Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008 (Centers for Disease Control)

(Excerpted by Chris Brand, FODAC, for application to most DME/AT ReUse centers. Complete CDC guide is available in the Knowledge Base.)

Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, EtO gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities. Sterilization is intended to convey an absolute meaning; unfortunately, however, some health professionals and the technical and commercial literature refer to “disinfection” as “sterilization” and items as “partially sterile.” When chemicals are used to destroy all forms of microbiologic life, they can be called chemical sterilants. These same germicides used for shorter exposure periods also can be part of the disinfection process (i.e., high-level disinfection).

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects (see Tables 1 and 2 in complete CDC Guide). In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of disinfection can nullify or limit the efficacy of the process. Terms with the suffix -cide or -cidal for killing action also are commonly used. For example, a germicide is an agent that can kill microorganisms, particularly pathogenic organisms (“germs”). The term germicide includes both antiseptics and disinfectants. Antiseptics are germicides applied to living tissue and skin; disinfectants are antimicrobials applied only to inanimate objects. In general, antiseptics are used only on the skin and not for surface disinfection, and disinfectants are not used for skin antisepsis because they can injure skin and other tissues.

Factors that affect the efficacy of both disinfection and sterilization include prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; physical nature of the object (e.g., crevices, hinges, and lumens); presence of biofilms; temperature and pH of the disinfection process;

Cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the
surfaces of instruments interfere with the effectiveness of these processes. Decontamination removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

More than 30 years ago, Earle H. Spaulding devised a rational approach to disinfection and sterilization of patient-care items and equipment. This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization. Spaulding believed the nature of disinfection could be understood readily if instruments and items for patient care were categorized as critical, semicritical, and noncritical according to the degree of risk for infection involved in use of the items.

Noncritical Items

Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical." In this guideline, noncritical items are divided into noncritical patient care items and noncritical environmental surfaces. Examples of noncritical patient-care items are bedpans, blood pressure cuffs, crutches and computers. In contrast to critical and some semicritical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. Virtually no risk has been documented for transmission of infectious agents to patients through noncritical items when they are used as noncritical items and do not contact non-intact skin and/or mucous membranes. Table 1 lists several low-level disinfectants that may be used for noncritical items.

Most Environmental Protection Agency (EPA)-registered disinfectants have a 10-minute label claim. However, multiple investigators have demonstrated the effectiveness of these disinfectants against vegetative bacteria (e.g., *Listeria, Escherichia coli, Salmonella*, vancomycin-resistant *Enterococci*, methicillin-resistant *Staphylococcus aureus*), yeasts (e.g., *Candida*), mycobacteria (e.g., *Mycobacterium tuberculosis*), and viruses (e.g., *poliovirus*) at exposure times of 30–60 seconds. Federal law requires all applicable label instructions on EPA-registered products to be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use, and disposal). If the user selects exposure conditions (e.g., exposure time) that differ from those on the EPA-registered products label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
Noncritical environmental surfaces include bed rails, some food utensils, bedside tables, patient furniture and floors. Noncritical environmental surfaces frequently touched by hand (e.g., bedside tables, bed rails) potentially could contribute to secondary transmission by contaminating hands of health-care workers or by contacting medical equipment that subsequently contacts patients. Mops and reusable cleaning cloths are regularly used to achieve low-level disinfection on environmental surfaces. However, they often are not adequately cleaned and disinfected, and if the water-disinfectant mixture is not changed regularly (e.g., after every three to four rooms, at no longer than 60-minute intervals), the mopping procedure actually can spread heavy microbial contamination throughout the health-care facility. In one study, standard laundering provided acceptable decontamination of heavily contaminated mop heads but chemical disinfection with a phenolic was less effective. Frequent laundering of mops (e.g., daily), therefore, is recommended. Single-use disposable towels impregnated with a disinfectant also can be used for low-level disinfection when spot-cleaning of noncritical surfaces is needed.

**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).

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. 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).

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*. Common commercial disinfectants designed for home use also are effective against selected antibiotic-resistant bacteria.

Public concerns have been raised that the use of antimicrobials in the home can promote development of antibiotic-resistant bacteria. 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, use of hypochlorites markedly reduces bacteria, and good standards of hygiene (e.g., food hygiene, hand hygiene) can help reduce infections in the home. In addition, laboratory studies indicate that many commercially prepared household disinfectants are effective against common pathogens and can interrupt surface-to-human transmission of pathogens. 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.

**Surface Disinfection - Is Surface Disinfection Necessary?**

The effective use of disinfectants is part of a multi-barrier strategy to prevent healthcare–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. A 1991 study expanded the Spaulding scheme by dividing the noncritical environmental surfaces into housekeeping surfaces and medical equipment surfaces. 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 healthcare–associated infections. 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 tables) also could potentially contribute to cross-transmission by contamination of healthcare personnel from hand contact with contaminated surfaces, medical equipment, or patients. A paper reviews the epidemiologic and microbiologic data (see Table 3 in complete CDC Guide) regarding the use of disinfectants on noncritical surfaces.
Of the seven reasons to use 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 controlling 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). However, a few hours after floor disinfection, the bacterial count was nearly back to the pretreatment level.

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. OSHA requires that surfaces contaminated with blood and other potentially infectious materials (e.g., amniotic, pleural fluid) be disinfected. Using a single product throughout the facility can simplify both training and appropriate practice.

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 can be contaminated with epidemiologically important microbes (such as VRE and MRSA); and data showing these organisms survive on various hospital surfaces; some researchers have suggested that such surfaces should be disinfected on a regular schedule. 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. 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.

**Contact Times for Surface Disinfectants**
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. 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.

Chlorine and Chlorine Compounds Overview

Hypochlorites, the most widely used of the chlorine disinfectants, are available as liquid (e.g., sodium hypochlorite) or solid (e.g., calcium hypochlorite). The most prevalent chlorine products in the United States are aqueous solutions of 5.25%–6.15% sodium hypochlorite, usually called household bleach. They have a broad spectrum of antimicrobial activity, do not leave toxic residues, are unaffected by water hardness, are inexpensive and fast acting, remove dried or fixed organisms and biofilms from surfaces, and have a low incidence of serious toxicity. Sodium hypochlorite at the concentration used in household bleach (5.25-6.15%) can produce ocular irritation or oropharyngeal, esophageal, and gastric burns. Other disadvantages of hypochlorites include corrosiveness to metals in high concentrations (>500 ppm), inactivation by organic matter, discoloring or “bleaching” of fabrics, release of toxic chlorine gas when mixed with ammonia or acid (e.g., household cleaning agents), and relative stability.

The microbicidal activity of chlorine is attributed largely to undissociated hypochlorous acid (HOCl). The dissociation of HOCl to the less microbicidal form (hypochlorite ion OCl-) depends on pH. The disinfecting efficacy of chlorine decreases with an increase in pH that parallels the conversion of undissociated HOCl to OCl-. A potential hazard is production of the carcinogen bis(chloromethyl) ether when hypochlorite solutions contact formaldehyde and the production of the animal carcinogen trihalomethane when hot water is hyperchlorinated. After reviewing environmental fate and ecologic data, EPA has determined the currently registered uses of hypochlorites will not result in unreasonable adverse effects to the environment.
Microbicidal Activity. Low concentrations of free available chlorine (e.g., HOCl, OCl-, and elemental chlorine-Cl2) have a biocidal effect on mycoplasma (25 ppm) and vegetative bacteria (<5 ppm) in seconds in the absence of an organic load. Higher concentrations (1,000 ppm) of chlorine are required to kill M. tuberculosis using the Association of Official Analytical Chemists (AOAC) tuberculocidal test. A concentration of 100 ppm will kill >99.9% of B. atrophaeus spores within 5 minutes and destroy mycotic agents in <1 hour 329. Acidified bleach and regular bleach (5,000 ppm chlorine) can inactivate Clostridium difficile spores in <10 minutes. One study reported that 25 different viruses were inactivated in 10 minutes with 200 ppm available chlorine. Several studies have demonstrated the effectiveness of diluted sodium hypochlorite and other disinfectants to inactivate HIV. Chlorine (500 ppm) showed inhibition of Candida after 30 seconds of exposure. In experiments using the AOAC Use-Dilution Method, 100 ppm of free chlorine killed 106–107 S. aureus, Salmonella choleraesuis, and P. aeruginosa in <10 minutes. Because household bleach contains 5.25%–6.15% sodium hypochlorite, or 52,500–61,500 ppm available chlorine, a 1:1,000 dilution provides about 53–62 ppm available chlorine, and a 1:10 dilution of household bleach provides about 5250–6150 ppm.

Uses. Hypochlorites are widely used in healthcare facilities in a variety of settings. Inorganic chlorine solution is used for disinfecting tonometer heads and for spot-disinfection of countertops and floors. A 1:10–1:100 dilution of 5.25%–6.15% sodium hypochlorite (i.e., household bleach) or an EPA-registered tuberculocidal disinfectant has been recommended for decontaminating blood spills. For small spills of blood (i.e., drops of blood) on noncritical surfaces, the area can be disinfected with a 1:100 dilution of 5.25%-6.15% sodium hypochlorite or an EPA-registered tuberculocidal disinfectant. Because hypochlorites and other germicides are substantially inactivated in the presence of blood, large spills of blood require that the surface be cleaned before an EPA-registered disinfectant or a 1:10 (final concentration) solution of household bleach is applied. If a sharps injury is possible, the surface initially should be decontaminated, then cleaned and disinfected (1:10 final concentration).

Steam Sterilization Overview

Of all the methods available for sterilization, moist heat in the form of saturated steam under pressure is the most widely used and the most dependable. Steam sterilization is nontoxic, inexpensive, rapidly microbicidal, sporicidal, and rapidly heats and penetrates fabrics.

Like all sterilization processes, steam sterilization has some deleterious effects on some materials, including corrosion and combustion of lubricants associated with dental handpieces; reduction in ability to transmit light associated with laryngoscopes; and increased hardening time (5.6 fold) with plaster-cast. The basic principle of steam
sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time. Thus, there are four parameters of steam sterilization: steam, pressure, temperature, and time. The ideal steam for sterilization is dry saturated steam and entrained water (dryness fraction >97%). Pressure serves as a means to obtain the high temperatures necessary to quickly kill microorganisms. Specific temperatures must be obtained to ensure the microbicidal activity. The two common steam-sterilizing temperatures are 121°C (250°F) and 132°C (270°F). These temperatures (and other high temperatures) must be maintained for a minimal time to kill microorganisms. Recognized minimum exposure periods for sterilization of wrapped healthcare supplies are 30 minutes at 121°C (250°F) in a gravity displacement sterilizer or 4 minutes at 132°C (270°C) in a prevacuum sterilizer. At constant temperatures, sterilization times vary depending on the type of item (e.g., metal versus rubber, plastic, items with lumens), whether the item is wrapped or unwrapped, and the sterilizer type.

Portable (table-top) steam sterilizers are used in outpatient, dental, and rural clinics. These sterilizers are designed for small instruments, such as hypodermic syringes and needles and dental instruments. The ability of the sterilizer to reach physical parameters necessary to achieve sterilization should be monitored by mechanical, chemical, and biological indicators.

Microbicidal Activity. The oldest and most recognized agent for inactivation of microorganisms is heat. D-values (time to reduce the surviving population by 90% or 1 log10) allow a direct comparison of the heat resistance of microorganisms. Because a D-value can be determined at various temperatures, a subscript is used to designate the exposure temperature (i.e., D121°C). D121C-values for Geobacillus stearothermophilus used to monitor the steam sterilization process range from 1 to 2 minutes. Heat-resistant nonspore-forming bacteria, yeasts, and fungi have such low D121C values that they cannot be experimentally measured.

Mode of Action. Moist heat destroys microorganisms by the irreversible coagulation and denaturation of enzymes and structural proteins. In support of this fact, it has been found that the presence of moisture significantly affects the coagulation temperature of proteins and the temperature at which microorganisms are destroyed.

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