

## 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.<sup>14</sup> 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.<sup>1, 13, 15, 17, 19, 20</sup> 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. The CDC *Guideline for Handwashing and Hospital Environmental Control*<sup>21</sup>, *Guidelines for the Prevention of Transmission of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) to Health-Care and Public-Safety Workers*<sup>22</sup>, and *Guideline for Environmental Infection Control in Health-Care Facilities*<sup>23</sup> employ this terminology.

### Critical Items

Critical items confer a high risk for infection if they are contaminated with any microorganism. Thus, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. Most of the items in this category should be purchased as sterile or be sterilized with steam if possible. Heat-sensitive objects can be treated with EtO, hydrogen peroxide gas plasma; or if other methods are unsuitable, by liquid chemical sterilants. Germicides categorized as chemical sterilants include  $\geq 2.4\%$  glutaraldehyde-based formulations, 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.5% stabilized hydrogen peroxide, 7.35% hydrogen peroxide with 0.23% peracetic acid, 0.2% peracetic acid, and 0.08% peracetic acid with 1.0% hydrogen peroxide. Liquid chemical sterilants reliably produce sterility only if cleaning precedes treatment and if proper guidelines are followed regarding concentration, contact time, temperature, and pH.

### Semicritical Items

Semicritical items contact mucous membranes or nonintact skin. This category includes respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades<sup>24</sup>, esophageal manometry probes, cystoscopes<sup>25</sup>, anorectal manometry catheters, and diaphragm fitting rings. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible. Intact mucous membranes, such as those of the lungs and the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, *ortho*-phthalaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (Table 1). When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered.

High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The FDA definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-log<sub>10</sub> kill of an appropriate *Mycobacterium* species. Cleaning followed by high-level disinfection should eliminate enough pathogens to prevent transmission of infection.<sup>26, 27</sup>

Laparoscopes and arthroscopes entering sterile tissue ideally should be sterilized between patients. However, in the United States, this equipment sometimes undergoes only high-level disinfection between patients.<sup>28-30</sup> As with flexible endoscopes, these devices can be difficult to clean and high-level disinfect or sterilize because of intricate device design (e.g., long narrow lumens, hinges). Meticulous

cleaning must precede any high-level disinfection or sterilization process. Although sterilization is preferred, no reports have been published of outbreaks resulting from high-level disinfection of these scopes when they are properly cleaned and high-level disinfected. Newer models of these instruments can withstand steam sterilization that for critical items would be preferable to high-level disinfection.

Rinsing endoscopes and flushing channels with sterile water, filtered water, or tap water will prevent adverse effects associated with disinfectant retained in the endoscope (e.g., disinfectant-induced colitis). Items can be rinsed and flushed using sterile water after high-level disinfection to prevent contamination with organisms in tap water, such as nontuberculous mycobacteria,<sup>10, 31, 32</sup> *Legionella*,<sup>33-35</sup> or gram-negative bacilli such as *Pseudomonas*.<sup>1, 17, 36-38</sup> Alternatively, a tapwater or filtered water (0.2µ filter) rinse should be followed by an alcohol rinse and forced air drying.<sup>28, 38-40</sup> Forced-air drying markedly reduces bacterial contamination of stored endoscopes, most likely by removing the wet environment favorable for bacterial growth.<sup>39</sup> After rinsing, items should be dried and stored (e.g., packaged) in a manner that protects them from recontamination.

Some items that may come in contact with nonintact skin for a brief period of time (i.e., hydrotherapy tanks, bed side rails) are usually considered noncritical surfaces and are disinfected with intermediate-level disinfectants (i.e., phenolic, iodophor, alcohol, chlorine)<sup>23</sup>. Since hydrotherapy tanks have been associated with spread of infection, some facilities have chosen to disinfect them with recommended levels of chlorine<sup>23, 41</sup>.

In the past, high-level disinfection was recommended for mouthpieces and spirometry tubing (e.g., glutaraldehyde) but cleaning the interior surfaces of the spirometers was considered unnecessary.<sup>42</sup> This was based on a study that showed that mouthpieces and spirometry tubing become contaminated with microorganisms but there was no bacterial contamination of the surfaces inside the spirometers. Filters have been used to prevent contamination of this equipment distal to the filter; such filters and the proximal mouthpiece are changed between patients.

## 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<sup>43, 44</sup>. Examples of noncritical patient-care items are bedpans, blood pressure cuffs, crutches and computers<sup>45</sup>. 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<sup>37</sup> 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<sup>46-64</sup>. 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)<sup>65</sup>.

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<sup>13, 46-48, 51, 66, 67</sup>. 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<sup>68</sup>. In one study, standard laundering provided acceptable decontamination of heavily contaminated mopheads but chemical disinfection with a phenolic was less effective.<sup>68</sup> 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<sup>45</sup>.

### Changes in Disinfection and Sterilization Since 1981

The Table in the CDC *Guideline for Environmental Control* prepared in 1981 as a guide to the appropriate selection and use of disinfectants has undergone several important changes (Table 1).<sup>15</sup> First, formaldehyde-alcohol has been deleted as a recommended chemical sterilant or high-level disinfectant because it is irritating and toxic and not commonly used. Second, several new chemical sterilants have been added, including hydrogen peroxide, peracetic acid<sup>58, 69, 70</sup>, and peracetic acid and hydrogen peroxide in combination. Third, 3% phenolics and iodophors have been deleted as high-level disinfectants because of their unproven efficacy against bacterial spores, *M. tuberculosis*, and/or some fungi.<sup>55, 71</sup> Fourth, isopropyl alcohol and ethyl alcohol have been excluded as high-level disinfectants<sup>15</sup> because of their inability to inactivate bacterial spores and because of the inability of isopropyl alcohol to inactivate hydrophilic viruses (i.e., poliovirus, coxsackie virus).<sup>72</sup> Fifth, a 1:16 dilution of 2.0% glutaraldehyde-7.05% phenol-1.20% sodium phenate (which contained 0.125% glutaraldehyde, 0.440% phenol, and 0.075% sodium phenate when diluted) has been deleted as a high-level disinfectant because this product was removed from the marketplace in December 1991 because of a lack of bactericidal activity in the presence of organic matter; a lack of fungicidal, tuberculocidal and sporicidal activity; and reduced virucidal activity.<sup>49, 55, 56, 71, 73-79</sup> Sixth, the exposure time required to achieve high-level disinfection has been changed from 10-30 minutes to 12 minutes or more depending on the FDA-cleared label claim and the scientific literature.<sup>27, 55, 69, 76, 80-84</sup> A glutaraldehyde and an ortho-phthalaldehyde have an FDA-cleared label claim of 5 minutes when used at 35°C and 25°C, respectively, in an automated endoscope reprocessor with FDA-cleared capability to maintain the solution at the appropriate temperature.<sup>85</sup>

In addition, many new subjects have been added to the guideline. These include inactivation of emerging pathogens, bioterrorist agents, and bloodborne pathogens; toxicologic, environmental, and occupational concerns associated with disinfection and sterilization practices; disinfection of patient-care equipment used in ambulatory and home care; inactivation of antibiotic-resistant bacteria; new sterilization processes, such as hydrogen peroxide gas plasma and liquid peracetic acid; and disinfection of complex medical instruments (e.g., endoscopes).