



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

# Disinfection and Sterilization in Health Care Facilities: An Overview and Current Issues



William A. Rutala, PhD, MPH<sup>a,b,\*</sup>, David J. Weber, MD, MPH<sup>a,b</sup>

## KEYWORDS

• Disinfection • Sterilization • Health care facilities

## KEY POINTS

- All invasive procedures involve contact by a medical device or surgical instrument with patients' sterile tissue or mucous membrane.
- The level of disinfection or sterilization depends on the intended use of the object: critical (items that contact sterile tissue, such as surgical instrument), semicritical (items that contact mucous membranes, such as endoscopes), and noncritical (items that contact only intact skin, such as stethoscopes) require sterilization, high-level disinfection, or low-level disinfection, respectively.
- Cleaning must precede high-level disinfection and sterilization.
- Failure to properly disinfect devices used in health care (eg, endoscopes) has led to many outbreaks.
- Health care providers should be familiar with current issues, such as the role of the environment in disease transmission, reprocessing semicritical items (eg, endoscopes), and new technologies (eg, hydrogen peroxide mist).

## INTRODUCTION

In the United States in 2010 there were approximately 51.4 million inpatient surgical procedures and an even larger number of invasive medical procedures.<sup>1</sup> In 2009, there were more than 6.9 million gastrointestinal (GI) upper, 11.5 million GI lower, and 228,000 biliary endoscopies performed.<sup>2</sup> Each of these procedures involves contact by a medical device or surgical instrument with patients' sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic

---

Potential Conflicts of Interest: Dr W.A. Rutala is a consultant for Clorox and has received honoraria from 3M. Dr D.J. Weber is a consultant for Clorox and Germitec.

<sup>a</sup> Hospital Epidemiology, University of North Carolina Health Care System, Chapel Hill, NC 27514, USA; <sup>b</sup> Division of Infectious Diseases, University of North Carolina School of Medicine, Chapel Hill, NC 27599-7030, USA

\* Corresponding author. Hospital Epidemiology, UNC Hospitals, Room 1001, West Wing, Manning Drive, Chapel Hill, NC 27599-7030.

E-mail address: [brutala@unch.unc.edu](mailto:brutala@unch.unc.edu)

Infect Dis Clin N Am 30 (2016) 609–637  
<http://dx.doi.org/10.1016/j.idc.2016.04.002>

[id.theclinics.com](http://id.theclinics.com)

0891-5520/16/\$ – see front matter © 2016 Elsevier Inc. All rights reserved.

microbes, which can lead to infection. Failure to properly disinfect or sterilize equipment may lead to transmission via contaminated medical and surgical devices (eg, carbapenem-resistant *Enterobacteriaceae* [CRE]).<sup>3,4</sup>

Achieving disinfection and sterilization through the use of disinfectants and sterilization practices is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because it is not necessary to sterilize all patient-care items, health care policies must identify whether cleaning, disinfection, or sterilization is indicated based primarily on each item's intended use, manufacturers recommendations, and guidelines.

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization.<sup>5</sup> Failure to comply with scientifically based guidelines has led to numerous outbreaks and patient exposures.<sup>6–8</sup> Because of noncompliance with recommended reprocessing procedures, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) issued a health advisory alerting health care providers and facilities about the public health need to properly maintain, clean, and disinfect and sterilize reusable medical devices in September 2015.<sup>9</sup> In this article, which is an updated and modified version of earlier articles,<sup>10–14</sup> a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes is presented, based on well-designed studies assessing the efficacy (via laboratory investigations) and effectiveness (via clinical studies) of disinfection and sterilization procedures.

## A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

Almost 50 years ago, Earle H. Spaulding<sup>15</sup> 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.<sup>10–14</sup> Spaulding thought 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, semicritical, and noncritical. This terminology is used by the CDC's "Guidelines for Environmental Infection Control in Healthcare Facilities"<sup>16</sup> and the CDC's "Guideline for Disinfection and Sterilization in Healthcare Facilities."<sup>13</sup> 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-level disinfection (HLD) and low-level disinfection.<sup>22</sup>

In May 2015, the 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 (ERCP) procedures.<sup>23</sup> 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 HLD to sterilization.<sup>24</sup> This change could be accomplished by shifting from HLD 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 duodenoscope) enter normally sterile tissue of the vascular system of through which blood flows should be sterile."<sup>24,25</sup> Implementation of this

**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 <sup>a</sup>	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), HP gas plasma (28–52 min), HP and ozone (46 min), HP vapor (55 min)	Heat-sensitive critical and semicritical patient-care items
		Liquid immersion	Chemical sterilants <sup>b</sup> : >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); ≥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 some bacterial spores	Heat automated	Pasteurization (65°C–77°C, 30 min)	Heat-sensitive semicritical items (eg, respiratory therapy equipment)
		Liquid immersion	Chemical sterilants/HLDs <sup>b</sup> : >2% glut (20–90 min at 20°C–25°C); >2% glut (5 min at 35.0°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); 3.4% glut with 26% isopropanol (10 min at 20°C)	Heat-sensitive semicritical items (eg, GI endoscopes, bronchoscopes, endocavitary probes)

(continued on next page)

**Table 1**  
(continued)

Process	Level of Microbial Inactivation	Method	Examples (with Processing Times)	Health Care Application (Examples)
Low-level disinfection	Destroys vegetative bacteria and 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 HP, HP plus PA, 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

*Abbreviations:* EPA, Environmental Protection Agency; glut, glutaraldehyde; HLD, high-level disinfection; HP, hydrogen peroxide; OPA, ortho-phthalaldehyde; PA, peracetic acid; ppm, parts per million.

<sup>a</sup> Prions (such as Creutzfeldt-Jakob disease) exhibit an unusual resistance to conventional chemical and physical decontamination methods and are not readily inactivated by conventional sterilization procedures.<sup>17</sup>

<sup>b</sup> Consult the FDA-cleared package insert for information about the cleared contact time and temperature, and see reference<sup>18</sup> for discussion why greater than 2% glutaraldehyde products are used at a reduced exposure time (2% glutaraldehyde at 20 minutes, 20°C). Increasing the temperature using an automated endoscope reprocessor (AER) will reduce the contact time (eg, ortho-phthalaldehyde 12 minutes at 20°C but 5 minutes at 25°C in AER). Exposure temperatures for some of the aforementioned high-level disinfectants varies from 20°C to 25°C; check FDA-cleared temperature conditions.<sup>19</sup> Tubing must be completely filled for high-level disinfection and liquid chemical sterilization. Material compatibility should be investigated when appropriate (eg, hydrogen peroxide [HP] and HP with peracetic acid 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 [Table 1](#) as there as there is no device or surface for which intermediate-level disinfection is specifically recommended over low-level disinfection.

*Adapted from Refs.* <sup>11–13,20,21</sup>

recommendations requires sterilization technology that achieves a sterility assurance level of  $10^{-6}$  of complex medical instruments, such as 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, GI endoscopes).<sup>24,25</sup>

### **Critical Items**

---

Critical items are so called because of the high risk of infection if such an item is contaminated with any microorganism, including bacterial spores. Thus, 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, and implants 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 (ETO), hydrogen peroxide (HP) gas plasma, vaporized HP, HP vapor (HPV) plus ozone, or by liquid chemical sterilants if other methods are unsuitable. **Table 1** and **Tables 2** and **3** list sterilization processes and liquid chemical sterilants and the advantages and disadvantages of each. 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 to 12 hours.<sup>19</sup> 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; thus, it is impossible to maintain sterility following processing and during storage. Furthermore, devices may require rinsing following 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.

In contrast to semicritical items that have been associated with greater than 100 outbreaks of infection,<sup>6</sup> critical items have rarely,<sup>26</sup> if ever, been associated with disease transmission. For example, any deviation from proper reprocessing (such as crevices associated with the elevator channel) of an endoscope could lead to failure to eliminate contamination with a possibility of subsequent patient-to-patient transmission due to a low or nonexistent margin of safety. This low (or nonexistent) margin of safety associated with endoscope reprocessing compares with the 17- $\log_{10}$  margin of safety associated with cleaning and sterilization of surgical instruments (ie, 12- $\log_{10}$  reduction via sterilization and at least a net 5- $\log_{10}$  reduction based on the microbial load on surgical instruments [2-logs]<sup>27</sup> and microbial reduction via a washer disinfectant [7-logs]).<sup>18</sup>

### **Semicritical Items**

---

Semicritical items are those that come in contact with mucous membranes or nonintact skin. Respiratory therapy and anesthesia equipment, gastrointestinal endoscopes, bronchoscopes, laryngoscopes, endocavitary probes, prostate biopsy probes,<sup>28</sup> cystoscopes,<sup>29</sup> hysteroscopes, infrared coagulation devices,<sup>30</sup> and diaphragm fitting rings are included in this category. These medical devices should be free of all microorganisms (ie, mycobacteria, fungi, viruses, bacteria), although small numbers of bacterial spores may be present. Intact mucous membranes, such as those of the lungs or the gastrointestinal tract, are generally resistant to infection by

**Table 2**  
**Summary of advantages and disadvantages of chemical agents used as chemical sterilants<sup>3</sup> or as high-level disinfectants**

Sterilization		
Method	Advantages	Disadvantages
Peracetic acid/HP	<ul style="list-style-type: none"> <li>• No activation required</li> <li>• Odor or irritation not significant</li> </ul>	<ul style="list-style-type: none"> <li>• Material compatibility concerns (lead, brass, copper, zinc) both cosmetic and functional</li> <li>• Limited clinical experience</li> <li>• Potential for eye and skin damage</li> </ul>
Glutaraldehyde	<ul style="list-style-type: none"> <li>• Numerous use studies published</li> <li>• Relatively inexpensive</li> <li>• Excellent material compatibility</li> </ul>	<ul style="list-style-type: none"> <li>• Respiratory irritation from glutaraldehyde vapor</li> <li>• Pungent and irritating odor</li> <li>• Relatively slow mycobactericidal activity (unless other disinfectants added such as phenolic, alcohol)</li> <li>• Coagulates blood and fixes tissue to surfaces</li> <li>• Allergic contact dermatitis</li> </ul>
HP	<ul style="list-style-type: none"> <li>• No activation required</li> <li>• May enhance removal of organic matter and organisms</li> <li>• No disposal issues</li> <li>• No odor or irritation issues</li> <li>• Does not coagulate blood or fix tissues to surfaces</li> <li>• Inactivates <i>Cryptosporidium</i></li> <li>• Use studies published</li> </ul>	<ul style="list-style-type: none"> <li>• Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional</li> <li>• Serious eye damage with contact</li> </ul>
OPA	<ul style="list-style-type: none"> <li>• Fast-acting high-level disinfectant</li> <li>• No activation required</li> <li>• Odor not significant</li> <li>• Excellent materials compatibility claimed</li> <li>• Does not coagulate blood or fix tissues to surfaces claimed</li> </ul>	<ul style="list-style-type: none"> <li>• Stains protein gray (eg, skin, mucous membranes, clothing, and environmental surfaces)</li> <li>• Limited clinical experience</li> <li>• More expensive than glutaraldehyde</li> <li>• Eye irritation with contact</li> <li>• Slow sporicidal activity</li> <li>• Anaphylactic reactions to OPA in patients with bladder cancer with repeated exposure to OPA through cystoscopy</li> </ul>

Peracetic acid	<ul style="list-style-type: none"> <li>Standardized cycle (eg, Liquid Chemical Sterilant Processing System using Peracetic Acid, rinsed with extensively treated potable water)</li> <li>Low temperature (50°C–55°C) liquid immersion sterilization</li> <li>Environmental friendly byproducts (acetic acid, O<sub>2</sub>, H<sub>2</sub>O)</li> <li>Fully automated</li> <li>Single-use system eliminates need for concentration testing</li> <li>May enhance removal of organic material and endotoxin</li> <li>No adverse health effects to operators under normal operating conditions</li> <li>Compatible with many materials and instruments</li> <li>Does not coagulate blood or fix tissues to surfaces</li> <li>Sterilant flows through scope facilitating salt, protein, and microbe removal</li> <li>Rapidly sporicidal</li> <li>Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)</li> </ul>	<ul style="list-style-type: none"> <li>Potential material incompatibility (eg, aluminum anodized coating becomes dull)</li> <li>Used for immersible instruments only</li> <li>Biological indicator may not be suitable for routine monitoring</li> <li>One scope or a small number of instruments can be processed in a cycle</li> <li>More expensive (endoscope repairs, operating costs, purchase costs) than high-level disinfection</li> <li>Serious eye and skin damage (concentrated solution) with contact</li> <li>Point-of-use system, no sterile storage</li> <li>An AER using 0.2% peracetic acid not FDA cleared as sterilization process but HLD</li> </ul>
Improved HP (2.0%); HLD	<ul style="list-style-type: none"> <li>No activation required</li> <li>No odor</li> <li>Nonstaining</li> <li>No special venting requirements</li> <li>Manual or automated applications</li> <li>12-mo shelf-life, 14-d reuse</li> <li>8 min at 20°C HLD claim</li> </ul>	<ul style="list-style-type: none"> <li>Material compatibility concerns due to limited clinical experience</li> <li>Antimicrobial claims not independently verified</li> <li>Organic material resistance concerns due to limited data</li> </ul>

Abbreviations: AER, automated endoscope reprocessor; OPA, ortho-phthalaldehyde.

<sup>a</sup> All products effective in presence of organic soil, relatively easy to use, and have a broad spectrum of antimicrobial activity (bacteria, fungi, viruses, bacterial spores, and mycobacteria). The aforementioned characteristics are documented in the literature; contact the manufacturer of the instrument and sterilant for additional information. All products listed are cleared by the FDA as chemical sterilants except ortho-phthalaldehyde, which is an FDA-cleared HLD.

Adapted from Refs. <sup>10–13,20</sup>



**Table 3**  
**Summary of advantages and disadvantages of commonly used sterilization technologies**

Sterilization		
Method	Advantages	Disadvantages
Steam	<ul style="list-style-type: none"> <li>• Nontoxic to patients, staff, environment</li> <li>• Cycle easy to control and monitor</li> <li>• Rapidly microbicidal</li> <li>• Least affected by organic/inorganic soils among sterilization processes listed</li> <li>• Rapid cycle time</li> <li>• Penetrates medical packaging, device lumens</li> </ul>	<ul style="list-style-type: none"> <li>• It is deleterious for heat-sensitive instruments.</li> <li>• Microsurgical instruments are damaged by repeated exposure.</li> <li>• It may leave instruments wet, causing them to rust.</li> <li>• There is potential for burns.</li> </ul>
HP gas plasma	<ul style="list-style-type: none"> <li>• Safe for the environment and health care personnel</li> <li>• Leaves no toxic residuals</li> <li>• Cycle time <math>\geq 28</math> min, and no aeration necessary</li> <li>• Used for heat- and moisture-sensitive items because process temperature <math>&lt; 50^\circ\text{C}</math></li> <li>• Simple to operate, install (208-V outlet), and monitor</li> <li>• Compatible with most medical devices</li> <li>• Only requires electrical outlet</li> </ul>	<ul style="list-style-type: none"> <li>• Cellulose (paper), linens, and liquids cannot be processed.</li> <li>• Endoscope or medical device restrictions are based on lumen internal diameter and length (see manufacturer's recommendations).</li> <li>• It requires synthetic packaging (polypropylene wraps, polyolefin pouches) and a special container tray.</li> <li>• HP may be toxic at levels <math>&gt; 1</math> ppm TWA.</li> </ul>
100% ETO	<ul style="list-style-type: none"> <li>• Penetrates packaging materials, device lumens</li> <li>• Potential for gas leak and ETO exposure minimized by single-dose cartridge and negative-pressure chamber</li> <li>• Simple to operate and monitor</li> <li>• Compatible with most medical materials</li> </ul>	<ul style="list-style-type: none"> <li>• It requires aeration time to remove ETO residue.</li> <li>• ETO is toxic, a carcinogen, and flammable.</li> <li>• ETO emission is regulated by states, but catalytic cell removes 99.9% of ETO and converts it to carbon dioxide and water.</li> <li>• ETO cartridges should be stored in flammable liquid storage cabinet.</li> <li>• It has a lengthy cycle/aeration time.</li> </ul>
Vaporized HP	<ul style="list-style-type: none"> <li>• Safe for the environment and health care personnel</li> <li>• Leaves no toxic residue; no aeration necessary</li> <li>• Cycle time 55 min</li> <li>• Used for heat- and moisture-sensitive items (metal and nonmetal devices)</li> </ul>	<ul style="list-style-type: none"> <li>• Medical device restrictions are based on lumen internal diameter and length; see manufacturer's recommendations (eg, stainless steel lumen 1 mm diameter, 125 mm length).</li> <li>• It is not used for liquid, linens, powders, or any cellulose materials.</li> <li>• Requires synthetic packaging (polypropylene).</li> <li>• There are limited materials compatibility data.</li> <li>• There are limited clinical use and comparative microbicidal efficacy data.</li> </ul>

(continued on next page)

**Table 3**  
(continued)

Sterilization Method	Advantages	Disadvantages
HP and ozone	<ul style="list-style-type: none"> <li>• Safe for the environment and health care personnel</li> <li>• Uses dual sterilants, HP, and ozone</li> <li>• Does not need aeration because of no toxic byproducts</li> <li>• Compatible with common medical devices</li> <li>• Cycle time 46 min</li> <li>• FDA cleared for general instruments, single-channel flexible endoscopes, and rigid and semirigid channeled devices</li> </ul>	<ul style="list-style-type: none"> <li>• Endoscope or medical device restrictions are based on lumen internal diameter and length (see manufacturer's recommendations).</li> <li>• There are limited clinical use (no published data on material compatibility/penetrability/organic material resistance) and limited microbicidal efficacy data.</li> <li>• It requires synthetic packaging (polypropylene wraps, polyolefin pouches) and a special container tray.</li> </ul>

Abbreviations: ETO, ethylene oxide; HP, hydrogen peroxide; TWA, time-weighted average.

Adapted from Refs. <sup>10–13,20</sup>

common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semicritical items minimally require HLD using chemical disinfectants. Glutaraldehyde, HP, ortho-phthalaldehyde (OPA), peracetic acid with HP, and chlorine (via electrochemical activation) are cleared by the FDA<sup>19</sup> and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (see **Tables 1** and **2**). The exposure time for most high-level disinfectants varies from 8 to 45 minutes at 20°C to 25°C.<sup>19</sup>

Because semicritical equipment has been associated with reprocessing errors that result in patient lookback and patient notifications, it is essential that control measures be instituted to prevent patient exposures.<sup>7</sup> Before new equipment (especially semicritical equipment as the margin of safety is less than that for sterilization)<sup>25</sup> is used for patient care on more than one patient, reprocessing procedures for that equipment should be developed. Staff should receive training on the safe use and reprocessing of the equipment and be competency tested. At the University of North Carolina (UNC) Hospitals, to ensure patient-safe instruments, all staff that reprocess semicritical instruments (eg, instruments which contact a mucous membrane such as vaginal probes, endoscopes, prostate probes) are required to attend a 3-hour class on HLD of semicritical instruments. The class includes the rationale for and importance of high-level disinfection, discussion of high-level disinfectants and exposure times, reprocessing steps, monitoring minimum effective concentration, personal protective equipment, and the reprocessing environment (establish dirty-to-clean flow). Infection control rounds or audits should be conducted annually in all clinical areas that reprocess critical and semicritical devices to ensure adherence to the reprocessing standards and policies. Results of infection control rounds should be provided to the unit managers, and deficiencies in reprocessing should be corrected and the corrective measures documented to infection control within 2 weeks (immediately correct patient safety issues, such as exposure time to high-level disinfectant).

### 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.” Examples of noncritical items are bedpans, blood pressure cuffs, crutches, bed rails, linens, bedside tables, patient furniture, and floors. 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. There is virtually no documented risk of transmitting infectious agents to patients via noncritical items<sup>31</sup> when they are used as noncritical items and do not contact nonintact skin and/or mucous membranes. However, these items (eg, bedside tables, bed rails) could potentially contribute to secondary transmission by contaminating hands of healthcare personnel or by contact with medical equipment that will subsequently come in contact with patients.<sup>32</sup> **Table 1** and **Table 4** list several low-level disinfectants that may be used for noncritical items. **Table 4** lists the advantages and disadvantages of the low-level disinfectants that are used on noncritical patient care items (eg, blood pressure cuffs) and noncritical environmental surfaces. The exposure time for low-level disinfection of noncritical items is at least 1 minute.

## CURRENT ISSUES IN DISINFECTION AND STERILIZATION

### *Reprocessing of Endoscopes*

---

Physicians use endoscopes to diagnose and treat numerous medical disorders. Although endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine, more health care–associated outbreaks have been linked to contaminated endoscopes than to any other reusable medical device.<sup>6,8</sup> Additionally, endemic transmission of infections associated with GI endoscopes may go unrecognized for several reasons, including inadequate surveillance of outpatient procedures, long lag time between colonization and infection, low frequency of infection, and because pathogens are the usual enteric flora. In addition, the risk of some procedures might be lower than others (eg, colonoscopy vs ERCP), whereby normally sterile areas are contaminated in the latter. In order to prevent the spread of health care–associated infections (HAIs), all heat-sensitive endoscopes (eg, GI endoscopes, bronchoscopes, nasopharyngoscopes) must be properly cleaned and, at a minimum, subjected to HLD following each use. HLD can be expected to destroy all microorganisms; although when high numbers of bacterial spores are present, a few spores may survive.

Recommendations for the cleaning and disinfection of endoscopic equipment have been published and should be strictly followed.<sup>13,35,36</sup> Unfortunately, audits have shown that personnel often do not adhere to guidelines on reprocessing<sup>5</sup> and outbreaks of infection continue to occur.<sup>3,6,8,37</sup> Additionally, recent studies have suggested that current reprocessing guidelines are not sufficient to ensure successful decontamination.<sup>38</sup> In order to minimize patient risks and ensure that reprocessing personnel are properly trained, there should be initial and annual competency testing for each individual who is involved in reprocessing endoscopic instruments.<sup>13,35,36</sup>

In general, endoscope disinfection or sterilization with a liquid chemical sterilant or high-level disinfectant involves 5 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 enzymatic cleaner or detergent; (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

**Table 4**  
**Summary of advantages and disadvantages of disinfectants used as low-level disinfectants**

Disinfectant	Advantages	Disadvantages
Alcohol	<ul style="list-style-type: none"> <li>• Bactericidal, tuberculocidal, fungicidal, virucidal</li> <li>• Fast acting</li> <li>• Noncorrosive</li> <li>• Nonstaining</li> <li>• Used to disinfect small surfaces, such as rubber stoppers on medication vials</li> <li>• No toxic residue</li> </ul>	<ul style="list-style-type: none"> <li>• It is not sporicidal.</li> <li>• It is affected by organic matter.</li> <li>• It is slow acting against non-enveloped viruses (eg, norovirus).</li> <li>• It has no detergent or cleaning properties.</li> <li>• It is not EPA registered.</li> <li>• It damages some instruments (eg, harden rubber, deterioration glue).</li> <li>• It is flammable. (Large amounts require special storage.)</li> <li>• It evaporates rapidly making contact time compliance difficult.</li> <li>• It is not recommended for use on large surfaces.</li> <li>• Outbreaks are ascribed to contaminated alcohol.<sup>33</sup></li> </ul>
Sodium hypochlorite	<ul style="list-style-type: none"> <li>• Bactericidal, tuberculocidal, fungicidal, virucidal</li> <li>• Sporicidal</li> <li>• Fast acting</li> <li>• Inexpensive (in diluted form)</li> <li>• Not flammable</li> <li>• Unaffected by water hardness</li> <li>• Reduces biofilms on surfaces</li> <li>• Relatively stable (eg, 50% reduction in chlorine concentration in 30 d)<sup>34</sup></li> <li>• Used as the disinfectant in water treatment</li> <li>• EPA registered</li> </ul>	<ul style="list-style-type: none"> <li>• There is a reaction hazard with acids and ammonias.</li> <li>• It leaves a salt residue.</li> <li>• Corrosive to metals (some ready-to-use products may be formulated with corrosion inhibitors)</li> <li>• It is unstable when active. (Some ready-to-use products may be formulated with stabilizers to achieve longer shelf-life.)</li> <li>• It is affected by organic matter.</li> <li>• It discolors/stains fabrics.</li> <li>• A potential hazard is production of trihalomethane.</li> <li>• It has an odor. (Some ready-to-use products may be formulated with odor inhibitors.). It is irritating at high concentrations.</li> </ul>
Improved HP	<ul style="list-style-type: none"> <li>• Bactericidal, tuberculocidal, fungicidal, virucidal</li> <li>• Fast efficacy</li> <li>• Easy compliance with wet-contact times</li> <li>• Safe for workers (lowest EPA toxicity category, IV)</li> <li>• Benign for the environment</li> <li>• Surface compatible</li> <li>• Nonstaining</li> <li>• EPA registered</li> <li>• Not flammable</li> </ul>	<ul style="list-style-type: none"> <li>• It is more expensive than most other disinfecting actives.</li> <li>• It is not sporicidal at low concentrations.</li> </ul>

(continued on next page)

<b>Table 4 (continued)</b>		
<b>Disinfectant Active</b>	<b>Advantages</b>	<b>Disadvantages</b>
Iodophors	<ul style="list-style-type: none"> <li>• Bactericidal, mycobactericidal, virucidal</li> <li>• Not flammable</li> <li>• Used for disinfecting blood culture bottles</li> </ul>	<ul style="list-style-type: none"> <li>• It is not sporicidal.</li> <li>• It is shown to degrade silicone catheters.</li> <li>• It requires prolonged contact to kill fungi.</li> <li>• It stains surfaces.</li> <li>• It is used mainly as an antiseptic rather than disinfectant.</li> </ul>
Phenolics	<ul style="list-style-type: none"> <li>• Bactericidal, tuberculocidal, fungicidal, virucidal</li> <li>• Inexpensive (in diluted form)</li> <li>• Nonstaining</li> <li>• Not flammable</li> <li>• EPA registered</li> </ul>	<ul style="list-style-type: none"> <li>• It is not sporicidal.</li> <li>• It is absorbed by porous materials and irritates tissue.</li> <li>• Depigmentation of skin is caused by certain phenolics.</li> <li>• It can cause hyperbilirubinaemia in infants when phenolic is not prepared as recommended.</li> </ul>
Quaternary ammonium compounds (eg, didecyl dimethyl ammonium bromide, dioctyl dimethyl ammonium bromide)	<ul style="list-style-type: none"> <li>• Bactericidal, fungicidal, virucidal against enveloped viruses (eg, HIV)</li> <li>• Good cleaning agents</li> <li>• EPA registered</li> <li>• Surface compatible</li> <li>• Persistent antimicrobial activity when undisturbed</li> <li>• Inexpensive (in diluted form)</li> </ul>	<ul style="list-style-type: none"> <li>• It is not sporicidal.</li> <li>• In general, it is not tuberculocidal and virucidal against nonenveloped viruses.</li> <li>• High water hardness and cotton/gauze can make less microbicidal.</li> <li>• A few reports documented asthma as a result of exposure to benzalkonium chloride.</li> <li>• It is affected by organic matter.</li> <li>• Multiple outbreaks ascribed to contaminated benzalkonium chloride.<sup>33</sup></li> </ul>
Peracetic acid/HP	<ul style="list-style-type: none"> <li>• Bactericidal, fungicidal, virucidal, and sporicidal (eg, <i>Clostridium difficile</i>)</li> <li>• Active in the presence of organic material</li> <li>• Environmental friendly by-products (acetic acid, O<sub>2</sub>, H<sub>2</sub>O)</li> <li>• EPA registered</li> <li>• Surface compatible</li> </ul>	<ul style="list-style-type: none"> <li>• It lacks stability.</li> <li>• It has potential for material incompatibility (eg, brass, copper).</li> <li>• It is more expensive than most other disinfecting actives.</li> <li>• The odor may be irritating.</li> </ul>

If low-level disinfectant is prepared on-site (not ready to use), document correct concentration at a routine frequency.

**Abbreviations:** EPA, Environmental Protection Agency; HIV, human immunodeficiency virus; HP, hydrogen peroxide.

*Adapted from* Rutala WA, Weber DJ. Selection of the ideal disinfectant. *Infect Control Hosp Epidemiol* 2014;35:855–65; and Rutala WA, Weber DJ. Disinfection and sterilization in healthcare facilities. In: Han J, editor. *SHEA practical healthcare epidemiology*. University of Chicago Press.

with automated endoscope reprocessors), or tap water; (4) dry: rinse the insertion tube and inner channels with alcohol and dry with forced air after disinfection and before storage; and (5) store: store the endoscope in a way that prevents recontamination and promotes drying (eg, hung vertically).

**Outbreaks of carbapenem-resistant Enterobacteriaceae infection associated with duodenoscopes: what can we do to prevent infections?**

In the past 3 years, multiple reports of outbreaks have led the FDA, the CDC, and national news to raise awareness among the public and health care professionals that the complex design of duodenoscopes (used primarily for ERCP) may impede effective reprocessing. Several recent publications have associated multidrug-resistant (MDR) bacterial infections, especially due to CRE, in patients who have undergone ERCP with reprocessed duodenoscopes.<sup>3,4,25,37,39</sup> Unlike other endoscope outbreaks,<sup>6</sup> these recent outbreaks occurred even when the manufacturer's instructions and professional guidelines were followed correctly.<sup>3,4</sup>

The key concern raised by these outbreaks is that current reprocessing guidelines are not adequate to ensure a patient-safe GI endoscope (one devoid of potential pathogens), as the margin of safety associated with reprocessing endoscopes is minimal or nonexistent. There are at least 2 (and maybe 3) reasons for this reprocessing failure and why outbreaks continue to occur. First, studies have shown that the internal channel of GI endoscopes, including duodenoscopes, may contain  $10^7$ – $10^{10}$  ( $7$ – $10$ -log<sub>10</sub>) enteric microorganisms.<sup>40,41</sup> Investigations have demonstrated that the cleaning step in endoscope reprocessing results in a 2- to 6-log<sub>10</sub> reduction of microbes and the HLD step results in another 4- to 6-log<sub>10</sub> reduction of mycobacteria for a total 6- to 12-log<sub>10</sub> reduction of microbes.<sup>40–42</sup> Thus, the margin of safety associated with cleaning and HLD of GI endoscopes is minimal or nonexistent (level of contamination: 4-log<sub>10</sub> [maximum contamination, minimal cleaning/HLD] to –5-log<sub>10</sub> [minimum contamination, maximum cleaning/HLD]). Therefore, any deviation from proper reprocessing (such as crevices associated with the elevator channel) could lead to failure to eliminate contamination with a possibility of subsequent patient-to-patient transmission. This low (or nonexistent) margin of safety associated with endoscope reprocessing compares with the 17-log<sub>10</sub> margin of safety associated with cleaning and sterilization of surgical instruments.<sup>23</sup>

Second, GI endoscopes not only have heavy microbial contamination ( $10^7$ – $10^{10}$  bacteria) but they are also complex with long, narrow channels, right-angle turns, and difficult-to-clean and disinfect components (eg, elevator channel). The elevator channel in duodenoscopes is unique to side-viewing endoscopes. It has a separate channel and provides orientation of catheters, guidewires, and accessories into the endoscopic visual field.<sup>25</sup> This channel is complex in design and has crevices that are difficult to access with a cleaning brush and may impede effective reprocessing.<sup>43</sup> Based on this and other recent studies, it is likely that MDR pathogens are acting as marker or indicator organisms for ineffective reprocessing of the complex design of duodenoscopes, which is an infectious risk to patients.

Third, biofilms could impact endoscope reprocessing failure and continued endoscope-related outbreaks.<sup>44</sup> Biofilms are multilayered bacteria plus exopolysaccharides that cement cells to surfaces. They develop in a wet environment. If reprocessing is performed promptly after use and the endoscope is dry, the opportunity for biofilm formation is minimal.<sup>45,46</sup> However, the formation of endoscopic biofilm during clinical practice may be related to reuse of reprocessing methods, such as reuse of detergent, manual cleaning, and incomplete drying.<sup>47</sup> Ideally, reprocessing should be initiated within an hour of use; however, there are no evidence-based guidelines on delayed endoscope reprocessing.<sup>48</sup> It is unclear if biofilms contribute to failure of endoscope reprocessing.

What should we do now? Unfortunately, there is currently no single, simple, and proven technology or prevention strategy that hospitals can use to guarantee patient safety. Of course, we must continue to emphasize the enforcement of

evidenced-based practices, including equipment maintenance, and routine audits with at least yearly competency testing of reprocessing staff.<sup>13,35,36</sup> All reprocessing personnel must be knowledgeable and thoroughly trained on the reprocessing instructions for duodenoscopes. This training includes the new recommendations to use a small bristle cleaning brush and for additional flushing and cleaning steps of the duodenoscope elevator channel ([http://medical.olympusamerica.com/sites/default/files/pdf/150326\\_TJF-Q180V\\_Customer\\_letter.pdf](http://medical.olympusamerica.com/sites/default/files/pdf/150326_TJF-Q180V_Customer_letter.pdf)). Although these steps were described as validated, no public data are available on the ability of these new cleaning recommendations to yield an ERCP scope devoid of bacteria. But we must do more or additional outbreaks will likely continue. For example, all hospitals that reprocess duodenoscopes should select one of the enhanced methods for reprocessing duodenoscopes. These enhanced methods have been priority ranked with the first providing the greatest margin of safety.<sup>25</sup> They include (1) ETO sterilization after HLD with periodic microbiologic surveillance; (2) double HLD with periodic microbiologic surveillance; (3) HLD with scope quarantine until negative culture results are returned; (4) liquid chemical sterilant processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance; (5) other FDA-cleared low-temperature sterilization technology (provided material compatibility and sterilization validation testing performed using the sterilizer and endoscope) after HLD, with periodic microbiologic surveillance; and (6) HLD with periodic microbiologic surveillance. These supplemental measures to enhance duodenoscope reprocessing made in May–June 2015<sup>25</sup> were reinforced by the FDA in August 2015.<sup>43</sup> UNC Hospitals has chosen ETO sterilization after HLD with periodic microbiologic surveillance as its primary reprocessing method for duodenoscopes and if the ETO sterilizer is not available, then double HLD with periodic microbiologic surveillance.<sup>49</sup>

### ***Role of the Environment in Disease Transmission***

---

There is excellent evidence in the scientific literature that environmental contamination plays an important role in the transmission of several key health care–associated pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus* (VRE), *Acinetobacter* sp, norovirus, and *Clostridium difficile*.<sup>50–53</sup> All these pathogens have been demonstrated to persist in the environment for days (in some cases months), frequently contaminate the environmental surfaces in rooms of colonized or infected patients, transiently colonize the hands of health care personnel, be transmitted by health care personnel, and cause outbreaks in which environmental transmission was deemed to play a role. Importantly, a study by Stiefel and colleagues<sup>54</sup> demonstrated that contact with the environment was just as likely to contaminate the hands of health care personnel as was direct contact with patients. Further, admission to a room in which the previous patient had been colonized or infected with MRSA, VRE, *Acinetobacter* or *C difficile* has been shown to be a risk factor for newly admitted patients to develop colonization or infection.<sup>55–57</sup>

### ***Improving room cleaning and disinfection and demonstrating the effectiveness of surface decontamination in reducing health care–associated infections***

Investigators have reported that intervention programs aimed at improving surface cleaning and disinfection reduced HAIs.<sup>58</sup> Such interventions have generally included multiple activities: disinfectant product substitutions and interventions to improve the effectiveness of cleaning and disinfection (eg, improved housekeeper education, monitoring the thoroughness of cleaning [eg, by use of ATP assays or fluorescent dyes] with feedback of performance to the environmental service workers, and/or use of cleaning checklists).<sup>58–61</sup> Health care facilities must also allow adequate time

for room processing to ensure adherence to all steps recommended by institutional policies and professional organization guidelines. The authors have found that collaboration between infection prevention and environmental services staff, nursing, and management is critical to an effective environmental cleaning program. This collaboration includes ensuring that environmental services staff recognize the significance and relationship of adhering to proper work procedures to reduction of microbial contamination. The assignment of cleaning responsibility (eg, medical equipment to be cleaned by nursing; environmental surfaces to be cleaned by environmental service) is also important to ensure all objects and surfaces in a patient room are decontaminated, especially the surfaces of medical equipment (eg, cardiac monitors). Improved environmental cleaning has been demonstrated to reduce the environmental contamination with VRE,<sup>61</sup> MRSA,<sup>62</sup> and *C difficile*.<sup>63</sup> Further, all studies have only focused improvement on a limited number of high-risk objects. Thus, a concern of published studies is that they have only demonstrated improved cleaning of a limited number of high-risk objects (or targeted objects) not an improvement in the overall thoroughness of room decontamination, which is the objective.

To the authors' knowledge only one study has objectively evaluated what constitutes high-touch objects in a patient room and no study has demonstrated epidemiologically what constitutes a high-risk object. Examples of what the literature refers to as high-touch objects includes bed rails, intravenous (IV) poles, call buttons, door knobs, floors, and bathroom facilities<sup>64</sup>; however, a study demonstrated high-touch objects in the intensive care unit were the bed rail, bed surface, and supply cart, whereas the high-touch surfaces in a patient ward were the bed rail, over-bed table, IV pump, and bed surface.<sup>65</sup> Importantly, the level of microbial contamination of room surfaces was not statistically different regardless of how often they were touched before and after cleaning. Until research identifies which objects and surfaces pose the greatest risk of pathogen transmission, all noncritical surfaces that are touched must be cleaned/disinfected.<sup>66</sup>

### ***No-touch (or mechanical) methods for room decontamination***

As noted earlier, multiple studies have demonstrated that environmental surfaces and objects in rooms are frequently not properly cleaned and these surfaces may be important in transmission of health care-associated pathogens. Further, although interventions aimed at improving cleaning thoroughness have demonstrated effectiveness, many surfaces remain inadequately cleaned and, therefore, potentially contaminated. For this reason, several manufacturers have developed room disinfection units that can decontaminate environmental surfaces and objects. These no-touch systems generally use one of 2 methods: either UV light or HPV/mist.<sup>53</sup> These technologies supplement, but do not replace, standard cleaning and disinfection because surfaces must be physically cleaned of dirt and debris.

**Ultraviolet light for room decontamination** UV radiation has been used for the control of pathogenic microorganisms in a variety of applications, such as control of legionellosis, as well as disinfection of air, surfaces, and instruments.<sup>53,67</sup> At certain wavelengths, UV light will break the molecular bonds in DNA, thereby destroying the organism. UV radiation has peak germicidal effectiveness in the wavelength range of 240 to 280 nm. Mercury gas bulbs emit UV-C at 254 nm, whereas xenon gas bulbs produce a broad spectrum of radiation that encompasses the UV (100–280 nm) and the visible (380–700 nm) electromagnetic spectra.<sup>68</sup> The efficacy of UV radiation is a function of many different parameters such as dose, distance, direct or shaded exposure, exposure time, lamp placement, pathogen, carrier or surface tested, inoculum



method, organic load and orientation of carriers (eg, parallel vs perpendicular). Data demonstrate that several UV systems have effectiveness (eg, eliminate  $>3\text{-log}_{10}$  vegetative bacteria [MRSA, VRE, *Acinetobacter baumannii*] and  $>2.4\text{-log}_{10}$  *C difficile*) at relatively short exposure times (eg, 5–25 minutes for bacteria, 10–60 minutes for *C difficile* spores).<sup>68–70</sup> The studies also demonstrated reduced effectiveness when surfaces were not in direct line-of-sight.<sup>68–72</sup>

**Hydrogen peroxide systems for room decontamination** Several systems that produce HP (eg, HPV, aerosolized dry mist HP) have been studied for their ability to decontaminate environmental surfaces and objects in hospital rooms. HPV has been used for the decontamination of rooms in health care.<sup>73–83</sup> Studies have demonstrated that HP systems are a highly effective method for eradicating various pathogens (eg, MRSA, *Mycobacterium tuberculosis*, *Serratia*, *C difficile* spores, *Clostridium botulinum* spores) from rooms, furniture, and equipment.

**Comparison of ultraviolet irradiation versus hydrogen peroxide for room decontamination** UV devices and HP systems have their own advantages and disadvantages (Table 5),<sup>53</sup> and there is now ample evidence that these no-touch systems can reduce environmental contamination with health care–associated pathogens and reduce HAIs.<sup>84</sup> However, each specific marketed system should be studied and its efficacy demonstrated before being introduced into health care facilities. The main advantage of both types of units is their ability to achieve substantial reductions in vegetative bacteria. Another advantage is their ability to substantially reduce *C difficile* spores, as low-level disinfectants (such as quaternary ammonium compounds) have only limited or no measurable activity against spore-forming bacteria.<sup>85</sup> Both systems are residual free, and they decontaminate all exposed surfaces and equipment in the room.

Based on data that demonstrated a reduction of colonizations and/or infections associated with these technologies, the authors recommend they should be used for terminal room decontamination after discharge of patients on contact precautions. Because different UV and HP systems vary substantially, infection preventionists should review the peer-reviewed literature and the advantages/disadvantages of each technology (Box 1) and choose only devices with demonstrated bactericidal capability as assessed by carrier tests and/or the ability to disinfect actual patient rooms. Ultimately, one would select a device that also has demonstrated the ability to reduce HAIs.<sup>84</sup>

### ***Assessing Risk to Patients from Disinfection and Sterilization Failures***

---

Disinfection and sterilization are critical components of infection control. Unfortunately, breaches of disinfection and sterilization guidelines are not uncommon. Patient notifications due to improper reprocessing of semicritical (eg, endoscopes) and critical medical instruments have occurred regularly.<sup>7</sup> This referenced article also provides a method for assessing patient risk for adverse events, especially infection. Use of a 14-step algorithm (Box 2) can guide an institution in managing potential disinfection and sterilization failures.<sup>7,86</sup>

### ***Human Papilloma Virus***

---

Human papilloma virus is an extremely common sexually acquired infection and is the most important cause of cervical cancer. A 2014 article reported that the FDA-cleared high-level disinfectants (ie, glutaraldehyde, OPA) tested did not inactivate human papilloma virus, a nonenveloped virus.<sup>87</sup> These findings are inconsistent with many

**Table 5**  
**Clinical trials using ultraviolet or hydrogen peroxide devices for terminal room disinfection to reduce health care–associated infections**

Author, Year	Design	Setting	Modality Tested	Pathogens	Outcome (HAI)	Assessment of HH Compliance	Assessment of EVS Cleaning	Other HAI Prevention Initiatives
Boyce, 2008	Before-after (CDI high incidence wards)	Community hospital	HPV (Bioquell)	CDI	2.28–1.28 per 1000 Pt-days ( $P = .047$ )	No	No	NA
Cooper, 2011	Before-after (2 cycles)	Hospitals	HPV (NS)	CDI	Decreased cases (incidence NS)	No	No	Yes
Levin, 2013	Before-after	Community hospital	UV-PX, Xenex	CDI	9.46–4.45 per 10,000 Pt-days ( $P = .01$ )	No	No	Yes
Passaretti, 2013	Prospective cohort (comparison of MDRO acquisition; admitted to rooms with or without HPV decontamination)	Academic center	HPV (Bioquell)	MRSA VRE CDI MDRO-all	2.3–1.2 ( $P = .30$ ) 7.2–2.4 ( $P < .01$ ) 2.4–1.0 ( $P = .19$ ) 12.6–6.2 per 1000 Pt-days ( $P < .01$ )	No	No	No
Manian, 2013	Before-after	Community hospital	HPV (Bioquell)	CDI	0.88–0.55 cases per 1000 Pt-days ( $P < .0001$ )	Yes	No	No

(continued on next page)

**Table 5**  
**(continued)**

Author, Year	Design	Setting	Modality Tested	Pathogens	Outcome (HAI)	Assessment of HH Compliance	Assessment of EVS Cleaning	Other HAI Prevention Initiatives
Hass, 2014	Before-after	Academic center	UV-PX, Xenex	CDI MRSA VRE MDRO-GNB Total	0.79–0.65 per 1000 Pt-days ( $P = .02$ ) 0.45–0.33 per 1000 Pt-days ( $P = .007$ ) 0.90–0.73 per 1000 Pt-days ( $P = .002$ ) 0.52–0.42 per 1000 Pt-days ( $P = .04$ ) 2.67–2.14 per 1000 Pt-days ( $P < .001$ )	No	Yes	Yes
Mitchell, 2014	Before-after	Acute care hospital	Dry hydrogen peroxide vapor (Nocospray, New York City, NY)	MRSA (colonization and infection)	9.0–5.3 per 10,000 Pt-days ( $P < .001$ )	Yes	No	Yes
Miller, 2015	Before-after	Urban hospital	UV-PX, Xenex	CDI	23.3–8.3 per 10,000 Pt-days ( $P = .02$ )	No	No	Yes
Nagaraja, 2015	Before-after	Academic center	UV-PX, Xenex	CDI	1.06–0.83 per 1000 Pt-days ( $P = .06$ )	No	No	No
Pegues, 2015	Before-after	Academic center	UV-C (Optimum)	CDI	30.34–22.85 per 10,000 Pt-days (IRR = 0.49, 95% CI 0.26–0.94, $P = .03$ )	Yes	Yes	No
Anderson, 2015	RCT	9 Hospitals	UV-C (Tru-D)	MRSA, VRE, CDI	51.3–33.9 per 10,000 Pt-days ( $P = .036$ )	Yes	Yes	No

*Abbreviations:* CDI, *Clostridium difficile* infections; CI, confidence interval; EVS, environmental service; GNB, gram-negative bacteria; HH, hand hygiene; IRR, incidence rate ratio; MDRO, multidrug-resistant organism; NA, not applicable; NS, not stated; Pt, patient; RCT, randomized controlled trial; UV-PX, ultraviolet light, pulsed xenon device.

*Adapted from* Weber DJ, Rutala WA, Anderson DJ, et al. Effectiveness of UV devices and hydrogen peroxide systems for terminal room decontamination: focus on clinical trials. *Am J Infect Control* 2016;44(5 Suppl):e77–84.

**Box 1****Advantages and disadvantages of room decontamination by ultraviolet irradiation units and hydrogen peroxide<sup>1</sup> systems***Ultraviolet irradiation***Advantages**

- There is reliable biocidal activity against a wide range of health care–associated pathogens.
- Room surfaces and equipment are decontaminated.
- There is rapid room decontamination (~5–25 minutes) for vegetative bacteria, which reduces the downtime of the room before another patient can be admitted.
- It is demonstrated to reduce HAIs (eg, *C difficile*, MRSA).
- It is effective against *C difficile*, although requires longer exposure (~10–50 minutes).
- HVAC system does not need to be disabled and the room does not need to be sealed.
- UV is residual free and does not give rise to health or safety concerns.
- There are no consumable products, so costs include only capital equipment and staff time.
- There is good distribution in the room of UV energy via an automated monitoring system.

**Disadvantages**

- All patients and staff must be removed from the room before decontamination, thus, limiting use to terminal room decontamination.
- Decontamination can only be accomplished at terminal disinfection (ie, cannot be used for daily disinfection) as room must be emptied of people.
- Capital equipment costs are substantial.
- It does not remove dust and stains, which are important to patients and visitors; hence, cleaning must precede UV decontamination.
- It is sensitive to use parameters (eg, dose, distance, carrier or surface tested, exposure time, pathogen).
- It requires that equipment and furniture be moved away from the walls.

*HP systems***Advantages**

- It has reliable biocidal activity against a wide range of health care–associated pathogens.
- Room surfaces and equipment are decontaminated.
- It has been demonstrated to reduce HAIs (eg, *C difficile*, MRSA, VRE).
- It is useful for disinfecting complex equipment and furniture.
- It does not require that furniture and equipment be moved away from the walls.
- HP is residual free and does not give rise to health or safety concerns (aeration unit converts HP into oxygen and water).
- There is uniform distribution in the room via an automated dispersal system.

**Disadvantages**

- All patients and staff must be removed from the room before decontamination, thus, limiting use to terminal room decontamination.
- HVAC system must be disabled to prevent unwanted dilution of HP during use, and the doors must be closed with gaps sealed by tape.
- Decontamination can only be accomplished as terminal disinfection (ie, cannot be used for daily disinfection) as room must be emptied of people.
- Capital equipment costs are substantial.
- Decontamination requires approximately 2.0 to 5.0 hours.
- It does not remove dust and stains, which are important to patients and visitors; hence, cleaning must precede UV decontamination.
- It is sensitive to use parameters (eg, HP concentration, pathogen, exposure time).

*Abbreviation:* HVAC, heating, ventilation, and air conditioning.

*Adapted from* Rutala WA, Weber DJ. Disinfectants used for environmental disinfection and new room decontamination technology. *Am J Infect Control* 2013;41:S36–41.

**Box 2****Protocol for exposure investigation after the failure to follow disinfection and sterilization principles**

1. Confirm disinfection or sterilization reprocessing failure
2. Embargo any improperly disinfected or sterilized items
3. Do not use the questionable disinfection or sterilization unit (eg, sterilizer, automated endoscope reprocessor)
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether disinfection or sterilization failure increases patient risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection or sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of state and federal authorities
12. Consider patient notification
13. Develop long-term follow-up plan
14. Perform after-action report

*Adapted from* Rutala WA, Weber DJ. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Infect Control Hosp Epidemiol* 2007;28:146–55.

articles in the peer-reviewed literature, which demonstrates that high-level disinfectants, such as OPA and glutaraldehyde, inactivate nonenveloped viruses, such as hepatitis A virus, polio, adenovirus, norovirus, and so forth. Because the high-level disinfectants are commonly used to disinfect endocavitary probes (eg, vaginal probes, rectal probes), there is an urgency to corroborating these data. In a conversation with CDC staff regarding this issue, it was determined hospitals should continue to use the FDA-cleared high-level disinfectants consistent with the manufacturers' instructions until the data can be corroborated. Data have demonstrated the activity of a HP mist device to inactivate human papilloma virus.<sup>88</sup>

### ***Hydrogen Peroxide Mist System for Probes***

Although the most common way of performing HLD of contaminated endocavitary probes is by immersion in an FDA-cleared high-level disinfectant (eg, glutaraldehyde), an alternative procedure for disinfecting the endocavitary and surface probes is a HP mist system, which uses 35% HP at 56°C with the probe reaching no more than 40°C (ie, Trophon EPR, Nanosonics, Alexandria, Australia). In one study, the results demonstrated complete inactivation (>6- $\log_{10}$  reduction) of VRE and a CRE-*Klebsiella pneumoniae* strain both in the presence and absence of 5% fetal calf serum (FCS). The Trophon EPR system showed good, but not complete, inactivation of *Mycobacterium terrae* (5.2- $\log_{10}$  reduction for *M terrae* with FCS, a 4.6- $\log_{10}$  reduction for *M terrae* without FCS) and *C difficile* spores (5.1- $\log_{10}$  reduction for *C difficile* spores with FCS, 6.2- $\log_{10}$  reduction for *C difficile* spores without FCS).<sup>89</sup> To simulate a

worse-case condition, cleaning was not done before disinfection in these experiments; but proper cleaning of probes is necessary to ensure the success of high-level disinfection. Other data have demonstrated the activity of Trophon to inactivate human papilloma virus<sup>88</sup> and other pathogens (eg, bacteria, mycobacteria, viruses) including a greater than 6-log<sub>10</sub> reduction of *M terrae* and *C difficile* spores in carrier tests and a greater than 6-log<sub>10</sub> reduction in *M terrae* on inoculated ultrasound probes.<sup>90</sup> These results differ slightly from those presented earlier, presumably because of the differences in testing methodology. In the authors' study only the probe devices were inoculated (carriers of different materials were not tested); for recovery of bacteria on the probe, the probes were immersed in media (not swabbed, which would likely result in lower recovery).<sup>89</sup> The Trophon system processes the portion of the probe that has mucous membrane contact but also the handle of endocavitary probes, which may be contaminated; it is an alternative to high-level chemical disinfection for ultrasound probes.

### ***Do Not Reuse Single-Use Devices***

---

The Department of Justice and the FDA have joined forces in prosecuting health care providers that reuse single-use devices. For example, one physician was criminally prosecuted for reusing needle guides meant for single use during prostate procedures. These prosecutions are based on conspiracy to commit adulteration and Medicare fraud. Third-party reprocessing is allowed by the FDA as the reprocessor is considered the device manufacturer as defined under the Code of Federal Regulations Title 21 Part 820.

### ***Storage of Semicritical Items***

---

In 2011, The Joint Commission (TJC) recommended that laryngoscope blades be packaged in a way that prevents recontamination. Examples of compliant storage include, but are not limited to, a peel pouch or a closed plastic bag. Examples of non-compliant storage would include unwrapped blades in an anesthesia drawer as well as an unwrapped blade on top of or within a code cart. The packaging not only prevents recontamination but also distinguishes a processed from a nonprocessed semicritical item, such as a specula, laryngoscope blade, or endoscope. The use of a tagging system, in both inpatient and outpatient facilities,<sup>91</sup> that separates processed from non-processed items minimizes the risk that a nondisinfected, semicritical device would be used and potentially lead to cross-transmission of a pathogen.<sup>7</sup> This tagging system could involve a tag (eg, green tag, patient ready; red tag, requires reprocessing) for GI endoscopes or a plastic sheath or plastic-paper peel pouch (eg, endocavitary probes). Ideally, hospitals and ambulatory care facilities<sup>91</sup> (as appropriate) should develop a strategy (eg, tagging, storage covers for patient-ready devices) that prevents patient exposures to contaminated devices.

### ***Immersion Versus Perfusion of Channel Scopes Such as Cystoscopes***

---

In the United States, it is estimated that more than 4 million cystoscopies are performed each year.<sup>29,92</sup> Cystoscopy is a diagnostic procedure that uses an endoscope especially designed to examine the bladder, lower urinary tract, and prostate gland or is used to collect urine samples, perform biopsies, and remove small stones. A flexible or rigid scope can be used to carry out the procedure. Because the procedure, and other channeled scopes (eg, hysteroscopes, some nasopharyngoscopes), involves a medical device in contact with the patients' mucous membranes, it is considered a semicritical device that must minimally be high-level disinfected.

The authors recently evaluated the disinfection of cystoscopes, and their results demonstrated that disinfection (ie, a reduction in bacterial load of greater than

7-log<sub>10</sub> colony-forming unit [CFU]) did not occur unless the channel was actively perfused with the glutaraldehyde. In fact, failure to perfuse the channel led to only minimal, if any, reduction in bacterial contamination. However, complete inactivation of 10<sup>8</sup> CFU of both VRE and CRE was achieved when the channel was actively perfused. It seems that no high-level disinfectant entered the channel unless it was actively perfused, as the level of microbial contamination was not reduced by immersion.<sup>29</sup> This failure to perfuse the channel occurs because the air pressure in the channel is stronger than the fluid pressure at the fluid-air interface. Recommendations are provided for cystoscope HLD and include actively perfusing the device while immersed in the high-level disinfectant.<sup>93</sup> Unfortunately, some cystoscope reprocessing recommendations published in the literature are incorrect. For example, investigators have recommended complete immersion of the cystoscope into the high-level disinfectant but did not mention perfusion of the high-level disinfectant into the channel.<sup>94</sup>

### **Laryngoscopes**

---

Laryngoscopes are routinely used to view the vocal cords and larynx and facilitate airway management. It typically consists of a blade that connects to a handle, which usually contains 2 batteries that power the light source. Limited guidelines are available for reprocessing laryngoscope blades and handles, and hospital practices vary.<sup>95–97</sup> For example, some guidelines recommend and hospitals use low-level disinfection of the handle as it does not have direct contact with a mucous membrane, whereas others recommend the handle be high-level disinfected to prevent disease transmission. Although blades have been linked to HAIs, handles have not been directly linked to HAIs. However, reports of contamination with blood (40% of the handles positive for occult blood) and potentially pathogenic microorganisms (86% of the handles deemed ready for patient use were contaminated with pathogens, such as *S aureus*, *Acinetobacter*) suggest its potential,<sup>97–100</sup> and the blade and handle function together. For this reason, it is ideal that the blades and handles be high-level disinfected or sterilized even if a protective barrier or sheath is used during the procedure. In 2007, the state of California required that both blades and handles be HLD or sterilized. UNC Hospitals is sterilizing the blades and handles (ie, blades via HP gas plasma, handle [without batteries] by steam). Other methods for HLD or sterilization are acceptable, but one must ensure the blade and handle are compatible with the HLD or sterilization process chosen. After sterilization the blades and handles are checked for function before packaging and then packaged in a Ziploc bag. Per TJC, the laryngoscope blade and handle must be packaged in a way that prevents recontamination after processing (Frequently Asked Questions, The Joint Commission, October 24, 2011). Examples of compliant storage include, but are not limited to, a peel pack after sterilization (long-term storage) or wrapping in a sterile towel (short-term storage).

Recent advances in video technology have led to the development of video laryngoscopes, such as the GlideScope (Verathon Medical, Bothell, WA) and McGrath (Medtronic, Minneapolis, MN) video laryngoscopes.<sup>92</sup> These new intubation devices assist in difficult airway management. For the McGrath an image is displayed on a liquid-crystal display screen that is contained within a monitor mounted to the handle of the device. A sterile, single-use disposable laryngoscope blade covers the camera and light-emitting diode assembly to prevent direct patient contact. Even though a cover is used, HLD or sterilization via ETO or HP gas plasma (battery removed) is recommended for the McGrath MAC video laryngoscope.<sup>93</sup> The manufacturer states, whenever practical, a HLD or sterilization is preferred to a wipe-based process.

The portable GlideScope video laryngoscope system is available in a single-use and a reusable configuration. They should be cleaned and disinfected per the manufacturer's recommendations. The single-use system features a reusable video baton and sterile stats that must be disposed of immediately after use. Low-level disinfection is recommended for the video baton after each use using an Environmental Protection Agency-registered disinfectant (eg, antimicrobial disposable wipe per manufacturer's instructions) after each use. The manufacturer recommends HLD for the video baton when it is visibly soiled.

The manufacturer recommends that the advanced video laryngoscope reusable blade be high-level disinfected and the GlideRite rigid stylets be sterilized.<sup>101</sup>

### ***Emerging Pathogens, Antibiotic-Resistant Bacteria, and Bioterrorism Agents***

Emerging pathogens are of growing concern to the general public and infection control professionals. Relevant pathogens include Ebola,<sup>102</sup> MDR organisms such as CRE, Enterovirus D68, MDR pathogens, Middle East respiratory syndrome-Coronavirus, MDR *M tuberculosis*, human papilloma virus, norovirus, and nontuberculous mycobacteria (eg, *M chelonae*). The susceptibility of each of these pathogens to chemical disinfectants/sterilants has been studied; all of these pathogens (or surrogate microbes such as feline-calicivirus for Norwalk virus, vaccinia for variola,<sup>103</sup> and *Bacillus atrophaeus* [formerly *B subtilis*] for *B anthracis*) are susceptible to currently available chemical disinfectants/sterilants.<sup>19,104</sup> Standard sterilization and disinfection procedures for patient-care equipment (as recommended in this article) are adequate to sterilize or disinfect instruments or devices contaminated with blood or other body fluids from persons infected with blood-borne pathogens, emerging pathogens, and bioterrorism agents, with the exception of prions, HPV, and *C difficile* spores (see earlier discussion). No changes in current procedures for cleaning, disinfecting, or sterilizing need to be made.<sup>13</sup>

In addition, there are no data to show that antibiotic-resistant bacteria (MRSA, VRE, MDR *M tuberculosis*) are less sensitive to the liquid chemical germicides than antibiotic-sensitive bacteria at currently used germicide contact conditions and concentrations.<sup>105–107</sup>

### **SUMMARY**

When properly used, disinfection and sterilization can ensure the safe use of invasive and noninvasive medical devices. The method of disinfection and sterilization depends on the intended use of the medical device: critical items (contact sterile tissue) must be sterilized before use; semicritical items (contact mucous membranes or non-intact skin) must be high-level disinfected; and noncritical items (contact intact skin) should receive low-level disinfection. Cleaning should always precede HLD and sterilization. Current disinfection and sterilization guidelines must be strictly followed.

### **REFERENCES**

1. Centers for Disease Control and Prevention. National hospital discharge survey: 2010 table, procedures by selected patient characteristics-number by procedure category and age. 2010.
2. Peery AF, Dellon ES, Lund J, et al. Burden of gastrointestinal disease in the United States: 2012 update. *Gastroenterology* 2012;143:1179–87.
3. Epstein L, Hunter JC, Arwady MA, et al. New Delhi metallo-beta-lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. *JAMA* 2014;312:1447–55.



4. Wendorf KA, Kay M, Baliga C, et al. Endoscopic retrograde cholangiopancreatography-associated AmpC *Escherichia coli* outbreak. *Infect Control Hosp Epidemiol* 2015;36:634–42.
5. Ofstead CL, Wetzler HP, Snyder AK, et al. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. *Gastroenterol Nurs* 2010;33:304–11.
6. Kovaleva J, Peters FT, van der Mei HC, et al. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clin Microbiol Rev* 2013;26:231–54.
7. Rutala WA, Weber DJ. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Infect Control Hosp Epidemiol* 2007;28:146–55.
8. Weber DJ, Rutala WA. Lessons learned from outbreaks and pseudo-outbreaks associated with bronchoscopy. *Infect Control Hosp Epidemiol* 2012;33:230–4.
9. Centers for Disease Control and Prevention. Immediate need for healthcare facilities to review procedures for cleaning, disinfecting, and sterilizing reusable medical devices. 2015. Available at: <http://emergency.cdc.gov/han/han00382.asp>. Accessed 18 May, 2016.
10. Rutala WA, Weber DJ. Disinfection, sterilization and control of hospital waste. In: Bennett JE, Dolan R, Blaser MJ, editors. *Principles and practice of infectious diseases*. Philadelphia: Elsevier Saunders; 2015. p. 3294–309.
11. Rutala WA, Weber DJ. Disinfection, Sterilization and Antisepsis: An Overview. *Am J Infect Control* 2016;44:e1–66.
12. Rutala WA, Weber DJ. Cleaning, disinfection and sterilization. In: Grota P, editor. *APIC text of infection control and epidemiology*. 4th edition. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc.; 2014. p. 31.1–31.15.
13. Rutala WA, Weber DJ, HICPAC. Guideline for disinfection and sterilization in healthcare facilities, 2008. Atlanta (GA): Centers for Disease Control and Prevention; 2008. Available at: [http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection\\_Nov\\_2008.pdf](http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf).
14. Rutala WA, Weber DJ. Disinfection and sterilization in healthcare facilities. In: Han J, editor *Practical healthcare epidemiology*. 4th edition: University of Chicago Press, in press.
15. Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence C, Block SS, editors. *Disinfection, sterilization, and preservation*. Philadelphia: Lea & Febiger; 1968. p. 517–31.
16. Sehulster L, Chinn RYW, Healthcare Infection Control Practices Advisory Committee. Guidelines for environmental infection control in health-care facilities. *MMWR Morb Mortal Wkly Rep* 2003;52:1–44.
17. Rutala WA, Weber DJ. Disinfection and sterilization of prion-contaminated medical instruments, reply to Belay. *Infect Control Hosp Epidemiol* 2010;31:1306–7.
18. Rutala WA, Gergen MF, Weber DJ. Efficacy of a washer-disinfector in eliminating healthcare-associated pathogens from surgical instruments. *Infect Control Hosp Epidemiol* 2014;35:883–5.
19. Food and Drug Administration. FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices, March 2015. Available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm>. Accessed 19 May, 2016.

20. Rutala WA, Weber DJ. Disinfection and sterilization in healthcare facilities. In: Han J, ed. SHEA practical healthcare epidemiology University of Chicago Press.
21. Kohn WG, Collins AS, Cleveland JL, et al. Guidelines for infection control in dental health-care settings—2003. *MMWR Recomm Rep* 2003;52:1–61.
22. McDonnell G, Burke P. Disinfection: is it time to reconsider Spaulding? *J Hosp Infect* 2011;78:163–70.
23. Food and Drug Administration. Brief summary of the gastroenterology and urology devices panel meeting. 2015.
24. