *Infect Control Hosp Epidemiol*. 2000;21:33–38.
45. Rutala WA, Gergen MF, Weber DJ. Efficacy of improved hydrogen peroxide against important healthcare-associated pathogens. *Infect Control Hosp Epidemiol*. 2012;33:1159–1161.
47. Rutala WA, Weber DJ. Surface disinfection: treatment time (wipes and sprays) versus contact time (liquids). *Infect Control Hosp Epidemiol*. 2018;39:329–331.
60. Carling PC, Parry MF, Von Beheren SM, et al. Identifying opportunities to enhance environmental cleaning in 23 acute care hospitals. *Infect Control Hosp Epidemiol*. 2008;29:1–7.
63. Weber DJ, Rutala WA. Occupational risks associated with the use of selected disinfectants and sterilants. In: Rutala WA, ed. *Disinfection, Sterilization, and Antisepsis in Healthcare*. Champlain (NY): Polyscience Publications; 1998:211–226.
77. Weber DJ, Consoli SA, Rutala WA. Occupational health risks associated with the use of germicides in healthcare. *Am J Infec Control*. 2016;44:e85–e89.
79. Rutala WA, Cole EC, Thomann CA, et al. Stability and bactericidal activity of chlorine solutions. *Infect Control Hosp Epidemiol*. 1998;19:323–327.
85. Weber DJ, Barbee SL, Sobsey MD, et al. The effect of blood on the antiviral activity of sodium hypochlorite, a phenolic, and a quaternary ammonium compound. *Infect Control Hosp Epidemiol*. 1999;20:821–827.
86. Donskey CJ. Does improving surface cleaning and disinfection reduce health care–associated infections? *Am J Infect Control*. 2013;41:S12–S19.
94. Rutala WA, Gergen MF, Weber DJ. Inactivation of *Clostridium difficile* spores by disinfectants. *Infect Control Hosp Epidemiol*. 1993;14:36–39.
104. Mbithi JN, Springthorpe VS, Sattar SA, et al. Bactericidal, virucidal, and mycobactericidal activities of reused alkaline glutaraldehyde in an endoscopy unit. *J Clin Microbiol*. 1993;31:2988–2995.
122. Omidbakhsh N. A new peroxide-based flexible endoscope-compatible high-level disinfectant. *Am J Infect Control*. 2006;34:571–577.
134. Weber DJ, Rutala WA, Sickbert-Bennett EE. Outbreaks associated with contaminated antiseptics and disinfectants. *Antimicrob Agents Chemother*. 2007;51:4217–4224.
135. Rutala WA, Cole EC, Wannamaker NS, et al. Inactivation of *Mycobacterium tuberculosis* and *Mycobacterium bovis* by 14 hospital disinfectants. *Am J Med*. 1991;91:267S–271S.
142. Walsh SE, Maillard JY, Russell AD. Ortho-phthalaldehyde: a possible alternative to glutaraldehyde for high level disinfection. *J Appl Microbiol*. 1999;86:1039–1046.
154. Alfa MJ, DeGagne P, Olson N, et al. Comparison of liquid chemical sterilization with peracetic acid and ethylene oxide sterilization for long narrow lumens. *Am J Infect Control*. 1998;26:469–477.
169. Rutala WA, Cole EC. Ineffectiveness of hospital disinfectants against bacteria: a collaborative study. *Infect Control*. 1987;8:501–506.
199. 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;28:146–155.
210. Immediate-Use Steam Sterilization. Association for the Advancement of Medical Instrumentation, ANSI. http://www.aami.org/publications/standards/ST79_Immediate_Use_Statement.pdf. Accessed January 2018.
238. Rutala WA, Weber DJ, Society for Healthcare Epidemiology of America. Guideline for disinfection and sterilization of prion-contaminated medical instruments. *Infect Control Hosp Epidemiol*. 2010;31:107–117.
239. Belay ED, Blasé J, Sehulster LM, et al. Management of neurosurgical instruments and patients exposed to Creutzfeldt-Jakob disease. *Infect Control Hosp Epidemiol*. 2013;34:1272–1280.
249. Bringhurst J. Special problems associated with reprocessing instruments in outpatient care facilities. *Am J Infect Control*. 2016;2016:e63–e67.
250. Rutala WA, Kanamori H, Sickbert-Bennett EE, et al. 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;47S:A62–A66.
252. Meyers J, Ryndock E, Conway MJ, et al. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. *J Antimicrob Chemother*. 2014;69:1546–1550.
255. Rutala WA, Gergen MF, Bringhurst J, et al. Effective high-level disinfection of cystoscopes: is perfusion of channels required? *Infect Control Hosp Epidemiol*. 2016;37:228–231.
259. Weber DJ, Kanamori H, Rutala WA. "No Touch" technologies for environmental decontamination: focus on ultraviolet devices and hydrogen peroxide systems. *Curr Opin Infect Dis*. 2016;29:424–431.
266. Shaughnessy MK, Micielli RL, DePestel DD, et al. Evaluation of hospital room assignment and acquisition of *Clostridium difficile* infection. *Infect Control Hosp Epidemiol*. 2011;32:201–206.
267. Kundrapu S, Sunkesula V, Jury LA, et al. Daily disinfection of high-touch surfaces in isolation rooms to reduce contamination of healthcare workers' hands. *Infect Control Hosp Epidemiol*. 2012;33:1039–1042.
268. Alfa MJ, Lo E, Olson N, et al. Use of a daily disinfectant cleaner instead of a daily cleaner reduced hospital-acquired infection rates. *Am J Infect Control*. 2015;43:141–146.
276. Rutala WA, Gergen MF, Weber DJ. Room decontamination with UV radiation. *Infect Control Hosp Epidemiol*. 2010;31:1025–1029.
279. Anderson DJ, Chen LF, Weber DJ, et al. The benefits of enhanced terminal room (BETR) disinfection study: a prospective, cluster randomized, multicenter, crossover study to evaluate the impact of enhanced terminal room disinfection on acquisition and infection caused by multidrug-resistant organisms. *The Lancet*. 2017;389:805–814.
286. Boyce JM, Havill NL, Otter JA, et al. Impact of hydrogen peroxide vapor room decontamination on *Clostridium difficile* environmental contamination and transmission in a healthcare setting. *Infect Control Hosp Epidemiol*. 2008;29:723–729.
319. Rutala WA, Stiegel MM, Sarubbi FA, et al. Susceptibility of antibiotic-susceptible and antibiotic-resistant hospital bacteria to disinfectants. *Infect Control Hosp Epidemiol*. 1997;18:417–421.
320. Weber DJ, Rutala WA. Use of germicides in the home and the healthcare setting: is there a relationship between germicide use and antibiotic resistance? *Infect Control Hosp Epidemiol*. 2006;27:1107–1119.
323. Rutala WA, Odette RL, Samsa GP. Management of infectious waste by US hospitals. *JAMA*. 1989;262:1635–1640.
327. Rutala WA, Mayhall CG, Society for Hospital Epidemiology of America. SHEA position paper: medical waste. *Infect Control Hosp Epidemiol*. 1992;13:38–48.
330. Rutala WA, Weber DJ. Infectious waste–mismatch between science and policy. *N Engl J Med*. 1991;325:578–582.

References

1. Martin R. U.S. outpatient surgery passes inpatient, to 53 million a year. *Tampa Bay Times*. 2010.
2. Peery AF, Dellon ES, Lund JC, et al. Burden of gastrointestinal disease in the United States: 2012 update. *Gastroenterol*. 2012;143:1179–1187.
3. Rutala WA, Weber DJ. Outbreaks of carbapenem-resistant Enterobacteriaceae infections associated with duodenoscopes: what can we do to prevent infections? *Am J Infect Control*. 2016;44:e47–e51.
4. Kovaleva J, Peters FT, van der Mei HC, et al. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clin Microbiol Rev*. 2013;26:231–254.
5. Ofstead CL, Wetzler HP, Snyder AK, et al. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. *Gastroenterol Nurs*. 2010;33:304–311.
6. Murray P Preventable tragedies: Superbugs and how ineffective monitoring of medical device safety fails patients.2016. United States Senate Minority Report. https://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf. Accessed January 2018.
7. 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, Inc.; 2014:31.1–31.15.
8. Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities; 2008. https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf. Accessed January 2018.
9. Rutala WA, Weber DJ. Disinfection, sterilization and control of hospital waste. In: Bennett JE, Dolan R, Blaser MJ, eds. *Principles and Practice of Infectious Diseases*. 8th ed. Philadelphia: Elsevier Saunders; 2015:3294–3309.
10. Rutala WA, Weber DJ. Disinfection, sterilization, and antisepsis: an overview. *Am J Infect Control*. 2016;44:e1–e6.
11. Rutala WA, Weber DJ. Disinfection and sterilization in health care facilities: an overview and current issues. *Infect Dis Clin North Am*. 2016;30:609–637.
12. Rutala WA, Weber DJ. Selection and use of disinfectants in healthcare. In: Mayhall CG, ed. *Hospital Epidemiology and Infection Control*. 4th ed. Philadelphia PA: Wolters Kluwer/Lippincott Williams & Wilkins; 2012.
