Disinfection of Healthcare Equipment

Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

AT A GLANCE

Disinfection of healthcare equipment from the Guideline for Disinfection and Sterilization in Healthcare Facilities (2008).

ON THIS PAGE

Concerns about Implementing the Spaulding Scheme

One problem with implementing the aforementioned scheme is oversimplification. For example, the scheme does not consider problems with reprocessing of complicated medical equipment that often is heat-sensitive or problems of inactivating certain types of infectious agents (e.g., prions, such as Creutzfeldt-Jakob disease [CJD] agent). Thus, in some situations, choosing a method of disinfection remains difficult, even after consideration of the categories of risk to patients. This is true particularly for a few medical devices (e.g., arthroscopes, laparoscopes) in the critical category because of controversy about whether they should be sterilized or high-level disinfected. [28, 86] Heat-stable scopes (e.g., many rigid scopes) should be steam sterilized. Some of these items cannot be steam sterilized because they are heat-sensitive; additionally, sterilization using ethylene oxide (EtO) can be too time-consuming for routine use between patients (new technologies, such as hydrogen peroxide gas plasma and peracetic acid reprocessor, provide faster cycle times). However, evidence that sterilization of these items improves patient care by reducing the infection risk is lacking.[29, 87-91] Many newer models of these instruments can withstand steam sterilization, which for critical items is the preferred method.

Another problem with implementing the Spaulding scheme is processing of an instrument in the semicritical category (e.g., endoscope) that would be used in conjunction with a critical instrument that contacts sterile body tissues. For example, is an endoscope used for upper gastrointestinal tract investigation still a semicritical item when used with sterile biopsy forceps or in a patient who is bleeding heavily from esophageal varices? Provided that high-level disinfection is achieved, and all microorganisms except bacterial spores have been removed from

the endoscope, the device should not represent an infection risk and should remain in the semicritical category. [92-94] Infection with spore-forming bacteria has not been reported from appropriately high-level disinfected endoscopes.

An additional problem with implementation of the Spaulding system is that the optimal contact time for high-level disinfection has not been defined or varies among professional organizations, resulting in different strategies for disinfecting different types of semicritical items (e.g., endoscopes, applanation tonometers, endocavitary transducers, cryosurgical instruments, and diaphragm fitting rings). Until simpler and effective alternatives are identified for device disinfection in clinical settings, following this guideline, other CDC guidelines [1, 22, 95, 96] and FDA-cleared instructions for the liquid chemical sterilants/high-level disinfectants would be prudent.

Endoscopes, Laparoscopes, and Arthroscopes

Reprocessing of Endoscopes

Physicians use endoscopes to diagnose and treat numerous medical disorders. Even though endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with their use reportedly is very low (about 1 in 1.8 million procedures), [97] more healthcare–associated outbreaks have been linked to contaminated endoscopes than to any other medical device. [6-8, 12, 98] To prevent the spread of health-care–associated infections, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, nasopharygoscopes) must be properly cleaned and, at a minimum, subjected to high-level disinfection after each use. High-level disinfection can be expected to destroy all microorganisms, although when high numbers of bacterial spores are present, a few spores might survive.

Because of the types of body cavities they enter, flexible endoscopes acquire high levels of microbial contamination (bioburden) during each use. [99] For example, the bioburden found on flexible gastrointestinal endoscopes after use has ranged from 10^5 colony forming units (CFU)/mL to 10^{10} CFU/mL, with the highest levels found in the suction channels.[99-102] The average load on bronchoscopes before cleaning was 6.4×10^4 CFU/mL. Cleaning reduces the level of microbial contamination by 4–6 $\log_{10}$. [83, 103] Using human immunovirus (HIV)-contaminated endoscopes, several investigators have shown that cleaning completely eliminates the microbial contamination on the scopes. [104, 105] Similarly, other investigators found that EtO sterilization or soaking in 2% glutaraldehyde for 20 minutes was effective only when the device first was properly cleaned. [106]

FDA maintains a list of cleared liquid chemical sterilants and high-level disinfectants that can be used to reprocess heat-sensitive medical devices, such as flexible endoscopes [This link is no longer active: http://www.fda.gov/cdrh/ode/germlab.html. The current version of this document may differ from original version: FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices – March 2015external icon]. At this time, the FDA-cleared and marketed formulations include: ≥2.4% glutaraldehyde, 0.55% *ortho*-phthalaldehyde (OPA), 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.35% hydrogen peroxide with 0.23% peracetic acid, 1.0% hydrogen peroxide with 0.08% peracetic acid, and 7.5% hydrogen peroxide. [85] These products have excellent antimicrobial activity; however, some oxidizing chemicals (e.g., 7.5% hydrogen peroxide, and 1.0% hydrogen peroxide with 0.08% peracetic acid [latter product is no longer marketed]) reportedly have caused cosmetic and functional damage to endoscopes. [69] Users should check with device manufacturers for information about germicide compatibility with their device. If the germicide is FDA-cleared, then it is safe when used according to label directions; however, professionals should review the scientific literature for newly available data regarding human safety or materials compatibility. EtO sterilization of flexible endoscopes is infrequent because it requires a lengthy processing and aeration time (e.g., 12 hours) and is a potential hazard to staff and patients. The two products most commonly used for reprocessing endoscopes in the United States are glutaraldehyde and an automated, liquid chemical sterilization process that uses peracetic acid. [107] The American Society for Gastrointestinal Endoscopy (ASGE) recommends glutaraldehyde solutions that do not contain surfactants because the soapy residues of surfactants are difficult to remove during rinsing. [108] *ortho*-phthalaldehyde has begun to replace glutaraldehyde in many health-care facilities because it has several potential advantages over glutaraldehyde: is not known to irritate the eyes and nasal passages, does not require activation or exposure monitoring, and has a 12-minute high-level disinfection claim in the United States. [69] Disinfectants that are not FDA-cleared and should not be used for reprocessing endoscopes include iodophors, chlorine solutions, alcohols, quaternary ammonium compounds, and phenolics. These solutions might still be in use outside the United States, but their use should be strongly discouraged because of lack of proven efficacy against all microorganisms or materials incompatibility.

FDA clearance of the contact conditions listed on germicide labeling is based on the manufacturer's test results [This link is no longer active: http://www.fda.gov/cdrh/ode/germlab.html. The current version of this document may differ from original version: FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices – March 2015external icon]. Manufacturers test the product under worst-case conditions for germicide formulation (i.e., minimum recommended concentration of the active ingredient), and include organic soil. Typically manufacturers use 5% serum as the organic soil and hard water as examples of organic and inorganic challenges. The soil represents the organic loading to which the device is exposed during actual use and that would remain on the device in the absence of cleaning. This method ensures that the contact conditions completely eliminate the test mycobacteria (e.g., 10^5 to 10^6 *Mycobacteria tuberculosis* in organic soil and dried on a scope) if inoculated in the most difficult areas for the disinfectant to penetrate and contact in the absence of

cleaning and thus provides a margin of safety. [109] For 2.4% glutaraldehyde that requires a 45-minute immersion at 25°C to achieve high-level disinfection (i.e., 100% kill of *M. tuberculosis*). FDA itself does not conduct testing but relies solely on the disinfectant manufacturer's data. Data suggest that *M. tuberculosis* levels can be reduced by at least 8 $\log_{10}$ with cleaning (4 $\log_{10}$) [83, 101, 102, 110], followed by chemical disinfection for 20 minutes at 20°C (4 to 6 $\log_{10}$). [83, 93, 111, 112] On the basis of these data, APIC, [113], the Society of Gastroenterology Nurses and Associates (SGNA) [38, 114, 115], the ASGE [108], American College of Chest Physicians [12], and a multi-society guideline [116] recommend alternative contact conditions with 2% glutaraldehyde to achieve high-level disinfection (e.g., that equipment be immersed in 2% glutaraldehyde at 20°C for at least 20 minutes for high-level disinfection). Federal regulations are to follow the FDA-cleared label claim for high-level disinfectants. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25°C range from 20-90 minutes, depending upon the product based on three tier testing which includes AOAC sporicidal tests, simulated use testing with mycobacterial and in-use testing. The studies supporting the efficacy of >2% glutaraldehyde for 20 minutes at 20°C assume adequate cleaning prior to disinfection, whereas the FDA-cleared label claim incorporates an added margin of safety to accommodate possible lapses in cleaning practices. Facilities that have chosen to apply the 20 minute duration at 20°C have done so based on the IA recommendation in the July 2003 SHEA position paper, "Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes."[19, 57, 83, 94, 108, 111, 116-121]

Flexible GI Endoscope Reprocessing [June 2011]

Update: Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011 PDF

Flexible endoscopes are particularly difficult to disinfect [122] and easy to damage because of their intricate design and delicate materials. [123] Meticulous cleaning must precede any sterilization or high-level disinfection of these instruments. Failure to perform good cleaning can result in sterilization or disinfection failure, and outbreaks of infection can occur. Several studies have demonstrated the importance of cleaning in experimental studies with the duck hepatitis B virus (HBV) [106, 124], HIV [125]and *Helicobacter pylori*.[126]

An examination of health-care–associated infections related only to endoscopes through July 1992 found 281 infections transmitted by gastrointestinal endoscopy and 96 transmitted by bronchoscopy. The clinical spectrum ranged from asymptomatic colonization to death. *Salmonella* species and *Pseudomonas aeruginosa* repeatedly were identified as causative agents of infections transmitted by gastrointestinal endoscopy, and *M. tuberculosis*, atypical mycobacteria, and *P. aeruginosa* were the most common causes of infections transmitted by bronchoscopy. [12] Major reasons for transmission were inadequate cleaning, improper selection of a disinfecting agent, and failure to follow recommended cleaning and disinfection procedures [6, 8, 37, 98], and flaws in endoscope design [127, 128] or automated endoscope reprocessors. [7, 98] Failure to follow established guidelines has continued to result in infections associated with gastrointestinal endoscopes [8] and bronchoscopes. [7, 12] Potential device-associated problems should be reported to the FDA Center for Devices and Radiologic Health. One multistate investigation found that 23.9% of the bacterial cultures from the internal channels of 71 gastrointestinal endoscopes grew ³100,000 colonies of bacteria after completion of all disinfection and sterilization procedures (nine of 25 facilities were using a product that has been removed from the marketplace [six facilities using 1:16 glutaraldehyde phenate], is not FDA-cleared as a high-level disinfectant [an iodophor] or no disinfecting agent) and before use on the next patient.[129] The incidence of postendoscopic procedure infections from an improperly processed endoscope has not been rigorously assessed.

