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Major article

Disinfection, sterilization, and antisepsis: An overview

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All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. The level of disinfection or sterilization is dependent on the intended use of the object: critical (items that contact sterile tissue such as surgical instruments), semicritical (items that contact mucous membrane such as endoscopes), and noncritical (devices that contact only intact skin such as stethoscopes) items require sterilization, high-level disinfection and low-level disinfection, respectively. Cleaning must always precede high-level disinfection and sterilization.

Antiseptics are essential to infection prevention as part of a hand hygiene program as well as several other uses such as surgical hand antisepsis and pre-operative skin preparation.

All invasive procedures involve 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 pathogenic microbes leading to infection. Failure to properly disinfect or sterilize equipment may lead to transmission via contaminated medical and surgical devices (eg, *Mycobacterium tuberculosis*–contaminated bronchoscopes). This article will capsulize other articles on this subject and provide updated information of newer sterilization (eg, hydrogen peroxide vapor and ozone) and disinfection (eg, improved hydrogen peroxide) technologies.[1-4]

RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

Almost 50 years ago, Spaulding[5] devised a rational approach to disinfection and sterilization of patient care items or equipment. This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization.[1,6-8] Spaulding believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into 3 categories based on the degree of risk of infection involved in the use of the items. The 3 categories he described were critical (enters sterile tissue and must be sterile), semicritical (contacts mucous membranes or nonintact skin and requires high-level disinfection), and noncritical (comes in contact with intact skin and requires low-level disinfection). These categories and the methods to achieve sterilization, high-level disinfection, and low-level disinfection are summarized in Table 1. Although the scheme remains valid, there are some examples of disinfection studies with prions, viruses, mycobacteria, and protozoa that challenge the current definitions and expectations of high- and low-level disinfection.[10,12]

In May 2015, the Food and Drug Administration (FDA) convened a panel to discuss recent reports and epidemiologic investigations of the transmission of infections associated with the use of duodenoscopes in endoscopic retrograde cholangiopancreatography procedures.[13] After presentations from industry, professional societies, and invited speakers, the panel made several recommendations to include reclassifying duodenoscopes based on the Spaulding classification from semicritical to critical to support the shift from high-level disinfection to sterilization.[14] This could be accomplished by shifting from high-level disinfection for duodenoscopes to sterilization and modifying the Spaulding definition of critical items from "objects which enter sterile tissue or the vascular system or through which blood flows should be sterile" to objects which directly or secondarily (ie, via a mucous membrane, such as a duodenoscope) enter normally sterile tissue of the vascular system or through which blood flows should be sterile.[14-16] Implementation of these recommendations requires sterilization technology that achieves a sterility assurance level of 10^{-6} (ie, a 12 $\log_{10}$ reduction of spores) of complex medical instruments, such as

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duodenoscopes. Ideally, this shift would eventually involve not only endoscopes that secondarily enter normally sterile tissue (eg, duodenoscopes, bronchoscopes) but also other semicritical devices (eg, gastrointestinal endoscopes).[14-16]

Critical items

Critical items are critical because of the high risk of infection if such an item is contaminated with any microorganism, including bacterial spores. Therefore, it is critical that objects that enter sterile tissue or the vascular system be sterile because any microbial contamination could result in disease transmission. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. The items in this category should be purchased as sterile or be sterilized by steam sterilization if possible. If heat-sensitive, the object may be treated with ethylene oxide, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, hydrogen peroxide vapor and ozone, or liquid chemical sterilants if other methods are unsuitable. Tables 1–3 list sterilization processes and liquid chemical sterilants. With the exception of 0.2% peracetic acid (12 minutes at 50°C-56°C), the indicated exposure times for liquid chemical sterilants range from 3-12 hours.[11] Liquid chemical sterilants can be relied on to produce sterility only if cleaning, which eliminates organic and inorganic material, precedes treatment and if proper guidelines as to concentration, contact time, temperature, and pH are met. Another limitation to sterilization of devices with liquid chemical sterilants is that the devices cannot be wrapped during processing in a liquid chemical sterilant; therefore, it is impossible to maintain sterility after processing and during storage. Furthermore, devices may require rinsing after exposure to the liquid chemical sterilant with water that, in general, is not sterile. Therefore, because of the inherent limitations of using liquid chemical sterilants in a nonautomated (or automated) reprocessor, their use should be restricted to reprocessing critical devices that are heat-sensitive and incompatible with other sterilization methods.