13. Rutala WA, Weber DJ. Disinfection and sterilization in healthcare facilities. In: Lauterbach E, Malani PN, Woeltje KF, et al, eds. *SHEA Practical Healthcare Epidemiology*. 4th ed. Cambridge, UK: Cambridge University Press; 2018.
14. da Costa LC, Olson N, Tipple AE, et al. Evaluation of the ability of different detergents and disinfectants to remove and kill organisms in traditional biofilm. *Am J Infect Control*. 2016;44:e243–e249.
15. Favero MS, Bond WW. Chemical disinfection of medical and surgical materials. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. Philadelphia: Lea & Febiger; 2001:881–917.
16. Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence C, Block SS, eds. *Disinfection, Sterilization, and Preservation*. Philadelphia: Lea & Febiger; 1968:517–531.
17. 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.
18. Block SS. Definition of terms. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. 5th ed. Philadelphia: Lippincott Williams & Wilkins; 2001:19–28.
19. McDonnell G, Burke P. Disinfection: is it time to reconsider Spaulding? *J Hosp Infect*. 2011;78:163–170.
20. Alfa MJ, DeGagne P, Olson N, et al. 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.
21. Rutala WA, Gergen MF, Weber DJ. Efficacy of a washer-disinfector in eliminating healthcare-associated pathogens from surgical instruments. *Infect Control Hosp Epidemiol*. 2014;35:883–885.
22. Alfa MJ. Monitoring and improving the effectiveness of cleaning medical and surgical devices. *Am J Infect Control*. 2013;41:S56–S59.
23. Seavey R. High-level disinfection, sterilization, and antisepsis: current issues in reprocessing medical and surgical instruments. *Am J Infect Control*. 2013;41:S111–S117.
24. Rutala WA, Weber DJ. Reprocessing semicritical items: current issues and new technologies. *Am J Infect Control*. 2016;44:e53–e62.
25. Rutala WA, Weber DJ. New developments in reprocessing semicritical items. *Am J Infect Control*. 2013;41:S60–S66.
26. Rutala WA, Gergen MF, Weber DJ. Disinfection of a probe used in ultrasound-guided prostate biopsy. *Infect Control Hosp Epidemiol*. 2007;28:916–919.
27. Rutala WA, Gergen MF, Weber DJ. Disinfection of an infrared coagulation device used to treat hemorrhoids. *Am J Infect Control*. 2012;40:78–79.
28. Food and Drug Administration. FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices, March 2015. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347htm.
29. Kanamori H, Weber DJ, Rutala WA. Healthcare outbreaks associated with a water reservoir and infection prevention strategies. *Clin Infect Dis*. 2016;62:1423–1435.
30. Gerding DN, Peterson LR, Vennes JA. Cleaning and disinfection of fiberoptic endoscopes: evaluation of glutaraldehyde exposure time and forced-air drying. *Gastroenterology*. 1982;83:613–618.
31. Petersen B, Cohen J, Hambrick RD, et al. Multi-society guideline on reprocessing flexible gastrointestinal endoscopes, 2016. *Gastrointest Endosc*. 2017;85:282–294.
32. 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.
33. 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;65:1412–1419.
34. John A, Alhmidi H, Cadnum JL, et al. Contaminated portable equipment is a potential vector for dissemination of pathogens in the intensive care unit. *Infect Control Hosp Epidemiol*. 2017;38:1247–1249.
35. Suwantarat N, Supple LA, Cadnum JL, et al. Quantitative assessment on interactions between hospitalized patients and portable medical equipment and other fomites. *Am J Infect Control*. 2017;45:1276–1278.
36. Deshpande A, Cadnum JL, Fertelli D, et al. Are hospital floors an underappreciated reservoir for transmission of health care–associated pathogens. *Am J Infect Control*. 2017;45:336–338.
37. Koganti S, Alhmidi H, Tomas ME, et al. Evaluation of hospital floors as a potential source of pathogen dissemination using a nonpathogenic virus as a surrogate marker. *Infect Control Hosp Epidemiol*. 2016;37:1374–1377.
38. Huslage K, Rutala WA, Sickbert-Bennett E, et al. A quantitative approach to defining "high-touch" surfaces in hospitals. *Infect Control Hosp Epidemiol*. 2010;31:850–853.
39. 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.
40. Weber DJ, Rutala WA, Miller MB, et al. 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:S25–S33.
41. Best M, Sattar SA, Springthorpe VS, et al. Efficacies of selected disinfectants against *Mycobacterium tuberculosis*. *J Clin Microbiol*. 1990;28:2234–2239.
42. Best M, Kennedy ME, Coates F. Efficacy of a variety of disinfectants against *Listeria spp*. *Appl Environ Microbiol*. 1990;56:377–380.
43. 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;22:152–162.
44. Rutala WA, Barbee SL, Aguiar NC, et al. Antimicrobial activity of home disinfectants and natural products against potential human pathogens. *Infect Control Hosp Epidemiol*. 2000;21:33–38.
45. Rutala WA, Gergen MF, Weber DJ. Efficacy of improved hydrogen peroxide against important healthcare-associated pathogens. *Infect Control Hosp Epidemiol*. 2012;33:1159–1161.
46. Rutala WA, Weber DJ. Selection of the ideal disinfectant. *Infect Control Hosp Epidemiol*. 2014;35:855–865.
47. Rutala WA, Weber DJ. Surface disinfection: treatment time (wipes and sprays) versus contact time (liquids). *Infect Control Hosp Epidemiol*. 2018;39:329–331.
48. Rutala WA, Weber DJ. Monitoring and improving the effectiveness of surface cleaning and disinfection. *Am J Infect Control*. 2016;44:e69–e76.
49. Kenters N, Huijskens EGW, de Wit SCJ, et al. Effectiveness of cleaning-disinfection wipes and sprays against multidrug resistant outbreak strains. *Am J Infect Control*. 2017;45:e69–e73.
50. Rutala WA, Gergen MF, Weber DJ. Efficacy of different cleaning and disinfection methods against *Clostridium difficile* spores: importance of physical removal versus sporicidal inactivation. *Infect Control Hosp Epidemiol*. 2012;33:1255–1258.
51. Sifuentes LY, Gerba CP, Weart I, et al. Microbial contamination of hospital reusable cleaning towels. *Am J Infect Control*. 2013;41:912–915.
52. Sooklal S, Khan A, Kannangara S. Hospital *Clostridium difficile* outbreak linked to laundry machine malfunction. *Am J Infect Control*. 2014;42:674–675.
53. Rutala WA, Gergen MF, Weber DJ. Microbiologic evaluation of microfiber mops for surface disinfection. *Am J Infect Control*. 2007;35:569–573.
54. Westwood JC, Mitchell MA, Legace S. Hospital sanitation: the massive bacterial contamination of the wet mop. *Appl Microbiol*. 1971;21:693–697.
55. Cooper RA, Griffith CJ, Malik RE, et al. Monitoring the effectiveness of cleaning in four British hospitals. *Am J Infect Control*. 2007;35:338–341.
56. Boyce JM, Havill NL, Dumigan DG, et al. Monitoring the effectiveness of hospital cleaning practices by use of an adenosine triphosphate bioluminescence assay. *Infect Control Hosp Epidemiol*. 2009;30:678–684.
57. Lewis T, Griffith C, Gallo M, et al. A modified ATP benchmark for evaluating the cleaning of some hospital environmental surfaces. *J Hosp Infect*. 2008;69:156–163.
58. Carling PC, Briggs JL, Perkins J, et al. Improved cleaning of patient rooms using a new targeting method. *Clin Infect Dis*. 2006;42:385–388.
59. Carling P. Methods for assessing the adequacy of practice and improving room disinfection. *Am J Infect Control*. 2013;41:S20–S25.
60. Carling PC, Parry MF, Von Beheren SM, et al. Identifying opportunities to enhance environmental cleaning in 23 acute care hospitals. *Infect Control Hosp Epidemiol*. 2008;29:1–7.
61. Rutala WA, Kanamori H, Gergen MF, et al. Comparative analysis of four major hospital cleaning validation methods. *Am J Infect Control*. 2017;45:S37.
62. Cadnum JL, Jencson AL, O'Donnell MC, et al. An increase in healthcare-associated *Clostridium difficile* infection associated with use of a defective peracetic acid-based surface disinfectant. *Infect Control Hosp Epidemiol*. 2017;38:300–305.
63. Weber DJ, Rutala WA. Occupational risks associated with the use of selected disinfectants and sterilants. In: Rutala WA, ed. *Disinfection, Sterilization, and Antisepsis in Healthcare*. Champlain (NY): Polyscience Publications; 1998:211–226.
64. Quinn MM, Henneberger PK, National Institute for Occupational S, et al. Cleaning and disinfecting environmental surfaces in health care: toward an integrated framework for infection and occupational illness prevention. *Am J Infect Control*. 2015;43:424–434.