Automated endoscope reprocessors (AER) offer several advantages over manual reprocessing: they automate and standardize several important reprocessing steps[130-132], reduce the likelihood that an essential reprocessing step will be skipped, and reduce personnel exposure to high-level disinfectants or chemical sterilants. Failure of AERs has been linked to outbreaks of infections [133] or colonization [7, 134], and the AER water filtration system might not be able to reliably provide "sterile" or bacteria-free rinse water.[135, 136] Establishment of correct connectors between the AER and the device is critical to ensure complete flow of disinfectants and rinse water.[7, 137] In addition, some endoscopes such as the duodenoscopes (e.g., endoscopic retrograde cholangiopancreatography [ERCP]) contain features (e.g., elevator-wire channel) that require a flushing pressure that is not achieved by most AERs and must be reprocessed manually using a 2- to 5-mL syringe, until new duodenoscopes equipped with a wider elevator-channel that AERs can reliably reprocess become available.[132] Outbreaks involving removable endoscope parts [138, 139] such as suction valves and endoscopic accessories designed to be inserted through flexible endoscopes such as biopsy forceps emphasize the importance of cleaning to remove all foreign matter before high-level disinfection or sterilization. [140] Some types of valves are now available as single-use, disposable products (e.g., bronchoscope valves) or steam sterilizable products (e.g., gastrointestinal endoscope valves).

AERs need further development and redesign [7, 141], as do endoscopes, [123, 142] so that they do not represent a potential source of infectious agents. Endoscopes employing disposable components (e.g., protective barrier devices or sheaths) might provide an alternative to conventional liquid chemical high-level disinfection/sterilization.[143, 144] Another new technology is a swallowable camera-in-a-capsule that travels through the digestive tract and transmits color pictures of the small intestine to a receiver worn outside the body. This capsule currently does not replace colonoscopies.

Published recommendations for cleaning and disinfecting endoscopic equipment should be strictly followed.[12, 38, 108, 113-116, 145-148] Unfortunately, audits have shown that personnel do not consistently adhere to guidelines on reprocessing [149-151] and outbreaks of infection continue to occur. [152-154] To ensure reprocessing personnel are properly trained, each person who reprocesses endoscopic instruments should receive initial and annual competency testing.[38, 155]

In general, endoscope disinfection or sterilization with a liquid chemical sterilant 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 a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion).

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 AERs) or tap water (i.e., high-quality potable water that meets federal clean water standards at the point of use).

4. Dry: rinse the insertion tube and inner channels with alcohol, and dry with forced air after disinfection and before storage.

5. Store: store the endoscope in a way that prevents recontamination and promotes drying (e.g., hung vertically).

Drying the endoscope (steps 3 and 4) is essential to greatly reduce the chance of recontamination of the endoscope by microorganisms that can be present in the rinse water. [116, 156] One study demonstrated that reprocessed endoscopes (i.e., air/water channel, suction/biopsy channel) generally were negative (100% after 24 hours; 90% after 7 days [1 CFU of coagulase-negative *Staphylococcus* in one channel]) for bacterial growth when stored by hanging vertically in a ventilated cabinet.[157] Other investigators found all endoscopes were bacteria-free immediately after high-level disinfection, and only four of 135 scopes were positive during the subsequent 5-day assessment (skin bacteria cultured from endoscope surfaces). All flush-through samples remained sterile. [158] Because tapwater can contain low levels of microorganisms[159], some researchers have suggested that only sterile water (which can be prohibitively expensive) [160] or AER filtered water be used. The suggestion to use only sterile water or filtered water is not consistent with published guidelines that allow tapwater with an alcohol rinse and forced air-drying [38, 108, 113] or the scientific literature. [39, 93] In addition, no evidence of disease transmission has been found when a tap water rinse is followed by an alcohol rinse and forced-air drying. AERs produce filtered water by passage through a bacterial filter (e.g., 0.2 m). Filtered rinse water was identified as a source of bacterial contamination in a study that cultured the accessory and suction channels of endoscopes and the internal chambers of AERs during 1996–2001 and reported 8.7% of samples collected during 1996–1998 had bacterial growth, with 54% being *Pseudomonas* species. After a system of hot water flushing of the piping (60°C for 60 minutes daily) was introduced, the frequency of positive cultures fell to approximately 2% with only rare isolation of >10 CFU/mL. [161] In addition to the endoscope reprocessing steps, a protocol should be developed that ensures the user knows whether an endoscope has been appropriately cleaned and disinfected (e.g., using a room or cabinet for processed endoscopes only) or has not been reprocessed. When users leave endoscopes on movable carts, confusion can result about whether the endoscope has been processed. Although one guideline recommended endoscopes (e.g., duodenoscopes) be reprocessed immediately before use, [147] other guidelines do not require this activity [38, 108, 115] and except for the Association of periOperative Registered Nurses (AORN), professional organizations do not recommended that reprocessing be repeated as long as the original processing is done correctly. As part of a quality assurance program, healthcare facility personnel can consider random bacterial surveillance cultures of processed endoscopes to ensure high-level disinfection or sterilization.[7, 162-164] Reprocessed endoscopes should be free of microbial pathogens except for small numbers of relatively avirulent microbes that represent exogenous environmental contamination (e.g., coagulase-negative *Staphylococcus*, *Bacillus* species, diphtheroids). Although recommendations exist for the final rinse water used during endoscope reprocessing to be microbiologically cultured at least monthly [165], a microbiologic standard has not been set, and the value of routine endoscope cultures has not been shown. [166] In addition, neither the routine culture of reprocessed endoscopes nor the final rinse water has been validated by correlating viable counts on an endoscope to infection after an endoscopic procedure. If reprocessed endoscopes were cultured, sampling the endoscope would assess water quality and other important steps (e.g., disinfectant effectiveness, exposure time, cleaning) in the reprocessing procedure. A number of methods for sampling endoscopes and water have been described.[23, 157, 161, 163, 167, 168] Novel approaches (e.g., detection of adenosine triphosphate [ATP]) to evaluate the effectiveness of endoscope cleaning [169, 170] or endoscope reprocessing [171] also have been evaluated, but no method has been established as a standard for assessing the outcome of endoscope reprocessing.

The carrying case used to transport clean and reprocessed endoscopes outside the health-care environment should not be used to store an endoscope or to transport the instrument within the health-care facility. A contaminated endoscope should never be placed in the carrying case because the case can also become contaminated. When the endoscope is removed from the case, properly reprocessed, and put back in the case, the case could recontaminate the endoscope. A contaminated carrying case should be discarded (Olympus America, June 2002, written communication).

Infection-control professionals should ensure that institutional policies are consistent with national guidelines and conduct infection-control rounds periodically (e.g., at least annually) in areas where endoscopes are reprocessed to ensure policy compliance. Breaches in policy should be documented and corrective action instituted. In incidents in which endoscopes were not exposed to a high-level disinfection process, patients exposed to potentially contaminated endoscopes have been assessed for possible acquisition of HIV, HBV, and hepatitis C virus (HCV). A 14-step method for managing a failure incident associated with high-level disinfection or sterilization has been described [Rutala WA, 2006 #12512]. The possible transmission of bloodborne and other infectious agents highlights the importance of rigorous infection control.[172, 173]

Laparoscopes and Arthroscopes

Although high-level disinfection appears to be the minimum standard for processing laparoscopes and arthroscopes between patients [28, 86, 174, 175], this practice continues to be debated.[89, 90, 176] However, neither side in the high-level disinfection versus sterilization debate has sufficient data on which to base its conclusions. Proponents of high-level disinfection refer to membership surveys [29] or institutional experiences [87] involving more than 117,000 and 10,000 laparoscopic procedures, respectively, that cite a low risk for infection (<0.3%) when high-level disinfection is used for gynecologic laparoscopic equipment. Only one infection in the membership survey was linked to spores. In addition, growth of common skin microorganisms (e.g., *Staphylococcus epidermidis*, diphtheroids) has been documented from the umbilical area even after skin preparation with povidone-iodine and ethyl alcohol. Similar organisms were recovered in some instances from the pelvic serosal surfaces or from the laparoscopic telescopes, suggesting that the microorganisms probably were carried from the skin into the peritoneal cavity. [177, 178] Proponents of sterilization focus on the possibility of transmitting infection by spore-forming organisms. Researchers have proposed several reasons why sterility was not necessary for all laparoscopic equipment: only a limited number of organisms (usually ≤10) are introduced into the peritoneal cavity during laparoscopy; minimal damage is done to inner abdominal structures with little devitalized tissue; the peritoneal cavity tolerates small numbers of spore-forming bacteria; equipment is simple to clean and disinfect; surgical sterility is relative; the natural bioburden on rigid lumened devices is low[179]; and no evidence exists that high-level disinfection instead of sterilization increases the risk for infection. [87, 89, 90] With the advent of laparoscopic cholecystectomy, concern about high-level disinfection is justifiable because the degree of tissue damage and bacterial contamination is greater than with laparoscopic procedures in gynecology. Failure to completely dissemble, clean, and high-level disinfect laparoscope parts has led to infections in patients.[180] Data from one study suggested that disassembly, cleaning, and proper reassembly of laparoscopic equipment used in gynecologic procedures before steam sterilization presents no risk for infection.[181]