Semicritical items

Semicritical items are items that come in contact with mucous membranes or nonintact skin. Respiratory therapy and anesthesia equipment, gastrointestinal endoscopes, bronchoscopes, laryngoscopes, esophageal manometry probes, anorectal manometry catheters, endocavitary probes, prostate biopsy probes, cystoscopies, hysteroscopes, infrared coagulation devices, and diaphragm fitting rings are included in this category. These medical devices should be free of all microorganisms (ie, mycobacteria, fungi, viruses, bacteria); however, small numbers of bacterial spores may be present. Intact mucous membranes, such as those of the lungs or the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semicritical

Table 1
Methods for disinfection and sterilization of patient care items and environmental surfaces

Process	Level of microbial inactivation	Method	Examples (with processing times)	Health care application (examples)
Sterilization*	Destroys all microorganisms, including bacterial spores	High temperature	Steam (~40 min), dry heat (1-6 h depending on temperature)	Heat-tolerant critical (surgical instruments) and semicritical patient care items
		Low temperature	Ethylene oxide gas (~15 h), hydrogen peroxide gas plasma (28-52 min), hydrogen peroxide and ozone (46 min), hydrogen peroxide vapor (55 min), and ozone and hydrogen peroxide	Heat-sensitive critical and semicritical patient care items
		Liquid immersion	Chemical sterilants†: >2% glut (~10 h); 1.12% glut with 1.93% phenol (12 h); 7.35% HP with 0.23% PA (3 h); 8.3% HP with 7.0% PA (5 h); 7.5% HP (6 h); 1.0% HP with 0.08% PA (8 h); and ≥0.2% PA (12 min at 50°C-56°C)	Heat-sensitive critical and semicritical patient care items that can be immersed
HLD	Destroys all microorganisms except high numbers of bacterial spores	Heat-automated	Pasteurization (65-77°C, 30 min)	Heat-sensitive semicritical items (eg, respiratory therapy equipment)
		Liquid immersion	Chemical sterilants/HLDs‡: >2% glut (20-90 min at 20°C-25°C); >2% glut (5 min at 35°C-37.8°C); 0.55% OPA (12 min at 20°C); 1.12% glut with 1.93% phenol (20 min at 25°C); 7.35% HP with 0.23% PA (15 min at 20°C); 7.5% HP (30 min at 20°C); 1.0% HP with 0.08% PA (25 min); 400-450 ppm chlorine (10 min at 20°C); 2.0% HP (8 min at 20°C); and 3.4% glut with 26% isopropanol (10 min at 20°C)	Heat-sensitive semicritical items (eg, GI endoscopes, bronchoscopes, endocavitary probes)
Low-level disinfection	Destroys vegetative bacteria, some fungi and viruses but not mycobacteria or spores	Liquid contact	EPA-registered hospital disinfectant with no tuberculocidal claim (eg, chlorine-based products, phenolics, improved hydrogen peroxide, quaternary ammonium compounds—exposure times at least 1 min) or 70%-90% alcohol	Noncritical patient care item (blood pressure cuff) or surface (bedside table) with no visible blood

NOTE. Modified with permission from Rutala and Weber,[3] Rutala and Weber,[4] Rutala and Weber,[7] and Kohn et al.[9]
Abbreviations: *EPA*, Environmental Protection Agency; *GI*, gastrointestinal; *glut*, glutaraldehyde; *HLD*, high-level disinfection; *HP*, hydrogen peroxide; *OPA*, orthophthalaldehyde; *PA*, peracetic acid.
*Prions (eg, Creutzfeldt-Jakob disease) exhibit an unusual resistance to conventional chemical and physical decontamination methods and are not readily inactivated by conventional sterilization procedures.[10]
†Consult the Food and Drug Administration–cleared package insert for information about the cleared contact time and temperature, and see Rutala and Weber[1] for discussion on why >2% glutaraldehyde products are used at a reduced exposure time (2% glutaraldehyde at 20 min, 20°C). Increasing the temperature using an automated endoscope reprocess will reduce the contact time (eg, OPA 12 min at 20°C, but 5 min at 25°C in automated endoscope reprocess). Exposure temperatures for some high-level disinfectants previously mentioned vary from 20°C-25°C; check Food and Drug Administration–cleared temperature conditions.[11] Tubing and lumens (normally requires active perfusion) must be completely filled for high-level disinfection and liquid chemical sterilization. Material compatibility should be investigated when appropriate (eg, HP and HP with PA will cause functional damage to endoscopes). Intermediate-level disinfectants destroy vegetative bacteria, mycobacteria, most viruses, and most fungi, but not spores, and may include chlorine-based products, phenolics, and improved HP. Intermediate-level disinfectants are not included in the table because there are no devices or surfaces for which intermediate-level disinfection is specifically recommended over low-level disinfection.