65. Spaulding EH. Alcohol as a surgical disinfectant. *AORN J*. 1964;2:67–71.
66. Morton HE. The relationship of concentration and germicidal efficiency of ethyl alcohol. *Ann N Y Acad Sci*. 1950;53:191–196.
67. Ali Y, Dolan MJ, Fendler EJ, et al. Alcohols. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. 5th ed. Philadelphia: Lippincott Williams & Wilkins; 2001:229–254.
68. Nye RN, Mallory TB. A note on the fallacy of using alcohol for the sterilization of surgical instruments. *Boston Med Surg J*. 1923;189.
69. Rutala WA, White MS, Gergen MF, et al. Bacterial contamination of keyboards: efficacy and functional impact of disinfectants. *Infect Control Hosp Epidemiol*. 2006;27:372–377.
70. Rutala WA, Peacock JE, Gergen MF, et al. Efficacy of hospital germicides against adenovirus 8, a common cause of epidemic keratoconjunctivitis in health care facilities. *Antimicrob Agents Chemother*. 2006;50:1419–1424.
71. Rutala WA, Weber DJ. Uses of inorganic hypochlorite (bleach) in health-care facilities. *Clin Microbiol Rev*. 1997;10:597–610.
72. Merritt K, Hitchins VM, Brown SA. Safety and cleaning of medical materials and devices. *J Biomed Materials Res*. 2000;53:131–136.
73. Jakobsson SW, Rajs J, Jonsson JA, et al. Poisoning with sodium hypochlorite solution. Report of a fatal case, supplemented with an experimental and clinico-epidemiological study. *Am J Forensic Med Pathol*. 1991;12:320–327.
74. Heidemann SM, Goetting MG. Treatment of acute hypoxemic respiratory failure caused by chlorine exposure. *Pediatr Emerg Care*. 1991;7:87–88.

75. French RJ, Tabb HG, Rutledge LJ. Esophageal stenosis produced by ingestion of bleach: report of two cases. *South Med J*. 1970;63:1140–1144.
76. Ingram TA. Response of the human eye to accidental exposure to sodium hypochlorite. *J Endodontics*. 1990;16:235–238.
77. Weber DJ, Consoli SA, Rutala WA. Occupational health risks associated with the use of germicides in healthcare. *Am J Infec Control*. 2016;44:e85–e89.
78. Mrvos R, Dean BS, Krenzelok EP. Home exposures to chlorine/chloramine gas: review of 216 cases. *South Med J*. 1993;86:654–657.
79. Rutala WA, Cole EC, Thomann CA, et al. Stability and bactericidal activity of chlorine solutions. *Infect Control Hosp Epidemiol*. 1998;19:323–327.
80. Sampson MN, Muir AV. Not all super-oxidized waters are the same. *J Hosp Infect*. 2002;52:228–229.
81. Selkon JB, Babb JR, Morris R. Evaluation of the antimicrobial activity of a new super-oxidized water, Sterilox, for the disinfection of endoscopes. *J Hosp Infect*. 1999;41:59–70.
82. Shetty N, Srinivasan S, Holton J, et al. Evaluation of microbicidal activity of a new disinfectant: sterilox 2500 against *Clostridium difficile* spores, *Helicobacter pylori,* vancomycin resistant *Enterococcus species, Candida albicans* and several *Mycobacterium species*. *J Hosp Infect*. 1999;41:101–105.
83. Nagington J, Sutehall GM, Whipp P. Tonometer disinfection and viruses. *Br J Ophthalmol*. 1983;67:674–676.
84. Bloomfield SF, Miller EA. A comparison of hypochlorite and phenolic disinfectants for disinfection of clean and soiled surfaces and blood spillages. *J Hosp Infect*. 1989;13:231–239.
85. Weber DJ, Barbee SL, Sobsey MD, et al. The effect of blood on the antiviral activity of sodium hypochlorite, a phenolic, and a quaternary ammonium compound. *Infect Control Hosp Epidemiol*. 1999;20:821–827.
86. Donskey CJ. Does improving surface cleaning and disinfection reduce health care–associated infections? *Am J Infect Control*. 2013;41:S12–S19.
87. Helms CM, Massanari RM, Zeitler R, et al. Legionnaires' disease associated with a hospital water system: a cluster of 24 nosocomial cases. *Ann Intern Med*. 1983;99:172–178.
88. Helms C, Massanari R, Wenzel R Control of epidemic nosocomial legionellosis: A 5 year progress report on continuous hyperchlorination of a water distribution system. Abstracts of 27th Interscience Conference of Antimicrobial Agents and Chemotherapy. 1987:349, p. 158.
89. Cheung RJ, Ortiz D, DiMarino AJ Jr. GI endoscopic reprocessing practices in the United States. *Gastrointest Endosc*. 1999;50:362–368.
90. Miner NA, McDowell JW, Willcockson GW, et al. Antimicrobial and other properties of a new stabilized alkaline glutaraldehyde disinfectant/sterilizer. *Am J Hosp Pharm*. 1977;34:376–382.
91. Pepper RE. Comparison of the activities and stabilities of alkaline glutaraldehyde sterilizing solutions. *Infect Control*. 1980;1:90–92.
92. Scott EM, Gorman SP. Glutaraldehyde. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. 5th ed. Philadelphia: Lippincott Williams & Wilkins; 2001:361–381.
93. Russell AD. Glutaraldehyde: current status and uses. *Infect Control Hosp Epidemiol*. 1994;15:724–733.
94. Rutala WA, Gergen MF, Weber DJ. Inactivation of *Clostridium difficile* spores by disinfectants. *Infect Control Hosp Epidemiol*. 1993;14:36–39.
95. Dyas A, Das BC. The activity of glutaraldehyde against *Clostridium difficile*. *J Hosp Infect*. 1985;6:41–45.
96. van Klingeren B, Pullen W. Glutaraldehyde resistant mycobacteria from endoscope washers. *J Hosp Infect*. 1993;25:147–149.
97. Griffiths PA, Babb JR, Bradley CR, et al. Glutaraldehyde-resistant *Mycobacterium chelonae* from endoscope washer disinfectors. *J Appl Microbiol*. 1997;82:519–526.
98. Fisher CW, Fiorello A, Shaffer D, et al. Aldehyde-resistant mycobacteria bacteria associated with the use of endoscope reprocessing systems. *Am J Infect Control*. 2012;40:880–882.
99. Webster E, Ribner B, Streed LL, et al. Microbial contamination of activated 2% glutaraldehyde used in high-level disinfection of endoscopes (abstract). *Am J Infect Control*. 1996;24:153.
100. Barbee SL, Weber DJ, Sobsey MD, et al. Inactivation of *Cryptosporidium parvum* oocyst infectivity by disinfection and sterilization processes. *Gastrointest Endosc*. 1999;49:605–611.
101. Laskowski LF, Marr JJ, Spernoga JF, et al. Fastidious mycobacteria grown from porcine prosthetic-heart-valve cultures. *N Engl J Med*. 1977;297:101–102.
102. Lorena NS, Duarte RS, Pitombo MB. Rapidly growing mycobacteria infection after videosurgical procedures - the glutaraldehyde hypothesis. *Rev Col Bras Cir*. 2009;36:266–267.
103. Svetlikova Z, Skovierova H, Niederweis M, et al. Role of porins in the susceptibility of *Mycobacterium smegmatis* and *Mycobacterium chelonae* to aldehyde-based disinfectants and drugs. *Antimicrob Agents Chemotherapy*. 2009;53:4015–4018.
104. Mbithi JN, Springthorpe VS, Sattar SA, et al. Bactericidal, virucidal, and mycobactericidal activities of reused alkaline glutaraldehyde in an endoscopy unit. *J Clin Microbiol*. 1993;31:2988–2995.
105. Cole EC, Rutala WA, Nessen L, et al. Effect of methodology, dilution, and exposure time on the tuberculocidal activity of glutaraldehyde-based disinfectants. *Appl Environ Microbiol*. 1990;56:1813–1817.
106. Collins FM, Montalbine V. Mycobactericidal activity of glutaraldehyde solutions. *J Clin Microbiol*. 1976;4:408–412.
107. Overton D, Burgess JO, Beck B, et al. Glutaraldehyde test kits: evaluation for accuracy and range. *Gen Dent*. 1989;37:8.
108. Cooke RP, Goddard SV, Chatterley R, et al. Monitoring glutaraldehyde dilution in automated washer/disinfectors. *J Hosp Infect*. 2001;48:243–244.
109. Rutala WA, Weber DJ. FDA labeling requirements for disinfection of endoscopes: a counterpoint. *Infect Control Hosp Epidemiol*. 1995;16:231–235.
110. Farina A, Fievet MH, Plassart F, et al. Residual glutaraldehyde levels in fiberoptic endoscopes: measurement and implications for patient toxicity. *J Hosp Infect*. 1999;43:293–297.