As with laparoscopes and other equipment that enter sterile body sites, arthroscopes ideally should be sterilized before used. Older studies demonstrated that these instruments were commonly (57%) only high-level disinfected in the United States. [28, 86] A later survey (with a response rate of only 5%) reported that high-level disinfection was used by 31% and a sterilization process in the remainder of the health-care facilities[30] High-level disinfection rather than sterilization presumably has been used because the incidence of infection is low and the few infections identified probably are unrelated to the use of high-level disinfection rather than sterilization. A retrospective study of 12,505 arthroscopic procedures found an infection rate of 0.04% (five infections) when arthroscopes were soaked in 2% glutaraldehyde for 15–20 minutes. Four infections were caused by *S. aureus*; the fifth was an anaerobic streptococcal infection. [88] Because these organisms are very susceptible to high-level disinfectants, such as 2% glutaraldehyde, the infections most likely originated from the patient's skin. Two cases of *Clostridium perfringens* arthritis have been reported when the arthroscope was disinfected with glutaraldehyde for an exposure time that is not effective against spores. [182, 183]

Although only limited data are available, the evidence does not demonstrate that high-level disinfection of arthroscopes and laparoscopes poses an infection risk to the patient. For example, a prospective study that compared the reprocessing of arthroscopes and laparoscopes (per 1,000 procedures) with EtO sterilization to high-level disinfection with glutaraldehyde found no statistically significant difference in infection risk between the two methods (i.e., EtO, 7.5/1,000 procedures; glutaraldehyde, 2.5/1,000 procedures).[89] Although the debate for high-level disinfection versus sterilization of laparoscopes and arthroscopes will go unsettled until well-designed, randomized clinical trials are published, this guideline should be followed. [1, 17] That is, laparoscopes, arthroscopes, and other scopes that enter normally sterile tissue should be sterilized before each use; if this is not feasible, they should receive at least high-level disinfection.

Tonometers, Cervical Diaphragm Fitting Rings, Cryosurgical Instruments, and Endocavitary Probes

Disinfection strategies vary widely for other semicritical items (e.g., applanation tonometers, rectal/vaginal probes, cryosurgical instruments, and diaphragm fitting rings). FDA requests that device manufacturers include at least one validated cleaning and disinfection/sterilization protocol in the labeling for their devices. As with all medications and devices, users should be familiar with the label instructions. One study revealed that no uniform technique was in use for disinfection of applanation tonometers, with disinfectant contact times varying from <15 sec to 20 minutes. [28] In view of the potential for transmission of viruses (e.g., herpes simplex virus [HSV], adenovirus 8, or HIV) [184] by tonometer tips, CDC recommended that the tonometer tips be wiped clean and disinfected for 5-10 minutes with either 3% hydrogen peroxide, 5000 ppm chlorine, 70% ethyl alcohol, or 70% isopropyl alcohol. [95] However, more recent data suggest that 3% hydrogen peroxide and 70% isopropyl alcohol are

not effective against adenovirus capable of causing epidemic keratoconjunctivitis and similar viruses and should not be used for disinfecting applanation tonometers. [49, 185, 186] Structural damage to Schiotz tonometers has been observed with a 1:10 sodium hypochlorite (5,000 ppm chlorine) and 3% hydrogen peroxide.[187] After disinfection, the tonometer should be thoroughly rinsed in tapwater and air dried before use. Although these disinfectants and exposure times should kill pathogens that can infect the eyes, no studies directly support this. [188, 189] The guidelines of the American Academy of Ophthalmology for preventing infections in ophthalmology focus on only one potential pathogen: HIV. [190] Because a short and simple decontamination procedure is desirable in the clinical setting, swabbing the tonometer tip with a 70% isopropyl alcohol wipe sometimes is practiced. [189] Preliminary reports suggest that wiping the tonometer tip with an alcohol swab and then allowing the alcohol to evaporate might be effective in eliminating HSV, HIV, and adenovirus.[189, 191, 192] However, because these studies involved only a few replicates and were conducted in a controlled laboratory setting, further studies are needed before this technique can be recommended. In addition, two reports have found that disinfection of pneumotonometer tips between uses with a 70% isopropyl alcohol wipe contributed to outbreaks of epidemic keratoconjunctivitis caused by adenovirus type 8.[193, 194]

Limited studies have evaluated disinfection techniques for other items that contact mucous membranes, such as diaphragm fitting rings, cryosurgical probes, transesophageal echocardiography probes [195], flexible cystoscopes [196] or vaginal/rectal probes used in sonographic scanning. Lettau, Bond, and McDougal of CDC supported the recommendation of a diaphragm fitting ring manufacturer that involved using a soap-and-water wash followed by a 15-minute immersion in 70% alcohol.[96] This disinfection method should be adequate to inactivate HIV, HBV, and HSV even though alcohols are not classified as high-level disinfectants because their activity against picornaviruses is somewhat limited.[72] No data are available regarding inactivation of human papillomavirus (HPV) by alcohol or other disinfectants because in vitro replication of complete virions has not been achieved. Thus, even though alcohol for 15 minutes should kill pathogens of relevance in gynecology, no clinical studies directly support this practice.

Vaginal probes are used in sonographic scanning. A vaginal probe and all endocavitary probes without a probe cover are semicritical devices because they have direct contact with mucous membranes (e.g., vagina, rectum, pharynx). While use of the probe cover could be considered as changing the category, this guideline proposes use of a new condom/probe cover for the probe for each patient, and because condoms/probe covers can fail [195, 197-199], the probe also should be high-level disinfected. The relevance of this recommendation is reinforced with the findings that sterile transvaginal ultrasound probe covers have a very high rate of perforations even before use (0%, 25%, and 65% perforations from three suppliers). [199] One study found, after oocyte retrieval use, a very high rate of perforations in used endovaginal probe covers from two suppliers (75% and 81%),[199] other studies demonstrated a lower rate of perforations after use of condoms (2.0% and 0.9%). [197, 200] Condoms have been found superior to commercially available probe covers for covering the ultrasound probe (1.7% for condoms versus 8.3% leakage for probe covers).[201] These studies underscore the need for routine probe disinfection between examinations. Although most ultrasound manufacturers recommend use of 2% glutaraldehyde for high-level disinfection of contaminated transvaginal transducers, the this agent has been questioned [202] because it might shorten the life of the transducer and might have toxic effects on the gametes and embryos. [203] An alternative procedure for disinfecting the vaginal transducer involves the mechanical removal of the gel from the transducer, cleaning the transducer in soap and water, wiping the transducer with 70% alcohol or soaking it for 2 minutes in 500 ppm chlorine, and rinsing with tap water and air drying.[204] The effectiveness of this and other methods [200] has not been validated in either rigorous laboratory experiments or in clinical use. High-level disinfection with a product (e.g., hydrogen peroxide) that is not toxic to staff, patients, probes, and retrieved cells should be used until the effectiveness of alternative procedures against microbes of importance at the cavitary site is demonstrated by well-designed experimental scientific studies. Other probes such as rectal, cryosurgical, and transesophageal probes or devices also should be high-level disinfected between patients.

Ultrasound probes used during surgical procedures also can contact sterile body sites. These probes can be covered with a sterile sheath to reduce the level of contamination on the probe and reduce the risk for infection. However, because the sheath does not completely protect the probe, the probes should be sterilized between each patient use as with other critical items. If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.

Some cryosurgical probes are not fully immersible. During reprocessing, the tip of the probe should be immersed in a high-level disinfectant for the appropriate time; any other portion of the probe that could have mucous membrane contact can be disinfected by immersion or by wrapping with a cloth soaked in a high-level disinfectant to allow the recommended contact time. After disinfection, the probe should be rinsed with tap water and dried before use. Health-care facilities that use nonimmersible probes should replace them as soon as possible with fully immersible probes.

As with other high-level disinfection procedures, proper cleaning of probes is necessary to ensure the success of the subsequent disinfection. [205] One study demonstrated that vegetative bacteria inoculated on vaginal ultrasound probes decreased when the probes were cleaned with a towel. [206] No information is available about either the level of contamination of such probes by potential viral pathogens such as HBV and HPV or their removal by cleaning (such as with a towel). Because these pathogens might be present in vaginal and rectal secretions and contaminate probes during use, high-level disinfection of the probes after such use is recommended.

