

## EXECUTIVE SUMMARY

The Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, presents evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of patient-care medical devices and for cleaning and disinfecting the healthcare environment. This document supercedes the relevant sections contained in the 1985 Centers for Disease Control (CDC) Guideline for Handwashing and Environmental Control.<sup>1</sup> Because maximum effectiveness from disinfection and sterilization results from first cleaning and removing organic and inorganic materials, this document also reviews cleaning methods. The chemical disinfectants discussed for patient-care equipment include alcohols, glutaraldehyde, formaldehyde, hydrogen peroxide, iodophors, *ortho*-phthalaldehyde, peracetic acid, phenolics, quaternary ammonium compounds, and chlorine. The choice of disinfectant, concentration, and exposure time is based on the risk for infection associated with use of the equipment and other factors discussed in this guideline. The sterilization methods discussed include steam sterilization, ethylene oxide (ETO), hydrogen peroxide gas plasma, and liquid peracetic acid. When properly used, these cleaning, disinfection, and sterilization processes can reduce the risk for infection associated with use of invasive and noninvasive medical and surgical devices. However, for these processes to be effective, health-care workers should adhere strictly to the cleaning, disinfection, and sterilization recommendations in this document and to instructions on product labels.

In addition to updated recommendations, new topics addressed in this guideline include 1) inactivation of antibiotic-resistant bacteria, bioterrorist agents, emerging pathogens, and bloodborne pathogens; 2) toxicologic, environmental, and occupational concerns associated with disinfection and sterilization practices; 3) disinfection of patient-care equipment used in ambulatory settings and home care; 4) new sterilization processes, such as hydrogen peroxide gas plasma and liquid peracetic acid; and 5) disinfection of complex medical instruments (e.g., endoscopes).

## INTRODUCTION

In the United States, approximately 46.5 million surgical procedures and even more invasive medical procedures—including approximately 5 million gastrointestinal endoscopies—are performed each year.<sup>2</sup> Each procedure involves contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogens that can lead to infection. Failure to properly disinfect or sterilize equipment carries not only risk associated with breach of host barriers but also risk for person-to-person transmission (e.g., hepatitis B virus) and transmission of environmental pathogens (e.g., *Pseudomonas aeruginosa*).

Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because sterilization of all patient-care items is not necessary, health-care policies must identify, primarily on the basis of the items' intended use, whether cleaning, disinfection, or sterilization is indicated.

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization.<sup>3-6</sup> Failure to comply with scientifically-based guidelines has led to numerous outbreaks.<sup>6-12</sup> This guideline presents a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes; the approach is based on well-designed studies assessing the efficacy (through laboratory investigations) and effectiveness (through clinical studies) of disinfection and sterilization procedures.

## METHODS

This guideline resulted from a review of all MEDLINE articles in English listed under the MeSH headings of *disinfection* or *sterilization* (focusing on health-care equipment and supplies) from January 1980 through August 2006. References listed in these articles also were reviewed. Selected articles published before 1980 were reviewed and, if still relevant, included in the guideline. The three major peer-reviewed journals in infection control—*American Journal of Infection Control*, *Infection Control and Hospital Epidemiology*, and *Journal of Hospital Infection*—were searched for relevant articles published from January 1990 through August 2006. Abstracts presented at the annual meetings of the Society for Healthcare Epidemiology of America and Association for professionals in Infection Control and Epidemiology, Inc. during 1997–2006 also were reviewed; however, abstracts were not used to support the recommendations.

## DEFINITION OF TERMS

*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 (Tables 1 and 2). 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.

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; and in some cases, relative humidity of the sterilization process (e.g., ethylene oxide).

Unlike sterilization, disinfection is not sporicidal. A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called *chemical sterilants*. At similar concentrations but with shorter exposure periods (e.g., 20 minutes for 2% glutaraldehyde), these same disinfectants will kill all microorganisms except large numbers of bacterial spores; they are called *high-level disinfectants*. *Low-level disinfectants* can kill most vegetative bacteria, some fungi, and some viruses in a practical period of time ( $\leq 10$  minutes). *Intermediate-level disinfectants* might be cidal for mycobacteria, vegetative bacteria, most viruses, and most fungi but do not necessarily kill bacterial spores. Germicides differ markedly, primarily in their antimicrobial spectrum and rapidity of action.

*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.

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 antiseptics because they can injure skin and other tissues. Virucide, fungicide, bactericide, sporicide, and tuberculocide can kill the type of microorganism identified by the prefix. For example, a bactericide is an agent that kills bacteria.<sup>13-18</sup>