111. Dailey JR, Parnes RE, Aminlari A. Glutaraldehyde keratopathy. *Am J Ophthalmol*. 1993;115:256–258.
112. Newman MA, Kachuba JB. Glutaraldehyde: a potential health risk to nurses. *Gastroenterol Nurs*. 1992;14:296–301.
113. Turner FJ. Hydrogen peroxide and other oxidant disinfectants. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. Philadelphia: Lea & Febiger; 1983:240–250.
114. Block SS. Peroxygen compounds. In: Block SS, ed. *Disinfection, Sterilization and Preservation*. Philadelphia.: Lippincott Williams & Wilkins; 2001:185–294.
115. Rutala WA, Gergen MF, Weber DJ. Sporicidal activity of chemical sterilants used in hospitals. *Infect Control Hosp Epidemiol*. 1993;14:713–718.
116. Maillard JY. Innate resistance to sporicides and potential failure to decontaminate. *J Hosp Infect*. 2011;77:204–209.
117. Rutala WA, Weber DJ. Disinfection of endoscopes: review of new chemical sterilants used for high-level disinfection. *Infect Control Hosp Epidemiol*. 1999;20:69–76.
118. Silvany RE, Dougherty JM, McCulley JP, et al. The effect of currently available contact lens disinfection systems on *Acanthamoeba castellanii* and *Acanthamoeba polyphaga*. *Ophthalmology*. 1990;97:286–290.
119. Neely AN, Maley MP. The 1999 Lindberg award. 3% hydrogen peroxide for the gram-positive disinfection of fabrics. *J Burn Care Rehabil*. 1999;20:471–477.
120. Vesley D, Norlien KG, Nelson B, et al. Significant factors in the disinfection and sterilization of flexible endoscopes. *Am J Infect Control*. 1992;20:291–300.
121. Levenson JE. Corneal damage from improperly cleaned tonometer tips. *Arch Ophthalmol*. 1989;107:1117.
122. Omidbakhsh N. A new peroxide-based flexible endoscope-compatible high-level disinfectant. *Am J Infect Control*. 2006;34:571–577.
123. Boyce JM, Havill NL. Evaluation of a new hydrogen peroxide wipe disinfectant. *Infect Control Hosp Epidemiol*. 2013;34:521–523.
124. Sattar SA, Springthorpe VS, Rochon M. A product based on accelerated and stabilized hydrogen peroxide: evidence for broad-spectrum germicidal activity. *Canadian J Infect Control*. 1998;Winter:123–130.
125. Omidbakhsh N, Kenny N. An accelerated hydrogen peroxide (AHP)-based fast-acting and reusable microbicide for manual disinfection of heat-sensitive semi-critical medical devices. *Can J Infect Control*. 2008;23:81, 3, 5–8.
126. Sattar SA, Adegbunrin O, Ramirez J. Combined application of simulated reuse and quantitative carrier tests to assess high-level disinfection: experiments with an accelerated hydrogen peroxide-based formulation. *Am J Infect Control*. 2002;30:449–457.
127. Omidbakhsh N, Sattar SA. Broad-spectrum microbicidal activity, toxicologic assessment, and materials compatibility of a new generation of accelerated hydrogen peroxide-based environmental surface disinfectant. *Am J Infect Control*. 2006;34:251–257.
128. Rochon M. S, N. Products based on accelerated and stabilized hydrogen peroxide: evidence for cleaning and sanitizing efficiency, environmental and human safety and non-corrosiveness. *Can J Infect Control*. 1999;Summer:51–55.
129. Boyce JM, Guercia KA, Sullivan L, et al. Prospective cluster controlled crossover trial to compare the impact of an improved hydrogen peroxide disinfectant and a quaternary ammonium-based disinfectant on surface contamination and health care outcomes. *Am J Infect Control*. 2017;45:1006–1010.
130. Rutala WA, Gergen MF, Sickbert-Bennett EE, et al. Effectiveness of improved hydrogen peroxide in decontaminating privacy curtains contaminated with multidrug-resistant pathogens. *Am J Infect Control*. 2014;42:426–428.
131. Gottardi W. Iodine and Iodine compounds. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. Philadelphia: Lippincott Williams & Wilkins; 2001.
132. Craven DE, Moody B, Connolly MG, et al. Pseudobacteremia caused by povidone-iodine solution contaminated with *Pseudomonas cepacia*. *New Engl J Med*. 1981;305:621–623.
133. Berkelman RL, Lewin S, Allen JR, et al. Pseudobacteremia attributed to contamination of povidone-iodine with *Pseudomonas cepacia*. *Ann Intern Med*. 1981;95:32–36.
134. Weber DJ, Rutala WA, Sickbert-Bennett EE. Outbreaks associated with contaminated antiseptics and disinfectants. *Antimicrob Agents Chemother*. 2007;51:4217–4224.
135. Rutala WA, Cole EC, Wannamaker NS, et al. Inactivation of *Mycobacterium tuberculosis* and *Mycobacterium bovis* by 14 hospital disinfectants. *Am J Med*. 1991;91:267S–271S.
136. Klein M, DeForest A. The inactivation of viruses by germicides. *Chem Specialists Manuf Assoc Proc*. 1963;49:116–118.
137. Berkelman RL, Holland BW, Anderson RL. Increased bactericidal activity of dilute preparations of povidone-iodine solutions. *J Clin Microbiol*. 1982;15:635–639.
138. Wallbank AM, Drulak M, Poffenroth L, et al. Wescodyne: lack of activity against poliovirus in the presence of organic matter. *Health Lab Sci*. 1978;15:133–137.
139. Favero MS, Bond WW. Chemical disinfection of medical and surgical materials. In: Block SS, ed. *Disinfection, Sterilization and Preservation*. Philadelphia: Lea & Febiger; 1991:617–641.
140. Gordon MD, Ezzell RJ, Bruckner NI, et al. Enhancement of mycobactericidal activity of glutaraldehyde with a,ß-unsaturated and aromatic aldehydes. *J Indus Microbiol*. 1994;13:77–82.
141. Gregory AW, Schaalje GB, Smart JD, et al. The mycobactericidal efficacy of ortho-phthalaldehyde and the comparative resistances of *Mycobacterium bovis, Mycobacterium terrae*, and *Mycobacterium chelonae*. *Infect Control Hosp Epidemiol*. 1999;20:324–330.
142. Walsh SE, Maillard JY, Russell AD. Ortho-phthalaldehyde: a possible alternative to glutaraldehyde for high level disinfection. *J Appl Microbiol*. 1999;86:1039–1046.
143. Alfa MJ, Sitter DL. In-hospital evaluation of orthophthalaldehyde as a high level disinfectant for flexible endoscopes. *J Hosp Infect*. 1994;26:15–26.
144. Roberts CG, Chan-Myers HB, Favero MS. Virucidal activity of ortho-phthalaldehyde solutions against hepatitis B and C viruses. *Am J Infect Control*. 2008;36:223–226.
145. Sokol WN. Nine episodes of anaphylaxis following cystoscopy caused by Cidex OPA (ortho-phthalaldehyde) high-level disinfectant in 4 patients after cytoscopy. *J Allergy Clin Immunol*. 2004;114:392–397.
146. Rutala WA, Weber DJ. New disinfection and sterilization methods. *Emerg Infect Dis*. 2001;7:348–353.
147. Miyajima K, Yoshida J, Kumagai S. Ortho-phthalaldehyde exposure levels among endoscope disinfection workers. *Sangyo Eiseigaku Zasshi*. 2010;52:74.
148. Tucker RC, Lestini BJ, Marchant RE. Surface analysis of clinically used expanded PTFE endoscopic tubing treated by the STERIS PROCESS. *ASAIO J*. 1996;42:306–313.
149. Mannion PT. The use of peracetic acid for the reprocessing of flexible endoscopes and rigid cystoscopes and laparoscopes. *J Hosp Infect*. 1995;29:313–315.
150. Malchesky PS. Medical applications of peracetic acid. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. 5th ed. Philadelphia: Lippincott Williams & Wilkins; 2001:979–996.
151. McDonnell G, Ehrman M. Effectiveness of the System 1E liquid chemical sterilant processing system for reprocessing duodenoscopes. *Am J Infect Control*. 2016;44:685–688.
152. Bradley CR, Babb JR, Ayliffe GA. Evaluation of the Steris System 1 peracetic acid endoscope processor. *J Hosp Infect*. 1995;29:143–151.
153. Duc DL, Ribiollet A, Dode X, et al. Evaluation of the microbicidal efficacy of Steris System I for digestive

endoscopes using GERMANDE and ASTM validation protocols. *J Hosp Infect*. 2001;48:135–141.
154. Alfa MJ, DeGagne P, Olson N, et al. Comparison of liquid chemical sterilization with peracetic acid and ethylene oxide sterilization for long narrow lumens. *Am J Infect Control*. 1998;26:469–477.
155. Fuselier HA Jr, Mason C. Liquid sterilization versus high level disinfection in the urologic office. *Urology*. 1997;50:337–340.
156. Seballos RJ, Walsh AL, Mehta AC. Clinical evaluation of a liquid chemical sterilization system for flexible bronchoscopes. *J Bronch*. 1995;2:192–199.
157. Wallace CG, Agee PM, Demicco DD. Liquid chemical sterilization using peracetic acid. An alternative approach to endoscope processing. *ASAIO J*. 1995;41:151–154.
158. Centers for Disease Control and Prevention. Bronchoscopy-related infections and pseudoinfections–New York, 1996 and 1998. *MMWR Morb Mortal Wkly Rep*. 1999;48:557–560.
159. Middleton AM, Chadwick MV, Gaya H. Disinfection of bronchoscopes, contaminated in vitro with *Mycobacterium tuberculosis, Mycobacterium avium-intracellulare* and *Mycobacterium chelonae* in sputum, using stabilized, buffered peracetic acid solution ('Nu-Cidex'). *J Hosp Infect*. 1997;37:137–143.
160. Holton J, Shetty N. In-use stability of Nu-Cidex. *J Hosp Infect*. 1997;35:245–248.
161. Alasri A, Roques C, Michel G, et al. Bactericidal properties of peracetic acid and hydrogen peroxide, alone and in combination, and chlorine and formaldehyde against bacterial water strains. *Can J Microbiol*. 1992;38:635–642.
162. Deshpande A, Mana TS, Cadnum JL, et al. Evaluation of a sporicidal peracetic acid/hydrogen peroxide-based daily disinfectant cleaner. *Infect Control Hosp Epidemiol*. 2014;35:1414–1416.
163. Stanley P. Destruction of a glutaraldehyde-resistant mycobacterium by a per-oxygen disinfectant. (Abstract). *Am J Infect Control*. 1998;26:185.
164. Fleming SJ, Foreman K, Shanley K, et al. Dialyser reprocessing with Renalin. *Am J Nephrol*. 1991;11:27–31.
165. Casey ML, Hawley B, Edwards N, et al. Health problems and disinfectant product exposure among staff at a large multispecialty hospital. *Am J Infect Control*. 2017;45:1133–1138.
166. Valyko A, Lawrence J, Washer L, et al. Impact of the universal use of sporicidal disinfection on *Clostridium difficile* infections. *Am J Infect Control*. 2017;45:S23.
167. Finelli L, Miller JT, Tokars JI, et al. National surveillance of dialysis-associated diseases in the United States, 2002. *Semin Dial*. 2005;18:52–61.
168. Sattar SA, Springthorpe VS. Survival and disinfectant inactivation of the human immunodeficiency virus: a critical review. *Rev Infect Dis*. 1991;13:430–447.
169. Rutala WA, Cole EC. Ineffectiveness of hospital disinfectants against bacteria: a collaborative study. *Infect Control*. 1987;8:501–506.
170. Cole EC, Rutala WA, Samsa GP. Disinfectant testing using a modified use-dilution method: collaborative study. *J Assoc Off Anal Chem*. 1988;71:1187–1194.
171. Goddard PA, McCue KA. Phenolic compounds. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. 5th ed. Philadelphia: Lippincott Williams & Wilkins; 2001:255–281.
172. Sagripanti JL, Eklund CA, Trost PA, et al. Comparative sensitivity of 13 species of pathogenic bacteria to seven chemical germicides. *Am J Infect Control*. 1997;25:335–339.
173. Wysowski DK, Flynt JW Jr, Goldfield M, et al. Epidemic neonatal hyperbilirubinemia and use of a phenolic disinfectant detergent. *Pediatrics*. 1978;61:165–170.
174. Doan HM, Keith L, Shennan AT. Phenol and neonatal jaundice. *Pediatrics*. 1979;64:324–325.
175. Rutala WA. Disinfection and sterilization of patient-care items. *Infect Control Hosp Epidemiol*. 1996;17:377–384.
176. Shickman MD, Guze LB, Pearce ML. Bacteremia following cardiac catheterization; report of a case and studies on the source. *N Engl J Med*. 1959;260:1164–1166.
177. Ehrenkranz NJ, Bolyard EA, Wiener M, et al. Antibiotic-sensitive *Serratia marcescens* infections complicating cardiopulmonary operations: contaminated disinfectant as a reservoir. *Lancet*. 1980;2:1289–1292.
178. Mbithi JN, Springthorpe VS, Sattar SA. Chemical disinfection of hepatitis A virus on environmental surfaces. *Appl Environ Microbiol*. 1990;56:3601–3604.
179. Petrocci AN. Surface active agents: quaternary ammonium compounds. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. 3rd ed. Philadelphia: Lea & Febiger; 1983:309–329.
180. Springthorpe VS, Grenier JL, Lloyd-Evans N, et al. Chemical disinfection of human rotaviruses: efficacy of commercially-available products in suspension tests. *J Hyg (Lond)*. 1986;97:139–161.
181. Doultree JC, Druce JD, Birch CJ, et al. Inactivation of feline calicivirus, a Norwalk virus surrogate. *J Hosp Infect*. 1999;41:51–57.
182. Engelbrecht K, Ambrose D, Sifuentes L, et al. Decreased activity of commercially available disinfectants containing quaternary ammonium compounds when exposed to cotton towels. *Am J Infect Control*. 2013;41:908–911.
183. Boyce JM, Sullivan L, Booker A, et al. Quaternary ammonium disinfectant issues encountered in an environmental services department. *Infect Control Hosp Epidemiol*. 2016;37:340–342.
184. Rutala WA, Kanamori H, Gergen MF, et al. Susceptibility of *Candida auris* and *Candida albicans* to 21 germicides used in healthcare facilities. *Infect Control Hosp Epidemiol*. 2019;40:380–382.
185. Cefai C, Richards J, Gould FK, et al. An outbreak of respiratory tract infection resulting from incomplete disinfection of ventilatory equipment. *J Hosp Infect*. 1990;15:177–182.
186. Gurevich I, Tafuro P, Ristuccia P, et al. Disinfection of respirator tubing: a comparison of chemical versus hot water machine-assisted processing. *J Hosp Infect*. 1983;4:199–208.
187. Rutala WA, Weber DJ, Gergen MF, et al. Efficacy of a washer-pasteurizer for disinfection of respiratory-care equipment. *Infect Control Hosp Epidemiol*. 2000;21:333–336.
188. Jette LP, Lambert NG. Evaluation of two hot water washer disinfectors for medical instruments. *Infect Control Hosp Epidemiol*. 1988;9:194–199.
189. Bak J, Ladefoged SD, Tvede M, et al. Dose requirements for UVC disinfection of catheter biofilms. *Biofouling*. 2009;25:289–296.
190. Kac G, Guenneret M, Rodi A, et al. Evaluation of a new disinfection procedure for ultrasound probes using ultraviolet light. *J Hosp Infect*. 2007;65:163–168.
191. Singh J, Bhatia R, Gandhi JC, et al. Outbreak of viral hepatitis B in a rural community in India linked to inadequately sterilized needles and syringes. *Bull World Health Organ*. 1998;76:93–98.
192. Eickhoff TC. An outbreak of surgical wound infections due to *Clostridium perfringens*. *Surg Gynecol Obstet*. 1962;114:102–108.
193. Tosh PK, Disbot M, Duffy JM, et al. Outbreak of *Pseudomonas aeruginosa* surgical site infections after arthroscopic procedures: texas, 2009. *Infect Control Hosp Epidemiol*. 2011;32:1179–1186.
194. Favero MS. Sterility assurance: concepts for patient safety. In: Rutala WA, ed. *Disinfection, Sterilization and Antisepsis: Principles and Practices in Healthcare Facilities*. Washington, DC: Association for Professional in Infection Control and Epidemiology; 2001:110–119.
195. Oxborrow GS, Berube R. Sterility testing-validation of sterilization processes, and sporicide testing. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. Philadelphia: Lea & Febiger; 1991:1047–1057.
196. Rutala WA, Weber DJ. Clinical effectiveness of low-temperature sterilization technologies. *Infect Control Hosp Epidemiol*. 1998;19:798–804.
197. Alfa MJ. Current issues result in a paradigm shift in reprocessing medical and surgical instruments. *Am J Infect Control*. 2016;44:e41–e45.
198. Centers for Disease Control and Prevention. Immediate need for healthcare facilities to review procedures for cleaning, disinfecting, and sterilizing reusable medical devices. 2015. http://emergency.cdc.gov/han/han00382.asp. Accessed January 2018.
199. 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;28:146–155.
200. Adler S, Scherrer M, Daschner FD. Costs of low-temperature plasma sterilization compared with other sterilization methods. *J Hosp Infect*. 1998;40:125–134.
201. Joslyn LJ. Sterilization by heat. In: Block SS, ed. *Disinfection, Sterilization and Preservation*. 5th ed. Philadelphia: Lippincott Williams & Wilkins; 2001.
202. Silverstone SE, Hill DE. Evaluation of sterilization of dental handpieces by heating in synthetic compressor lubricant. *Gen Dent*. 1999;47:158–160.
203. Bucx ML, Veldman DJ, Beenhakker MM, et al. The effect of steam sterilization at 134 degrees C on light intensity provided by fibrelight Macintosh laryngoscopes. *Anaesthesia*. 2000;55:185–186.