Dental Instruments

Scientific articles and increased publicity about the potential for transmitting infectious agents in dentistry have focused attention on dental instruments as possible agents for pathogen transmission.[207, 208] The American Dental Association recommends that surgical and other instruments that normally penetrate soft tissue or bone (e.g., extraction forceps, scalpel blades, bone chisels, periodontal scalers, and surgical burs) be classified as critical devices that should be sterilized after each use or discarded. Instruments not intended to penetrate oral soft tissues or bone (e.g., amalgam condensers, and air/water syringes) but that could contact oral tissues are classified as semicritical, but sterilization after each use is recommended if the instruments are heat-tolerant. [43, 209] If a semicritical item is heat–sensitive, it should, at a minimum, be processed with high-level disinfection. [43, 210] Handpieces can be contaminated internally with patient material and should be heat sterilized after each patient. Handpieces that cannot be heat sterilized should not be used. [211] Methods of sterilization that can be used for critical or semicritical dental instruments and materials that are heat-stable include steam under pressure (autoclave), chemical (formaldehyde) vapor, and dry heat (e.g., 320°F for 2 hours). Dental professionals most commonly use the steam sterilizer. [212] All three sterilization procedures can damage some dental instruments, including steam-sterilized hand pieces. [213] Heat-tolerant alternatives are available for most clinical dental applications and are preferred.[43]

CDC has divided noncritical surfaces in dental offices into clinical contact and housekeeping surfaces.[43] Clinical contact surfaces are surfaces that might be touched frequently with gloved hands during patient care or that might become contaminated with blood or other potentially infectious material and subsequently contact instruments, hands, gloves, or devices (e.g., light handles, switches, dental X-ray equipment, chair-side computers). Barrier protective coverings (e.g., clear plastic wraps) can be used for these surfaces, particularly those that are difficult to clean (e.g., light handles, chair switches). The coverings should be changed when visibly soiled or damaged and routinely (e.g., between patients). Protected surfaces should be disinfected at the end of each day or if contamination is evident. If not barrier-protected, these surfaces should be disinfected between patients with an intermediate-disinfectant (i.e., EPA-registered hospital disinfectant with tuberculocidal claim) or low-level disinfectant (i.e., EPA-registered hospital disinfectant with an HBV and HIV label claim). [43, 214, 215]

Most housekeeping surfaces need to be cleaned only with a detergent and water or an EPA-registered hospital disinfectant, depending of the nature of the surface and the type and degree of contamination. When housekeeping surfaces are visibly contaminated by blood or body substances, however, prompt removal and surface disinfection is a sound infection control practice and required by the Occupational Safety and Health Administration (OSHA). [43, 214]

Several studies have demonstrated variability among dental practices while trying to meet these recommendations.[216, 217] For example, 68% of respondents believed they were sterilizing their instruments but did not use appropriate chemical sterilants or exposure times and 49% of respondents did not challenge autoclaves with biological indicators.[216] Other investigators using biologic indicators have found a high proportion (15%–65%) of positive spore tests after assessing the efficacy of sterilizers used in dental offices. In one study of Minnesota dental offices, operator error, rather than mechanical malfunction[218], caused 87% of sterilization failures. Common factors in the improper use of sterilizers include chamber overload, low temperature setting, inadequate exposure time, failure to preheat the sterilizer, and interruption of the cycle.

Mail-return sterilization monitoring services use spore strips to test sterilizers in dental clinics, but delay caused by mailing to the test laboratory could potentially cause false-negatives results. Studies revealed, however, that the post-sterilization time and temperature after a 7-day delay had no influence on the test results.[219] Delays (7 days at 27°C and 37°C, 3-day mail delay) did not cause any predictable pattern of inaccurate spore tests. [220]

Disinfection of HBV-, HCV-, HIV- or TB-Contaminated Devices

The CDC recommendation for high-level disinfection of HBV-, HCV-, HIV- or TB-contaminated devices is appropriate because experiments have demonstrated the effectiveness of high-level disinfectants to inactivate these and other pathogens that might contaminate semicritical devices. [61, 62, 73, 81, 105, 121, 125, 221-238] Nonetheless, some healthcare facilities have modified their disinfection procedures when endoscopes are used with a patient known or suspected to be infected with HBV, HIV, or *M. tuberculosis*. [28, 239] This is inconsistent with the concept of Standard Precautions that presumes all patients are potentially infected with bloodborne pathogens.[228] Several studies have highlighted the inability to distinguish HBV- or HIV-infected patients from noninfected patients on clinical grounds.[240-242] In addition, mycobacterial infection is unlikely to be clinically apparent in many patients. In most instances, hospitals that altered their disinfection procedure used EtO sterilization on the endoscopic instruments because they believed this practice reduced the risk for infection. [28, 239] EtO is not routinely used for endoscope sterilization because of the lengthy processing time. Endoscopes and other semicritical devices should be managed the same way regardless of whether the patient is known to be infected with HBV, HCV, HIV or *M. tuberculosis*.

An evaluation of a manual disinfection procedure to eliminate HCV from experimentally contaminated endoscopes provided some evidence that cleaning and 2% glutaraldehyde for 20 minutes should prevent transmission. [236] A study that used experimentally contaminated hysteroscopes

detected HCV by polymerase chain reaction (PCR) in one (3%) of 34 samples after cleaning with a detergent, but no samples were positive after treatment with a 2% glutaraldehyde solution for 20 minutes. [120] Another study demonstrated complete elimination of HCV (as detected by PCR) from endoscopes used on chronically infected patients after cleaning and disinfection for 3–5 minutes in glutaraldehyde. [118] Similarly, PCR was used to demonstrate complete elimination of HCV after standard disinfection of experimentally contaminated endoscopes [236] and endoscopes used on HCV-antibody–positive patients had no detectable HCV RNA after high-level disinfection. [243] The inhibitory activity of a phenolic and a chlorine compound on HCV showed that the phenolic inhibited the binding and replication of HCV, but the chlorine was ineffective, probably because of its low concentration and its neutralization in the presence of organic matter. [244]

Disinfection in the Hemodialysis Unit

Hemodialysis systems include hemodialysis machines, water supply, water-treatment systems, and distribution systems. During hemodialysis, patients have acquired bloodborne viruses and pathogenic bacteria. [245-247] Cleaning and disinfection are important components of infection control in a hemodialysis center. EPA and FDA regulate disinfectants used to reprocess hemodialyzers, hemodialysis machines, and water-treatment systems.

Noncritical surfaces (e.g., dialysis bed or chair, countertops, external surfaces of dialysis machines, and equipment [scissors, hemostats, clamps, blood pressure cuffs, stethoscopes]) should be disinfected with an EPA-registered disinfectant unless the item is visibly contaminated with blood; in that case a tuberculocidal agent (or a disinfectant with specific label claims for HBV and HIV) or a 1:100 dilution of a hypochlorite solution (500–600 ppm free chlorine) should be used. [246, 248] This procedure accomplishes two goals: it removes soil on a regular basis and maintains an environment that is consistent with good patient care. Hemodialyzers are disinfected with peracetic acid, formaldehyde, glutaraldehyde, heat pasteurization with citric acid, and chlorine-containing compounds. [249] Hemodialysis systems usually are disinfected by chlorine-based disinfectants (e.g., sodium hypochlorite), aqueous formaldehyde, heat pasteurization, ozone, or peracetic acid. [250, 251] All products must be used according to the manufacturers' recommendations. Some dialysis systems use hot-water disinfection to control microbial contamination.

At its high point, 82% of U.S. chronic hemodialysis centers were reprocessing (i.e., reusing) dialyzers for the same patient using high-level disinfection. [249] However, one of the large dialysis organizations has decided to phase out reuse and, by 2002 the percentage of dialysis facilities reprocessing hemodialyzers had decreased to 63%. [252] The two commonly used disinfectants to reprocess dialyzers were peracetic acid and formaldehyde; 72% used peracetic acid and 20% used formaldehyde to disinfect hemodialyzers. Another 4% of the facilities used either glutaraldehyde or heat pasteurization in combination with citric acid. [252] Infection-control recommendations, including disinfection and sterilization and the use of dedicated machines for hepatitis B surface antigen (HBsAg)-positive patients, in the hemodialysis setting were detailed in two reviews. [245, 246] The Association for the Advancement of Medical Instrumentation(AAMI) has published recommendations for the reuse of hemodialyzers.[253]

Inactivation of *Clostridium difficile*

The source of health-care–associated acquisition of *Clostridium difficile* in nonepidemic settings has not been determined. The environment and carriage on the hands of health-care personnel have been considered possible sources of infection. [66, 254] Carpeted rooms occupied by a patient with *C. difficile* were more heavily contaminated with *C. difficile* than were noncarpeted rooms [255]. Because *C. difficile* spore-production can increase when exposed to nonchlorine-based cleaning agents and the spores are more resistant than vegetative cells to commonly used surface disinfectants[256], some investigators have recommended use of dilute solutions of hypochlorite (1,600 ppm available chlorine) for routine environmental disinfection of rooms of patients with *C. difficile*-associated diarrhea or colitis [257], to reduce the incidence of *C. difficile* diarrhea [258], or in units with high *C. difficile* rates. [259] Stool samples of patients with symptomatic *C. difficile* colitis contain spores of the organism, as demonstrated by ethanol treatment of the stool to reduce the overgrowth of fecal flora when isolating *C. difficile* in the laboratory[260, 261]. *C. difficile*-associated diarrhea rates were shown to have decreased markedly in a bone-marrow transplant unit (from 8.6 to 3.3 cases per 1,000 patient-days) during a period of bleach disinfection (1:10 dilution) of environmental surfaces compared with cleaning with a quaternary ammonium compound.

C. difficile Update [April 2019]

EPA-registered products specific for inactivating *C. difficile* spores, should be used in units with high *C. difficile* rates. Thus, combined use of appropriate hand hygiene, barrier precautions, and meticulous environmental cleaning, and use of an EPA-registered disinfectant that is appropriate for the level of risk, should effectively prevent spread of the organism LIST K: EPA's Registered Antimicrobial Products Effective against Clostridium difficile Spores.

Acidified bleach and regular bleach (5000 ppm chlorine) can inactivate 10^6 *C. difficile* spores in ≤10 minutes [262]. However, studies have shown that asymptomatic patients constitute an important reservoir within the health-care facility and that person-to-person transmission is the principal means of transmission between patients. Thus, combined use of hand washing, barrier precautions, and meticulous environmental cleaning with an EPA-registered disinfectant (e.g., germicidal detergent) should effectively prevent spread of the organism [263].