204. Gilbert JA, Phillips HO. The effect of steam sterilization on plaster casting material. *Clin Orthop Relat Res*. 1984;190:241–244.
205. Association for the Advancement of Medical Instrumentation. *ANSI. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2010.
206. Bryce EA, Roberts FJ, Clements B, et al. When the biological indicator is positive: investigating autoclave failures. *Infect Control Hosp Epidemiol*. 1997;18:654–656.
207. Rutala WA, Stiegel MM, Sarubbi FA Jr. Decontamination of laboratory microbiological waste by steam sterilization. *Appl Environ Microbiol*. 1982;43:1311–1316.
208. Rutala WA. Disinfection and flash sterilization in the operating room. *J Ophthalmic Nurs Technol*. 1991;10:106–115.
209. Seavey R. Immediate use steam sterilization: moving beyond current policy. *Am J Infect Control*. 2013;41:S46–S48.
210. Immediate-Use Steam Sterilization. Association for the Advancement of Medical Instrumentation, ANSI. http://www.aami.org/publications/standards/ST79_Immediate_Use_Statement.pdf. Accessed January 2018.
211. Foster S, Sullivan SC, Brandt J, et al. Code flash: how an interdisciplinary team eradicated immediate-use steam sterilization. *Infect Control Hosp Epidemiol*. 2015;36:112–113.
212. Alexander SK, Ciocca C, Santos LH, et al. Sustained elimination of immediate use steam sterilization-Bridging the implementation gap. *Am J Infect Control*. 2017;45:S3.
213. Ernst RR, Doyle JE. Sterilization with gaseous ethylene oxide: a review of chemical and physical factors. *Biotech Bioeng*. 1968;10:1–31.
214. Joslyn LJ. Gaseous chemical sterilization. In: Block SS, ed. *Disinfection, Sterilization and Preservation*. 5th ed. Philadelphia.: Lippincott Williams & Wilkins; 2001:337–360.
215. Association for the Advancement of Medical Instrumentation. Ethylene oxide sterilization in health care facilities: Safety and effectiveness. 2008. https://my.aami.org/aamiresources/previewfiles/ST41_1211_preview.pdf. Accessed January 2018.
216. Environmental Protection Agency. Ethylene oxide. 2000. https://www.epa.gov/sites/production/files/2016-09/documents/ethylene-oxide.pdf. Accessed January 2018.
217. Anonymous. Ethylene oxide sterilization: how hospitals can adapt to the changes. *Health Devices*. 1994;23:485–492.
218. Ries MD, Weaver K, Beals N. Safety and efficacy of ethylene oxide sterilized polyethylene in total knee arthroplasty. *Clin Orthop Relat Res*. 1996;331:159–163.
219. Rutala WA, Gergen MF, Weber DJ. Comparative evaluation of the sporicidal activity of new low-temperature sterilization technologies: ethylene oxide, 2 plasma sterilization systems, and liquid peracetic acid. *Am J Infect Control*. 1998;26:393–398.
220. Alfa MJ, DeGagne P, Olson N. Bacterial killing ability of 10% ethylene oxide plus 90% hydrochlorofluorocarbon sterilizing gas. *Infect Control Hosp Epidemiol*. 1997;18:641–645.
221. Parisi AN, Young WE. Sterilization with ethylene oxide and other gases. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. 4th ed. Philadelphia: Lea & Febiger; 1991:580–595.
222. Holler C, Martiny H, Christiansen B, et al. The efficacy of low temperature plasma (LTP) sterilization, a new sterilization technique. *Zentralbl Hyg Umweltmed*. 1993;194:380–391.
223. Rutala WA, Clontz EP, Weber DJ, et al. Disinfection practices for endoscopes and other semicritical items. *Infect Control Hosp Epidemiol*. 1991;12:282–288.
224. Naryzhny I, Silas D, Chi K. Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant Enterobacteriaceae outbreak. *Gastrointest Endosc*. 2016;84:259–262.
225. Parker HH, Johnson RB. Effectiveness of ethylene oxide for sterilization of dental handpieces. *J Dent*. 1995;23:113–115.
226. Borneff M, Ruppert J, Okpara J. Efficacy testing of low-temperature plasma sterilization (LTP) with test object models simulating practice conditions. *Zentr Steril*. 1995;3:361–371.
227. Borneff-Lipp M, Okpara J, Bodendorf M, et al. Validation of low-temperature-plasma (LPT) sterilization systems: comparison of two technical versions, the Sterrad 100, 1.8 and the 100S. *Hygiene und Mikrobiologie*. 1997;3:21–28.
228. Borneff-Lipp M, Kaetzke A, Durr M. Evaluation of low temperature hydrogen peroxide plasma sterilization. *Zentr Steril*. 2008;16:35–42.
229. Rutala WA, Gergen MF, Weber DJ. Sporicidal activity of a new low-temperature sterilization technology: the Sterrad 50 sterilizer. *Infect Control Hosp Epidemiol*. 1999;20:514–516.
230. Roberts C, Antonoplos P. Inactivation of human immunodeficiency virus type 1, hepatitis A virus, respiratory syncytial virus, vaccinia virus, herpes simplex virus type 1, and poliovirus type 2 by hydrogen peroxide gas plasma sterilization. *Am J Infect Control*. 1998;26:94–101.
231. Jacobs PT, Lin SM. Sterilization processes utilizing low-temperature plasma. In: Block SS, ed. *Disinfection,*

Sterilization, and Preservation. Philadelphia: Lippincott Williams & Wilkins; 2001:747–763.
232. Kyi MS, Holton J, Ridgway GL. Assessment of the efficacy of a low temperature hydrogen peroxide gas plasma sterilization system. *J Hosp Infect*. 1995;31:275–284.
233. Feldman LA, Hui HK. Compatibility of medical devices and materials with low-temperature hydrogen peroxide gas plasma. *Med Dev Diag Indust*. 1997;19(December):57–62.
234. Jacobs PT, Smith D. The new Sterrad 100S sterilization system: features and advantages. *Zentr Steril*. 1998;6:86–94.
235. Steris. V-PRO maX Low Temperature Sterilization Syustem, Technical Data Monograph. 2017. https://www.steris.com/onbdocs/v431/1547/823762.pdf. Accessed January 2018.
236. Dufresne S, Richards R. The first dual-sterilant low-temperature sterilization system. *Canad J Infect Control*. 2016;31:169–174.
237. Anonymous. TSO_3 receives U.S. clearance for extended claims for its breakthrough medical device sterilizer. 2016. https://www.prnewswire.com/news-releases/tso3-receives-us-clearance-for-extended-claims-for-its-breakthrough-medical-device-sterilizer-585443841.html. Accessed January 2018.
238. Rutala WA, Weber DJ, Society for Healthcare Epidemiology of America. Guideline for disinfection and sterilization of prion-contaminated medical instruments. *Infect Control Hosp Epidemiol*. 2010;31:107–117.
239. Belay ED, Blasé J, Sehulster LM, et al. Management of neurosurgical instruments and patients exposed to Creutzfeldt-Jakob disease. *Infect Control Hosp Epidemiol*. 2013;34:1272–1280.
240. Brown P, Farrell M. A new practical diagnostic test for Creutzfeldt-Jakob Disease. *Infect Control Hosp Epidemiol*. 2016;36:849.
241. Belay ED, Schonberger LB, Brown P, et al. Disinfection and sterilization of prion-contaminated medical instruments. *Infect Control Hosp Epidemiol*. 2010;31:1304–1306, author reply 6–8.
242. Rutala WA, Weber DJ. Disinfection and sterilization of prion-contaminated medical instruments, Reply to Belay. *Infect Control Hosp Epidemiol*. 2010;31:1306–1307.
243. WHO infection control guidelines for transmissible spongiform encephalopathies. 2003. http://www.who.int/csr/resources/publications/bse/whocdscsraph2003.pdf. Accessed January 2018.
244. Secker TJ, Herve R, Keevil CW. Adsorption of prion and tissue proteins to surgical stainless steel surfaces and the efficacy of decontamination following dry and wet storage conditions. *J Hosp Infect*. 2011;78:251–255.
245. Rutala WA, Weber DJ. Creutzfeldt-Jakob disease: recommendations for disinfection and sterilization. *Clin Infect Dis*. 2001;32:1348–1356.
246. Taylor DM. Inactivation of prions by physical and chemical means. *J Hosp Infect*. 1999;43(suppl):S69–S76.
247. BC Ministry of Health. Best practice guideline for cleaning, disinfection and sterilization of critical and semi-critical medical devices. 2011. https://www.divisionsbc.ca/CMSMedia/WebPageRevisions/PageRev-9661/Best-practice-guidelines-cleaning.pdf. Accessed January 2018.
248. Rutala WA, Weber DJ. ERCP scopes: what can we do to prevent infections? *Infect Control Hosp Epidemiol*. 2015;36:643–648.
249. Bringhurst J. Special problems associated with reprocessing instruments in outpatient care facilities. *Am J Infect Control*. 2016;2016:e63–e67.
250. Rutala WA, Kanamori H, Sickbert-Bennett EE, et al. 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;47S:A62–A66.
251. Rutala WA, Weber DJ. Gastrointestinal endoscopes: a need to shift from disinfection to sterilization? *JAMA*. 2014;312:1405–1406.
252. Meyers J, Ryndock E, Conway MJ, et al. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. *J Antimicrob Chemother*. 2014;69:1546–1550.
253. Gallay C, Miranda E, Schaefer S, et al. Human papillomavirus (HPV) contamination of gynaecological equipment. *Sex Transm Infect*. 2016;92:19–23.
254. Ryndock E, Robison R, Meyers C. Susceptibility of HPV 16 and 18 to high-level disinfectants indicated for semi-critical ultrasound probes. *J Med Virol*. 2016;88:1076–1080.
255. Rutala WA, Gergen MF, Bringhurst J, et al. Effective high-level disinfection of cystoscopes: is perfusion of channels required? *Infect Control Hosp Epidemiol*. 2016;37:228–231.
256. Wendelboe AM, Baumbach J, Blossom DB, et al. Outbreak of cystoscopy related infections with *Pseudomonas aeruginosa*: new Mexico, 2007. *J Urology*. 2008;180:588–592.
257. Rutala WA, Gergen MF, Sickbert-Bennett EE. Effectiveness of a hydrogen peroxide mist (Trophon®) system in inactivating healthcare pathogens on surface and endocavitary probes. *Infect Control Hosp Epidemiol*. 2016;37:613–614.
258. Becker B, Bischoff B, Brill FH, et al. Virucidal efficacy of a sonicated hydrogen peroxide system (trophon EPR) following European and German test methods. *GMS Hyg Infect Control*. 2017;12:Doc02.
259. Weber DJ, Kanamori H, Rutala WA. "No Touch" technologies for environmental decontamination: focus on ultraviolet devices and hydrogen peroxide systems. *Curr Opin Infect Dis*. 2016;29:424–431.
260. Weber DJ, Anderson D, Rutala WA. The role of the surface environment in healthcare-associated infections. *Curr Opin Infect Dis*. 2013;26:338–344.
261. Otter JA, Yezli S, Salkeld JA, et al. Evidence that contaminated surfaces contribute to the transmission of hospital pathogens and an overview of strategies to address contaminated surfaces in hospital settings. *Am J Infect Control*. 2013;41:S6–S11.
262. Boyce JM. Environmental contamination makes an important contribution to hospital infection. *J Hosp Infect*. 2007;65(suppl 2):50–54.
263. Han JH, Sullivan N, Leas BF, et al. Cleaning hospital room surfaces to prevent health care–associated infections. *Ann Intern Med*. 2015.
264. Shams AM, Rose LJ, Edwards JR, et al. Assessment of the overall and multidrug-resistant organism bioburden on environmental surfaces in healthcare facilities. *Infect Control Hosp Epidemiol*. 2016;37:1426–1432.
265. Stiefel U, Cadnum JL, Eckstein BC, et al. Contamination of hands with methicillin-resistant *Staphylococcus aureus* after contact with environmental surfaces and after contact with the skin of colonized patients. *Infect Control Hosp Epidemiol*. 2011;32:185–187.
266. Shaughnessy MK, Micielli RL, DePestel DD, et al. Evaluation of hospital room assignment and acquisition of *Clostridium difficile* infection. *Infect Control Hosp Epidemiol*. 2011;32:201–206.
267. Kundrapu S, Sunkesula V, Jury LA, et al. Daily disinfection of high-touch surfaces in isolation rooms to reduce contamination of healthcare workers' hands. *Infect Control Hosp Epidemiol*. 2012;33:1039–1042.
268. Alfa MJ, Lo E, Olson N, et al. Use of a daily disinfectant cleaner instead of a daily cleaner reduced hospital-acquired infection rates. *Am J Infect Control*. 2015;43:141–146.
269. Havill NL, Havill HL, Mangione E, et al. Cleanliness of portable medical equipment disinfected by nursing staff. *Am J Infect Control*. 2011;39:602–604.
270. Carling P, Herwaldt LA. The Iowa disinfection cleaning project: opportunities, successes, and challenges of a structured intervention program in 56 hospitals. *Infect Control Hosp Epidemiol*. 2017;38:960–965.
271. Smith PW, Beam E, Sayles H, et al. Impact of adenosine triphosphate detection and feedback on hospital room cleaning. *Infect Control Hosp Epidemiol*. 2014;35:564–569.
272. Mustapha A, Cadnum JL, Alhmidi H, et al. Evaluation of novel chemical additive that colorizes chlorine-based disinfectants to improve visualization of surface coverage. *Am J Infect Control*. 2018;46:119–121.
273. Hota B, Blom DW, Lyle EA, et al. Interventional evaluation of environmental contamination by vancomycin-resistant enterococci: failure of personnel, product or procedure? *J Hosp Infect*. 2009;71:123–131.
274. Goodman ER, Platt R, Bass R, et al. Impact of an environmental cleaning intervention on the presence of methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococci on surfaces in intensive care unit rooms. *Infect Control Hosp Epidemiol*. 2008;29:593–599.
275. Eckstein BC, Adams DA, Eckstein EC, et al. Reduction of *Clostridium difficile* and vancomycin-resistant *Enterococcus* contamination of environmental surfaces after an intervention to improve cleaning methods. *BMC Infect Dis*. 2007;7:61.
276. Rutala WA, Gergen MF, Weber DJ. Room decontamination with UV radiation. *Infect Control Hosp Epidemiol*. 2010;31:1025–1029.
277. Rutala WA, Weber DJ, Gergen MF, et al. Does coating all room surfaces with an ultraviolet C light-nanoreflective coating improve decontamination compared with coating only the walls? *Infect Control Hosp Epidemiol*. 2014;35:323–325.
278. Anderson DJ, Gergen MF, Smathers E, et al. Decontamination of targeted pathogens from patient rooms using an automated ultraviolet-C-emitting device. *Infect Control Hosp Epidemiol*. 2013;34:466–471.
279. Anderson DJ, Chen LF, Weber DJ, et al. The benefits of enhanced terminal room (BETR) disinfection study: a prospective, cluster randomized, multicenter, crossover study to evaluate the impact of enhanced terminal room disinfection on acquisition and infection caused by multidrug-resistant organisms. *The Lancet*. 2017;389:805–814.
280. Boyce JM, Havill NL, Moore BA. Terminal decontamination of patient rooms using an automated mobile UV light unit. *Infect Control Hosp Epidemiol*. 2011;32:737–742.
281. Havill NL, Moore BA, Boyce JM. Comparison of the microbiological efficacy of hydrogen peroxide vapor and ultraviolet light processes for room decontamination. *Infect Control Hosp Epidemiol*. 2012;33:507–512.
282. Nerandzic MM, Cadnum JL, Pultz MJ, et al. Evaluation of an automated ultraviolet radiation device for decontamination of *Clostridium difficile* and other healthcare-associated pathogens in hospital rooms. *BMC Infect Dis*. 2010;10:197.
283. Nerandzic MM, Thota P, Sankar CT, et al. Evaluation of a pulsed xenon ultraviolet disinfection system for reduction of healthcare-associated pathogens in hospital rooms. *Infect Control Hosp Epidemiol*. 2015;36:192–197.
284. Jinadatha C, Villamaria FC, Ganachari-Mallappa N, et al. Can pulsed xenon ultraviolet light systems disinfect aerobic bacteria in the absence of manual disinfection? *Am J Infect Control*. 2015;43:415–417.
285. Bates CJ, Pearse R. Use of hydrogen peroxide vapour for environmental control during a *Serratia* outbreak in a neonatal intensive care unit. *J Hosp Infect*. 2005;61:364–366.
286. Boyce JM, Havill NL, Otter JA, et al. Impact of hydrogen peroxide vapor room decontamination on *Clostridium difficile* environmental contamination and transmission in a healthcare setting. *Infect Control Hosp Epidemiol*. 2008;29:723–729.
287. French GL, Otter JA, Shannon KP, et al. Tackling contamination of the hospital environment by methicillin-resistant *Staphylococcus aureus* (MRSA): a comparison between conventional terminal cleaning and hydrogen peroxide vapour decontamination. *J Hosp Infect*. 2004;57:31–37.
288. Bartels MD, Kristoffersen K, Slotsbjerg T, et al. Environmental methicillin-resistant *Staphylococcus aureus* (MRSA) disinfection using dry-mist-generated hydrogen peroxide. *J Hosp Infect*. 2008;70:35–41.
289. Hall L, Otter JA, Chewins J, et al. Use of hydrogen peroxide vapor for deactivation of *Mycobacterium tuberculosis* in a biological safety cabinet and a room. *J Clin Microbiol*. 2007;45:810–815.
290. Hardy KJ, Gossain S, Henderson N, et al. Rapid recontamination with MRSA of the environment of an intensive care unit after decontamination with hydrogen peroxide vapour. *J Hosp Infect*. 2007;66:360–368.
291. Johnston MD, Lawson S, Otter JA. Evaluation of hydrogen peroxide vapour as a method for the decontamination of surfaces contaminated with *Clostridium botulinum* spores. *J Microbiol Methods*. 2005;60:403–411.
292. Klapes NA, Vesley D. Vapor-phase hydrogen peroxide as a surface decontaminant and sterilant. *Appl Environ Microbiol*. 1990;56:503–506.
293. Shapey S, Machin K, Levi K, et al. Activity of a dry mist hydrogen peroxide system against environmental *Clostridium difficile* contamination in elderly care wards. *J Hosp Infect*. 2008;70:136–141.
294. Otter JA, Barnicoat M, Down J, et al. Hydrogen peroxide vapour decontamination of a critical care unit room used to treat a patient with Lassa fever. *J Hosp Infect*. 2010;75:335–337.
295. Mana TS, Sitzlar B, Cadnum JL, et al. Evaluation of an automated room decontamination device using aerosolized peracetic acid. *Am J Infect Control*. 2017;45:327–329.
296. Blazejewski V, Wallet F, Rouze A, et al. Efficiency of hydrogen peroxide in improving disinfection in ICU rooms. *Crit Care*. 2015;19:30.
297. Rutala WA, Weber DJ. Are room decontamination units needed to prevent transmission of environmental pathogens? *Infect Control Hosp Epidemiol*. 2011;32:743–747.
298. Weber DJ, Rutala WA, Anderson DJ, et al. Effectiveness of UV devices and hydrogen peroxide systems for terminal room decontamination: focus on clinical trials. *Am J Infect Control*. 2016;44:e77–e84.
299. Memarzadeh F, Olmsted RN, Bartley JM. Applications of ultraviolet germicidal irradiation disinfection in health care facilities: effective adjunct, but not stand-alone technology. *Am J Infect Control*. 2010;38:S13–S24.
300. Weber DJ, Rutala WA, Anderson DJ, et al. Effectiveness of ultraviolet devices and hydrogen peroxide systems for terminal room decontamination: focus on clinical trials. *Am J Infect Control*. 2016;44:e77–e84.

301. Cadnum JL, Tomas ME, Sankar T, et al. Effect of variation in test methods on performance of ultraviolet-C radiation room decontamination. *Infect Control Hosp Epidemiol*. 2016;37:555–560.
302. Otter JA, Nowakowski E, Salkeld JA, et al. Saving costs through the decontamination of the packaging of unused medical supplies using hydrogen peroxide vapor. *Infect Control Hosp Epidemiol*. 2013;34:472–478.
303. Rutala WA, Weber DJ. Disinfectants used for environmental disinfection and new room decontamination technology. *Am J Infect Control*. 2013;41:S36–S41.
304. Pegues DA, Han J, Gilmar C, et al. Impact of ultraviolet germicidal irradiation for no-touch terminal room disinfection on *Clostridium difficile* infection incidence among hematology-oncology patients. *Infect Control Hosp Epidemiol*. 2017;38:39–44.
305. Rutala WA, Kanamori H, Gergen MF, et al. Enhanced disinfection leads to reduction of microbial contamination and a decrease in patient colonization and infection. *Infect Control Hosp Epidemiol*. 2018.
306. Rutala WA, Kanamori H, Laux J, et al. Continuous visible light disinfection against multidrug-resistant organisms and *Clostridium difficile*: efficacy analysis using a statistical model. *Am J Infect Control*. 2017;45:S21.
307. Tamimi AH, Carlino S, Gerba CP. Long-term efficacy of a self-disinfecting coating in an intensive care unit. *Am J Infect Control*. 2014;42:1178–1181.
308. Fitton K, Barber K, Karamon A, et al. Long acting water-stable organosilane and its sustained effect on reducing microbial load in the intensive care unit. *Am J Infect Control*. 2017;45:S23.
309. Weber DJ, Rutala WA. Self-disinfecting surfaces: review of current methodologies and future prospects. *Am J Infect Control*. 2013;41:S31–S35.
310. Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens: final rule. In: Department of Labor, ed. *Federal Register*. 29 CFR part 1910.1030. 1991:64175–64182.
311. Occupational Safety and Health Administration. EPA-registered disinfectants for HIV/HBV. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=22364. Accessed January 2018.
312. Payan C, Cottin J, Lemarie C, et al. Inactivation of hepatitis B virus in plasma by hospital in-use chemical disinfectants assessed by a modified HepG2 cell culture. *J Hosp Infect*. 2001;47:282–287.
313. Weber DJ, Rutala WA, Fischer WA, et al. Emerging infectious diseases: focus on infection control issues for novel coronaviruses (Severe Acute Respiratory Syndrome-CoV and Middle East Respiratory Syndrome-CoV), hemorrhagic fever viruses (Lassa and Ebola), and highly pathogenic avian influenza viruses, A(H5N1) and A(H7N9). *Am J Infect Control*. 2016;44:e91–e100.
314. Henderson DA. The looming threat of bioterrorism. *Science*. 1999;283:1279–1282.
315. Centers for Disease Control and Prevention. Biological and chemical terrorism: Strategic plan for preparedness and response. 2000. At: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4904a1.htm. Accessed January 2018.
316. Centers for Disease Control and Prevention. Recommendations for infection control for *Candida auris*. 2017. https://www.cdc.gov/fungal/diseases/candidiasis/c-auris-infection-control.html; 2017. Accessed January 2018.
317. Cadnum JC, Shaikh AA, Piedrahita CT, et al. Effectiveness of disinfectants against *Candida auris* and other *Candida* species. *Infect Control Hosp Epidemiol*. 2017;38:1240–1243.
318. Ryan SP, Calfee MW, Wood JP, et al. Research to support the decontamination of surfaces and buildings contaminated with biothreat agents. In: Rutala WA, ed. *Disinfection, Sterilization and Antisepsis: Principles, Practices, Current Issues, New Research, and New Technologies*. Washington, DC: Association for Professionals in Infection Control and Epidemiology; 2010:260–306.
319. Rutala WA, Stiegel MM, Sarubbi FA, et al. Susceptibility of antibiotic-susceptible and antibiotic-resistant hospital bacteria to disinfectants. *Infect Control Hosp Epidemiol*. 1997;18:417–421.
320. Weber DJ, Rutala WA. Use of germicides in the home and the healthcare setting: is there a relationship between germicide use and antibiotic resistance? *Infect Control Hosp Epidemiol*. 2006;27:1107–1119.
321. Kanamori H, Rutala WA, Gergen MF, et al. Germicidal activity against carbapenem/colistin resistant Enterobacteriaceae using a quantitative carrier test method. *Antimicrob Agents Chemother*. 2018;62. e00318-18.
322. Rutala WA, Sarubbi FA Jr. Management of infectious waste from hospitals. *Infect Control*. 1983;4:198–204.
323. Rutala WA, Odette RL, Samsa GP. Management of infectious waste by US hospitals. *JAMA*. 1989;262:1635–1640.
324. Environmental Protection Agency. *EPA Guide for Infectious Waste Management*. Washington, D.C.: U.S. Environmental Protection Agency; 1986.
325. Agency EP. Standards for the tracking and management of medical waste; interim final rule and request for comments. *Fed Regist*. 1989;12326–12395.
326. Council of State Governments. Model guidelines for state medical waste management. https://www.epa.gov/sites/production/files/2016-02/documents/model_guidelines_for_state_medical_waste_management.pdf. Accessed January 2018.
327. Rutala WA, Mayhall CG, Society for Hospital Epidemiology of America. SHEA position paper: medical waste. *Infect Control Hosp Epidemiol*. 1992;13:38–48.
328. Environmental Protection Agency. *EPA Guide for Infectious Waste Management*. Washington, DC: 1986.
329. Environmental Protection Agency. Standards for the tracking and management of medical waste. 1989. http://www.bvsde.paho.org/muwww/fulltext/repind62/epas/epas.html. Accessed January 2018.
330. Rutala WA, Weber DJ. Infectious waste–mismatch between science and policy. *N Engl J Med*. 1991;325:578–582.
331. Environmental Protection Agency. Hospital/Medical/Infectious Waste Incinerators: Summary of Requirements for Revised or New Section 111(d)/129 State Plans Following Amendments to the Emission Guidelines. 2010. https://nepis.epa.gov/Exe/ZyNET.exe/P1009ZW6.TXT?ZyActionD=ZyDocument&Client=EPA&Index=2006+Thru+2010&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C06thru10%5CTxt%5C00000024%5CP1009ZW6.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL. Accessed January 2018.
332. Department of Transportation. Infectious substances; final rule. *Fed Regist*. 1995;48779–48787.
333. Rutala WA, Weber DJ. Disinfection and sterilization: an overview. *Am J Infect Control*. 2013;41:S2–S5.
334. Kohn WG, Collins AS, Cleveland JL, et al. Guidelines for infection control in dental health-care settings–2003. *MMWR Recomm Rep*. 2003;52:1–61.