Contaminated medical devices, such as colonoscopes and thermometers,can be vehicles for transmission of *C. difficile* spores [264]. For this reason, investigators have studied commonly used disinfectants and exposure times to assess whether current practices can place patients at risk. Data demonstrate that 2% glutaraldehyde [79, 265-267] and peracetic acid [267, 268] reliably kill *C. difficile* spores using exposure times of 5–20 minutes. *ortho*-Phthalaldehyde and ≥0.2% peracetic acid (WA Rutala, personal communication, April 2006) also can inactivate ≥10^4 *C. difficile* spores in 10–12 minutes at 20°C [268]. Sodium dichloroisocyanurate at a concentration of 1000 ppm available chlorine achieved lower $\log_{10}$ reduction factors against *C. difficile* spores at 10 min, ranging from 0.7 to 1.5, than 0.26% peracetic acid with $\log_{10}$ reduction factors ranging from 2.7 to 6.0[268].

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 [214]. 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. Even though the OSHA standard does not specify the type of disinfectant or procedure, the OSHA original compliance document [269] suggested that a germicide must be tuberculocidal to kill the HBV. To follow the OSHA compliance document a tuberculocidal disinfectant (e.g., phenolic, and chlorine) would be needed to clean a blood spill. However, in February 1997, OSHA amended its policy and stated that EPA-registered disinfectants labeled as effective against HIV and HBV 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." When bloodborne pathogens other than HBV or HIV are of concern, OSHA continues to require use of EPA-registered tuberculocidal disinfectants or hypochlorite solution (diluted 1:10 or 1:100 with water) [215, 228]. Studies demonstrate 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 [63, 235] to minimize risk for infection to health-care personnel from percutaneous injury during cleanup.

Emerging Pathogens

Cryptosporidium, Helicobacter pylori, Escherichia coli O157:H7, Rotavirus, Human Papilloma Virus, Norovirus, Severe Acute Respiratory Syndrome (SARS) Coronavirus

Emerging pathogens are of growing concern to the general public and infection-control professionals. Relevant pathogens include *Cryptosporidium parvum, Helicobacter pylori, E. coli* O157:H7, HIV, HCV, rotavirus, norovirus, severe acute respiratory syndrome (SARS) coronavirus, multidrug-resistant *M. tuberculosis*, and nontuberculous mycobacteria (e.g., *M. chelonae*). The susceptibility of each of these pathogens to chemical disinfectants and sterilants has been studied. With the exceptions discussed below, all of these emerging pathogens are susceptible to currently available chemical disinfectants and sterilants [270].

Cryptosporidium is resistant to chlorine at concentrations used in potable water. *C. parvum* is not completely inactivated by most disinfectants used in healthcare including ethyl alcohol [271], glutaraldehyde [271, 272], 5.25% hypochlorite [271], peracetic acid [271], ortho-phthalaldehyde [271], phenol [271, 272], povidone-iodine [271, 272], and quaternary ammonium compounds[271]. The only chemical disinfectants and sterilants able to inactivate greater than 3 $\log_{10}$ of *C. parvum* were 6% and 7.5% hydrogen peroxide [271]. Sterilization methods will fully inactivate *C. parvum,* including steam [271], EtO [271, 273], and hydrogen peroxide gas plasma[271]. Although most disinfectants are ineffective against *C. parvum*, current cleaning and disinfection practices appear satisfactory to prevent healthcare-associated transmission. For example, endoscopes are unlikely to be an important vehicle for transmitting *C. parvum* because the results of bacterial studies indicate mechanical cleaning will remove approximately 10^4 organisms, and drying results in rapid loss of *C. parvum* viability (e.g., 30 minutes, 2.9 $\log_{10}$ decrease; and 60 minutes, 3.8 $\log_{10}$ decrease) [271].

Chlorine at ~1 ppm has been found capable of eliminating approximately 4 $\log_{10}$ of *E. coli* O157:H7 within 1 minute in a suspension test[64]. Electrolyzed oxidizing water at 23°C was effective in 10 minutes in producing a 5-$\log_{10}$ decrease in *E. coli* O157:H7 inoculated onto kitchen cutting boards[274]. The following disinfectants eliminated >5 $\log_{10}$ of *E. coli* O157:H7 within 30 seconds: a quaternary ammonium compound, a phenolic, a hypochlorite (1:10 dilution of 5.25% bleach), and ethanol[53]. Disinfectants including chlorine compounds can reduce *E. coli* O157:H7 experimentally inoculated onto alfalfa seeds or sprouts [275, 276] or beef carcass surfaces[277].

Data are limited on the susceptibility of *H. pylori* to disinfectants. Using a suspension test, one study assessed the effectiveness of a variety of disinfectants against nine strains of *H. pylori* [60]. Ethanol (80%) and glutaraldehyde (0.5%) killed all strains within 15 seconds; chlorhexidine gluconate (0.05%, 1.0%), benzalkonium chloride (0.025%, 0.1%), alkyldiaminoethylglycine hydrochloride (0.1%), povidone-iodine (0.1%), and sodium hypochlorite (150 ppm) killed all strains within 30 seconds. Both ethanol (80%) and glutaraldehyde (0.5%) retained similar bactericidal activity in the presence of organic matter; the other disinfectants showed reduced bactericidal activity. In particular, the bactericidal activity of povidone-iodine (0.1%) and sodium hypochlorite (150 ppm) markedly decreased in the presence of dried yeast solution with killing times increased to 5 – 10 minutes and 5 – 30 minutes, respectively.

Immersing biopsy forceps in formalin before obtaining a specimen does not affect the ability to culture *H. pylori* from the biopsy specimen [278]. The following methods are ineffective for eliminating *H. pylori* from endoscopes: cleaning with soap and water [119, 279], immersion in 70% ethanol for 3 minutes[280], instillation of 70% ethanol[126], instillation of 30 ml of 83% methanol[279], and instillation of 0.2% Hyamine solution[281]. The differing results with regard to the efficacy of ethyl alcohol against *Helicobacter* are unexplained. Cleaning followed by use of 2% alkaline glutaraldehyde (or automated peracetic acid) has been demonstrated by culture to be effective in eliminating *H. pylori* [119, 279, 282]. Epidemiologic investigations of patients who had undergone endoscopy with endoscopes mechanically washed and disinfected with 2.0%–2.3% glutaraldehyde have revealed no evidence of person-to-person transmission of *H. pylori* [126, 283]. Disinfection of experimentally contaminated endoscopes using 2% glutaraldehyde (10-minute, 20-minute, 45-minute exposure times) or the peracetic acid system (with and without active peracetic acid) has been demonstrated to be effective in eliminating *H. pylori* [119]. *H. pylori* DNA has been detected by PCR in fluid flushed from endoscope channels after cleaning and disinfection with 2% glutaraldehyde [284]. The clinical significance of this finding is unclear. *In vitro* experiments have demonstrated a >3.5-$\log_{10}$ reduction in *H. pylori* after exposure to 0.5 mg/L of free chlorine for 80 seconds[285].

An outbreak of healthcare-associated rotavirus gastroenteritis on a pediatric unit has been reported [286]. Person to person through the hands of health-care workers was proposed as the mechanism of transmission. Prolonged survival of rotavirus on environmental surfaces (90 minutes to >10 days at room temperature) and hands (>4 hours) has been demonstrated. Rotavirus suspended in feces can survive longer [287, 288]. Vectors have included hands, fomites, air, water, and food [288, 289]. Products with demonstrated efficacy (>3 $\log_{10}$ reduction in virus) against rotavirus within 1 minute include: 95% ethanol, 70% isopropanol, some phenolics, 2% glutaraldehyde, 0.35% peracetic acid, and some quaternary ammonium compounds [59, 290-293]. In a human challenge study, a disinfectant spray (0.1% ortho-phenylphenol and 79% ethanol), sodium hypochlorite (800 ppm free chlorine), and a phenol-based product (14.7% phenol diluted 1:256 in tapwater) when sprayed onto contaminated stainless steel disks**,** were effective in interrupting transfer of a human rotavirus from stainless steel disk to fingerpads of volunteers after an exposure time of 3- 10 minutes. A quaternary ammonium product (7.05% quaternary ammonium compound diluted 1:128 in tapwater) and tapwater allowed transfer of virus [52].

No data exist on the inactivation of HPV by alcohol or other disinfectants because in vitro replication of complete virions has not been achieved. Similarly, little is known about inactivation of noroviruses (members of the family *Caliciviridae* and important causes of gastroenteritis in humans) because they cannot be grown in tissue culture. Improper disinfection of environmental surfaces contaminated by feces or vomitus of infected patients is believed to play a role in the spread of noroviruses in some settings [294-296]. Prolonged survival of a norovirus surrogate (i.e., feline calicivirus virus [FCV], a closely related cultivable virus) has been demonstrated (e.g., at room temperature, FCV in a dried state survived for 21–18 days) [297]. Inactivation studies with FCV have shown the effectiveness of chlorine, glutaraldehyde, and iodine-based products whereas the quaternary ammonium compound, detergent, and ethanol failed to inactivate the virus completely. [297] An evaluation of the effectiveness of several disinfectants against the feline calicivirus found that bleach diluted to 1000 ppm of available chlorine reduced infectivity of FCV by 4.5 logs in 1 minute. Other effective ($\log_{10}$ reduction factor of >4 in virus) disinfectants included accelerated hydrogen peroxide, 5,000 ppm (3 min); chlorine dioxide, 1,000 ppm chlorine (1 min); a mixture of four quaternary ammonium compounds, 2,470 ppm (10 min); 79% ethanol with 0.1% quaternary ammonium compound (3 min); and 75% ethanol (10 min) [298]. A quaternary ammonium compound exhibited activity against feline calicivirus supensions dried on hard surface carriers in 10 minutes [299]. Seventy percent ethanol and 70% 1-propanol reduced FCV by a 3–4-$\log_{10}$ reduction in 30 seconds [300].

CDC announced that a previously unrecognized human virus from the coronavirus family is the leading hypothesis for the cause of a described syndrome of SARS [301]. Two coronaviruses that are known to infect humans cause one third of common colds and can cause gastroenteritis. The virucidal efficacy of chemical germicides against coronavirus has been investigated. A study of disinfectants against coronavirus 229E found several that were effective after a 1-minute contact time; these included sodium hypochlorite (at a free chlorine concentration of 1,000 ppm and 5,000 ppm), 70% ethyl alcohol, and povidone-iodine (1% iodine) [186]. In another study, 70% ethanol, 50% isopropanol, 0.05% benzalkonium chloride, 50 ppm iodine in iodophor, 0.23% sodium chlorite, 1% cresol soap and 0.7% formaldehyde inactivated >3 logs of two animal coronaviruses (mouse hepatitis virus, canine coronavirus) after a 10-minute exposure time [302]. The activity of povidone-iodine has been demonstrated against human coronaviruses 229E and OC43 [303]. A study also showed complete inactivation of the SARS coronavirus by 70% ethanol and povidone-iodine with an exposure times of 1 minute and 2.5% glutaraldehyde with an exposure time of 5 minute [304]. Because the SARS coronavirus is stable in feces and urine at room temperature for at least 1–2 days [The current version of this document may differ from original: First data on stability and resistance of SARS coronavirus compiled by members of WHO laboratory networkexternal icon], surfaces might be a possible source of contamination and lead to infection with the SARS coronavirus and should be disinfected. Until more precise information is available, environments in which SARS patients are housed should be considered heavily contaminated, and rooms and

equipment should be thoroughly disinfected daily and after the patient is discharged. EPA-registered disinfectants or 1:100 dilution of household bleach and water should be used for surface disinfection and disinfection on noncritical patient-care equipment. High-level disinfection and sterilization of semicritical and critical medical devices, respectively, does not need to be altered for patients with known or suspected SARS.

Free-living amoeba can be pathogenic and can harbor agents of pneumonia such as *Legionella pneumophila*. Limited studies have shown that 2% glutaraldehyde and peracetic acid do not completely inactivate *Acanthamoeba polyphaga* in a 20-minute exposure time for high-level disinfection. If amoeba are found to contaminate instruments and facilitate infection, longer immersion times or other disinfectants may need to be considered [305].

Inactivation of Bioterrorist Agents

Publications have highlighted concerns about the potential for biological terrorism[306, 307]. CDC has categorized several agents as "high priority" because they can be easily disseminated or transmitted from person to person, cause high mortality, and are likely to cause public panic and social disruption [308]. These agents include *Bacillus anthracis* (the cause of anthrax), *Yersinia pestis* (plague), variola major (smallpox), *Clostridium botulinum* toxin (botulism), *Francisella tularensis* (tularemia), filoviruses (Ebola hemorrhagic fever, Marburg hemorrhagic fever); and arenaviruses (Lassa [Lassa fever], Junin [Argentine hemorrhagic fever]), and related viruses[308].

A few comments can be made regarding the role of sterilization and disinfection of potential agents of bioterrorism[309]. First, the susceptibility of these agents to germicides *in vitro* is similar to that of other related pathogens. For example, variola is similar to vaccinia [72, 310, 311] and *B. anthracis* is similar to *B. atrophaeus* (formerly *B. subtilis)*[312, 313]. *B. subtilis* spores, for instance, proved as resistant as, if not more resistant than, *B. anthracis* spores (>6 $\log_{10}$ reduction of *B. anthracis* spores in 5 minutes with acidified bleach [5,250 ppm chlorine])[313]. Thus, one can extrapolate from the larger database available on the susceptibility of genetically similar organisms[314]. Second, many of the potential bioterrorist agents are stable enough in the environment that contaminated environmental surfaces or fomites could lead to transmission of agents such as *B. anthracis*, *F. tularensis*, variola major, *C. botulinum* toxin, and *C. burnetti* [315]. Third, data suggest that current disinfection and sterilization practices are appropriate for managing patient-care equipment and environmental surfaces when potentially contaminated patients are evaluated and/or admitted in a health-care facility after exposure to a bioterrorist agent. For example, sodium hypochlorite can be used for surface disinfection (see [This link is no longer active: http://www.epa.gov/pesticides/factsheets/chemicals/bleachfactsheet.htm.]). In instances where the health-care facility is the site of a bioterrorist attack, environmental decontamination might require special decontamination procedures (e.g., chlorine dioxide gas for *B. anthracis* spores). Because no antimicrobial products are registered for decontamination of biologic agents after a bioterrorist attack, EPA has granted a crises exemption for each product (see [This link is no longer active: http://www.epa.gov/pesticides/factsheets/chemicals/bleachfactsheet.htm.]). Of only theoretical concern is the possibility that a bioterrorist agent could be engineered to be less susceptible to disinfection and sterilization processes [309].

Toxicological, Environmental and Occupational Concerns

Health hazards associated with the use of germicides in healthcare vary from mucous membrane irritation to death, with the latter involving accidental injection by mentally disturbed patients[316]. Although their degrees of toxicity vary [317-320], all disinfectants should be used with the proper safety precautions [321] and only for the intended purpose.

Key factors associated with assessing the health risk of a chemical exposure include the duration, intensity (i.e., how much chemical is involved), and route (e.g., skin, mucous membranes, and inhalation) of exposure. Toxicity can be acute or chronic. Acute toxicity usually results from an accidental spill of a chemical substance. Exposure is sudden and often produces an emergency situation. Chronic toxicity results from repeated exposure to low levels of the chemical over a prolonged period. Employers are responsible for informing workers about the chemical hazards in the workplace and implementing control measures. The OSHA Hazard Communication Standard (29 CFR 1910.1200, 1915.99, 1917.28, 1918.90, 1926.59, and 1928.21) requires manufacturers and importers of hazardous chemicals to develop Material Safety Data Sheets (MSDS) for each chemical or mixture of chemicals. Employers must have these data sheets readily available to employees who work with the products to which they could be exposed.

Exposure limits have been published for many chemicals used in health care to help provide a safe environment and, as relevant, are discussed in each section of this guideline. Only the exposure limits published by OSHA carry the legal force of regulations. OSHA publishes a limit as a time-weighted average (TWA), that is, the average concentration for a normal 8-hour work day and a 40-hour work week to which nearly all workers can be repeatedly exposed to a chemical without adverse health effects. For example, the permissible exposure limit (PEL) for EtO is 1.0 ppm, 8 hour TWA. The CDC National Institute for Occupational Safety and Health (NIOSH) develops recommended exposure limits (RELs). RELs are occupational exposure limits recommended by NIOSH as being protective of worker health and safety over a working lifetime. This limit is frequently expressed as a 40-hour TWA exposure for up to 10 hours per day during a 40-hour work week. These exposure limits are designed

for inhalation exposures. Irritant and allergic effects can occur below the exposure limits, and skin contact can result in dermal effects or systemic absorption without inhalation. The American Conference on Governmental Industrial Hygienists (ACGIN) also provides guidelines on exposure limits [322]. Information about workplace exposures and methods to reduce them (e.g., work practices, engineering controls, PPE) is available on the OSHA and NIOSH websites.

Some states have excluded or limited concentrations of certain chemical germicides (e.g., glutaraldehyde, formaldehyde, and some phenols) from disposal through the sewer system. These rules are intended to minimize environmental harm. If health-care facilities exceed the maximum allowable concentration of a chemical (e.g., ≥5.0 mg/L), they have three options. First, they can switch to alternative products; for example, they can change from glutaraldehyde to another disinfectant for high-level disinfection or from phenolics to quaternary ammonium compounds for low-level disinfection. Second, the health-care facility can collect the disinfectant and dispose of it as a hazardous chemical. Third, the facility can use a commercially available small-scale treatment method (e.g., neutralize glutaraldehyde with glycine).

Safe disposal of regulated chemicals is important throughout the medical community. For disposal of large volumes of spent solutions, users might decide to neutralize the microbicidal activity before disposal (e.g., glutaraldehyde). Solutions can be neutralized by reaction with chemicals such as sodium bisulfite [323, 324] or glycine [325].

European authors have suggested that instruments and ventilation therapy equipment should be disinfected by heat rather than by chemicals. The concerns for chemical disinfection include toxic side effects for the patient caused by chemical residues on the instrument or object, occupational exposure to toxic chemicals, and recontamination by rinsing the disinfectant with microbially contaminated tap water [326].

Disinfection in Ambulatory Care, Home Care, and the Home

With the advent of managed healthcare, increasing numbers of patients are now being cared for in ambulatory-care and home settings. Many patients in these settings might have communicable diseases, immunocompromising conditions, or invasive devices. Therefore, adequate disinfection in these settings is necessary to provide a safe patient environment. Because the ambulatory-care setting (i.e., outpatient facility) provides the same risk for infection as the hospital, the Spaulding classification scheme described in this guideline should be followed (Table 1). [17]

The home environment should be much safer than hospitals or ambulatory care. Epidemics should not be a problem, and cross-infection should be rare. The healthcare provider is responsible for providing the responsible family member information about infection-control procedures to follow in the home, including hand hygiene, proper cleaning and disinfection of equipment, and safe storage of cleaned and disinfected devices. Among the products recommended for home disinfection of reusable objects are bleach, alcohol, and hydrogen peroxide. APIC recommends that reusable objects (e.g., tracheostomy tubes) that touch mucous membranes be disinfected by immersion in 70% isopropyl alcohol for 5 minutes or in 3% hydrogen peroxide for 30 minutes. Additionally, a 1:50 dilution of 5.25%–6.15% sodium hypochlorite (household bleach) for 5 minutes should be effective [327-329]. Noncritical items (e.g., blood pressure cuffs, crutches) can be cleaned with a detergent. Blood spills should be handled according to OSHA regulations as previously described (see section on OSHA Bloodborne Pathogen Standard). In general, sterilization of critical items is not practical in homes but theoretically could be accomplished by chemical sterilants or boiling. Single-use disposable items can be used or reusable items sterilized in a hospital [330, 331].

Some environmental groups advocate "environmentally safe" products as alternatives to commercial germicides in the home-care setting. These alternatives (e.g., ammonia, baking soda, vinegar, Borax, liquid detergent) are not registered with EPA and should not be used for disinfecting because they are ineffective against *S. aureus*. Borax, baking soda, and detergents also are ineffective against *Salmonella* Typhi and *E.coli*; however, undiluted vinegar and ammonia are effective against *S.* Typhi and *E.coli* [53, 332, 333]. Common commercial disinfectants designed for home use also are effective against selected antibiotic-resistant bacteria [53].

Public concerns have been raised that the use of antimicrobials in the home can promote development of antibiotic-resistant bacteria [334, 335]. This issue is unresolved and needs to be considered further through scientific and clinical investigations. The public health benefits of using disinfectants in the home are unknown. However, some facts are known: many sites in the home kitchen and bathroom are microbially contaminated [336], use of hypochlorites markedly reduces bacteria [337], and good standards of hygiene (e.g., food hygiene, hand hygiene) can help reduce infections in the home [338, 339]. In addition, laboratory studies indicate that many commercially prepared household disinfectants are effective against common pathogens [53] and can interrupt surface-to-human transmission of pathogens [48]. The "targeted hygiene concept"—which means identifying situations and areas (e.g., food-preparation surfaces and bathroom) where risk exists for transmission of pathogens—may be a reasonable way to identify when disinfection might be appropriate [340].

Susceptibility of Antibiotic-Resistant Bacteria to Disinfectants

As with antibiotics, reduced susceptibility (or acquired "resistance") of bacteria to disinfectants can arise by either chromosomal gene mutation or acquisition of genetic material in the form of plasmids or transposons [338, 341-343, 344 , 345, 346]. When changes occur in bacterial susceptibility that renders an antibiotic ineffective against an infection previously treatable by that antibiotic, the bacteria are referred to as "resistant." In contrast, reduced susceptibility to disinfectants does not correlate with failure of the disinfectant because concentrations used in disinfection still greatly exceed the cidal level. Thus, the word "resistance" when applied to these changes is incorrect, and the preferred term is "reduced susceptibility" or "increased tolerance"[344, 347]. No data are available that show that antibiotic-resistant bacteria are less sensitive to the liquid chemical germicides than antibiotic-sensitive bacteria at currently used germicide contact conditions and concentrations.

MRSA and vancomycin-resistant *Enterococcus* (VRE) are important health-care–associated agents. Some antiseptics and disinfectants have been known for years to be, because of MICs, somewhat less inhibitory to *S. aureus* strains that contain a plasmid-carrying gene encoding resistance to the antibiotic gentamicin [344]. For example, gentamicin resistance has been shown to also encode reduced susceptibility to propamidine, quaternary ammonium compounds, and ethidium bromide [348], and MRSA strains have been found to be less susceptible than methicillin-sensitive *S. aureus* (MSSA) strains to chlorhexidine, propamidine, and the quaternary ammonium compound cetrimide [349]. In other studies, MRSA and MSSA strains have been equally sensitive to phenols and chlorhexidine, but MRSA strains were slightly more tolerant to quaternary ammonium compounds [350]. Two gene families (*qac*CD [now referred to as *smr*] and *qac*AB) are involved in providing protection against agents that are components of disinfectant formulations such as quaternary ammonium compounds. Staphylococci have been proposed to evade destruction because the protein specified by the *qac*A determinant is a cytoplasmic-membrane–associated protein involved in an efflux system that actively reduces intracellular accumulation of toxicants, such as quaternary ammonium compounds, to intracellular targets. [351]

Other studies demonstrated that plasmid-mediated formaldehyde tolerance is transferable from *Serratia marcescens* to *E. coli* [352] and plasmid-mediated quaternary ammonium tolerance is transferable from *S. aureus* to *E. coli*.[353]. Tolerance to mercury and silver also is plasmid borne. [341, 343-346]

Because the concentrations of disinfectants used in practice are much higher than the MICs observed, even for the more tolerant strains, the clinical relevance of these observations is questionable. Several studies have found antibiotic-resistant hospital strains of common healthcare-associated pathogens (i.e., *Enterococcus, P. aeruginosa, Klebsiella pneumoniae, E. coli*, *S. aureus,* and *S. epidermidis*) to be equally susceptible to disinfectants as antibiotic-sensitive strains [53, 354-356]. The susceptibility of glycopeptide-intermediate *S. aureus* was similar to vancomycin-susceptible, MRSA [357]. On the basis of these data, routine disinfection and housekeeping protocols do not need to be altered because of antibiotic resistance provided the disinfection method is effective [358, 359]. A study that evaluated the efficacy of selected cleaning methods (e.g., QUAT-sprayed cloth, and QUAT-immersed cloth) for eliminating VRE found that currently used disinfection processes most likely are highly effective in eliminating VRE. However, surface disinfection must involve contact with all contaminated surfaces [358]. A new method using an invisible flurorescent marker to objectively evaluate the thoroughness of cleaning activities in patient rooms might lead to improvement in cleaning of all objects and surfaces but needs further evaluation. **[360]**

Lastly, does the use of antiseptics or disinfectants facilitate the development of disinfectant-tolerant organisms? Evidence and reviews indicate enhanced tolerance to disinfectants can be developed in response to disinfectant exposure [334, 335, 346, 347, 361]. However, the level of tolerance is not important in clinical terms because it is low and unlikely to compromise the effectiveness of disinfectants of which much higher concentrations are used [347, 362].

The issue of whether low-level tolerance to germicides selects for antibiotic-resistant strains is unsettled but might depend on the mechanism by which tolerance is attained. For example, changes in the permeability barrier or efflux mechanisms might affect susceptibility to both antibiotics and germicides, but specific changes to a target site might not. Some researchers have suggested that use of disinfectants or antiseptics (e.g., triclosan) could facilitate development of antibiotic-resistant microorganisms [334, 335, 363]. Although evidence in laboratory studies indicates low-level resistance to triclosan, the concentrations of triclosan in these studies were low (generally <1 µg/mL) and dissimilar from the higher levels used in antimicrobial products (2,000–20,000 µg/mL) [364, 365]. Thus, researchers can create laboratory-derived mutants that demonstrate reduced susceptibility to antiseptics or disinfectants. In some experiments, such bacteria have demonstrated reduced susceptibility to certain antibiotics [335]. There is no evidence that using antiseptics or disinfectants selects for antibiotic-resistant organisms in nature or that such mutants survive in nature[366].). In addition, the action of antibiotics and the action of disinfectants differ fundamentally. Antibiotics are selectively toxic and generally have a single target site in bacteria, thereby inhibiting a specific biosynthetic process. Germicides generally are considered nonspecific antimicrobials because of a multiplicity of toxic-effect mechanisms or target sites and are broader spectrum in the types of microorganisms against which they are effective [344, 347].

The rotational use of disinfectants in some environments (e.g., pharmacy production units) has been recommended and practiced in an attempt to prevent development of resistant microbes [367, 368]. There have been only rare case reports that appropriately used disinfectants have resulted in a clinical problem arising from the selection or development of nonsusceptible microorganisms [369].

Surface and Air Disinfection

Surface Disinfection

The effective use of disinfectants is part of a multibarrier strategy to prevent health-care–associated infections. Surfaces are considered noncritical items because they contact intact skin. Use of noncritical items or contact with noncritical surfaces carries little risk of causing an infection in patients or staff. Thus, the routine use of germicidal chemicals to disinfect hospital floors and other noncritical items is controversial [370-375]. A 1991 study expanded the Spaulding scheme by dividing the noncritical environmental surfaces into housekeeping surfaces and medical equipment surfaces [376]. The classes of disinfectants used on housekeeping and medical equipment surfaces can be similar. However, the frequency of decontaminating can vary (see Recommendations). Medical equipment surfaces (e.g., blood pressure cuffs, stethoscopes, hemodialysis machines, and X-ray machines) can become contaminated with infectious agents and contribute to the spread of health-care–associated infections [248, 375]. For this reason, noncritical medical equipment surfaces should be disinfected with an EPA-registered low- or intermediate-level disinfectant. Use of a disinfectant will provide antimicrobial activity that is likely to be achieved with minimal additional cost or work.

Environmental surfaces (e.g., bedside table) also could potentially contribute to cross-transmission by contamination of health-care personnel from hand contact with contaminated surfaces, medical equipment, or patients [50, 375, 377]. A paper reviews the epidemiologic and microbiologic data (Table 3) regarding the use of disinfectants on noncritical surfaces [378].

Of the seven reasons to usie a disinfectant on noncritical surfaces, five are particularly noteworthy and support the use of a germicidal detergent. First, hospital floors become contaminated with microorganisms from settling airborne bacteria: by contact with shoes, wheels, and other objects; and occasionally by spills. The removal of microbes is a component in controling health-care–associated infections. In an investigation of the cleaning of hospital floors, the use of soap and water (80% reduction) was less effective in reducing the numbers of bacteria than was a phenolic disinfectant (94%–99.9% reduction) [379]. However, a few hours after floor disinfection, the bacterial count was nearly back to the pretreatment level. Second, detergents become contaminated and result in seeding the patient's environment with bacteria. Investigators have shown that mop water becomes increasingly dirty during cleaning and becomes contaminated if soap and water is used rather than a disinfectant. For example, in one study, bacterial contamination in soap and water without a disinfectant increased from 10 CFU/mL to 34,000 CFU/mL after cleaning a ward, whereas contamination in a disinfectant solution did not change (20 CFU/mL) [380]. Contamination of surfaces close to the patient that are frequently touched by the patient or staff (e.g., bed rails) could result in patient exposures0 [381]. In a study, using of detergents on floors and patient room furniture, increased bacterial contamination of the patients' environmental surfaces was found after cleaning (average increase = 103.6 CFU/24cm^2) [382]. In addition, a *P. aeruginosa* outbreak was reported in a hematology-oncology unit associated with contamination of the surface cleaning equipment when nongermicidal cleaning solutions instead of disinfectants were used to decontaminate the patients' environment [383] and another study demonstrated the role of environmental cleaning in controlling an outbreak of *Acinetobacter baumannii* [384]. Studies also have shown that, in situations where the cleaning procedure failed to eliminate contamination from the surface and the cloth is used to wipe another surface, the contamination is transferred to that surface and the hands of the person holding the cloth[381, 385]. Third, the CDC Isolation Guideline recommends that noncritical equipment contaminated with blood, body fluids, secretions, or excretions be cleaned and disinfected after use. The same guideline recommends that, in addition to cleaning, disinfection of the bedside equipment and environmental surfaces (e.g., bedrails, bedside tables, carts, commodes, door-knobs, and faucet handles) is indicated for certain pathogens, e.g., enterococci, which can survive in the inanimate environment for prolonged periods [386]. Fourth, OSHA requires that surfaces contaminated with blood and other potentially infectious materials (e.g., amniotic, pleural fluid) be disinfected. Fifth, using a single product throughout the facility can simplify both training and appropriate practice.

Reasons also exist for using a detergent alone on floors because noncritical surfaces contribute minimally to endemic health-care–associated infections [387], and no differences have been found in healthcare–associated infections rates when floors are cleaned with detergent rather than disinfectant [382, 388, 389]. However, these studies have been small and of short duration and suffer from low statistical power because the outcome—healthcare–associated infections—is of low frequency. The low rate of infections makes the efficacy of an intervention statistically difficult to demonstrate. Because housekeeping surfaces are associated with the lowest risk for disease transmission, some researchers have suggested that either detergents or a disinfectant/detergent could be used [376]. No data exist that show reduced healthcare–associated infection rates with use of surface disinfection of floors, but some data demonstrate reduced microbial load associated with the use of disinfectants. Given this information; other information showing that environmental surfaces (e.g., bedside table, bed rails) close to the patient and in outpatient settings [390] can be contaminated with epidemiologically important microbes (such as VRE and MRSA)[47, 390-394]; and data showing these organisms survive on various hospital surfaces [395, 396]; some researchers have suggested that such surfaces should be disinfected on a regular schedule [378]. Spot decontamination on fabrics that remain in hospitals or clinic rooms while patients move in and out (e.g., privacy curtains) also should be considered. One study demonstrated the effectiveness of spraying the fabric with 3% hydrogen peroxide [397]. Future studies should evaluate the level of contamination on noncritical environmental surfaces as a function of high and low hand contact and whether some surfaces (e.g., bed rails) near the patient with high contact frequencies require more frequent disinfection. Regardless of whether a detergent or disinfectant is used on surfaces in a health-care facility, surfaces should be cleaned routinely and when dirty or soiled to provide an aesthetically pleasing environment and to prevent potentially contaminated objects from serving as a source for health-care–associated infections. [398] The

value of designing surfaces (e.g. hexyl-polyvinylpyridine) that kill bacteria on contact [399] or have sustained antimicrobial activity [400] should be further evaluated.

Several investigators have recognized heavy microbial contamination of wet mops and cleaning cloths and the potential for spread of such contamination [68, 401]. They have shown that wiping hard surfaces with contaminated cloths can contaminate hands, equipment, and other surfaces [68, 402]. Data have been published that can be used to formulate effective policies for decontamination and maintenance of reusable cleaning cloths. For example, heat was the most reliable treatment of cleaning cloths as a detergent washing followed by drying at 80°C for 2 hours produced elimination of contamination. However, the dry heating process might be a fire hazard if the mop head contains petroleum-based products or lint builds up within the equipment or vent hose (American Health Care Association, personal communication, March 2003). Alternatively, immersing the cloth in hypochlorite (4,000 ppm) for 2 minutes produced no detectable surviving organisms in 10 of 13 cloths [403]. If reusable cleaning cloths or mops are used, they should be decontaminated regularly to prevent surface contamination during cleaning with subsequent transfer of organisms from these surfaces to patients or equipment by the hands of health-care workers. Some hospitals have begun using a new mopping technique involving microfiber materials to clean floors. Microfibers are densely constructed, polyester and polyamide (nylon) fibers, that are approximately 1/16 the thickness of a human hair. The positively charged microfibers attract dust (which has a negative charge) and are more absorbent than a conventional, cotton-loop mop. Microfiber materials also can be wet with disinfectants, such as quaternary ammonium compounds. In one study, the microfiber system tested demonstrated superior microbial removal compared with conventional string mops when used with a detergent cleaner (94% vs 68%). The use of a disinfectant did not improve the microbial elimination demonstrated by the microfiber system (95% vs 94%). However, use of disinfectant significantly improved microbial removal when a conventional string mop was used (95% vs 68%) (WA Rutala, unpublished data, August 2006). The microfiber system also prevents the possibility of transferring microbes from room to room because a new microfiber pad is used in each room.

An important issue concerning use of disinfectants for noncritical surfaces in health-care settings is that the contact time specified on the label of the product is often too long to be practically followed. The labels of most products registered by EPA for use against HBV, HIV, or *M. tuberculosis* specify a contact time of 10 minutes. Such a long contact time is not practical for disinfection of environmental surfaces in a health-care setting because most health-care facilities apply a disinfectant and allow it to dry (~1 minute). Multiple scientific papers have demonstrated significant microbial reduction with contact times of 30 to 60 seconds[46-56, 58-64]. In addition, EPA will approve a shortened contact time for any product for which the manufacturers will submit confirmatory efficacy data.

Currently, some EPA-registered disinfectants have contact times of one to three minutes. By law, users must follow all applicable label instructions for EPA-registered products. Ideally, product users should consider and use products that have the shortened contact time. However, disinfectant manufacturers also need to obtain EPA approval for shortened contact times so these products will be used correctly and effectively in the health-care environment.

Air Disinfection

Disinfectant spray-fog techniques for antimicrobial control in hospital rooms has been used. This technique of spraying of disinfectants is an unsatisfactory method of decontaminating air and surfaces and is not recommended for general infection control in routine patient-care areas[386]. Disinfectant fogging is rarely, if ever, used in U.S. healthcare facilities for air and surface disinfection in patient-care areas. Methods (e.g., filtration, ultraviolet germicidal irradiation, chlorine dioxide) to reduce air contamination in the healthcare setting are discussed in another guideline [23].

Microbial Contamination of Disinfectants

Contaminated disinfectants and antiseptics have been occasional vehicles of health-care infections and pseudoepidemics for more than 50 years. Published reports describing contaminated disinfectants and antiseptic solutions leading to health-care-associated infections have been summarized [404]. Since this summary additional reports have been published [405-408]. An examination of reports of disinfectants contaminated with microorganisms revealed noteworthy observations. Perhaps most importantly, high-level disinfectants/liquid chemical sterilants have not been associated with outbreaks due to intrinsic or extrinsic contamination.Members of the genus *Pseudomonas* (e.g., *P. aeruginosa*) are the most frequent isolates from contaminated disinfectants—recovered from 80% of contaminated products. Their ability to remain viable or grow in use-dilutions of disinfectants is unparalleled. This survival advantage for *Pseudomonas* results presumably from their nutritional versatility, their unique outer membrane that constitutes an effective barrier to the passage of germicides, and/or efflux systems [409]. Although the concentrated solutions of the disinfectants have not been demonstrated to be contaminated at the point of manufacture, an undiluted phenolic can be contaminated by a *Pseudomonas* sp. during use [410]. In most of the reports that describe illness associated with contaminated disinfectants, the product was used to disinfect patient-care equipment, such as cystoscopes, cardiac catheters, and thermometers. Germicides used as disinfectants that were reported to have been contaminated include chlorhexidine, quaternary ammonium compounds, phenolics, and pine oil.

The following control measures should be instituted to reduce the frequency of bacterial growth in disinfectants and the threat of serious healthcare–associated infections from the use of such contaminated products [404]. First, some disinfectants should not be diluted; those that are diluted must be prepared correctly to achieve the manufacturers' recommended use-dilution. Second, infection-control professionals must learn from the literature what inappropriate activities result in extrinsic contamination (i.e., at the point of use) of germicides and train users to prevent recurrence. Common sources of extrinsic contamination of germicides in the reviewed literature are the water to make working dilutions, contaminated containers, and general contamination of the hospital areas where the germicides are prepared and/or used. Third, stock solutions of germicides must be stored as indicated on the product label. EPA verifies manufacturers' efficacy claims against microorganisms. These measures should provide assurance that products meeting the EPA registration requirements can achieve a certain level of antimicrobial activity when used as directed.

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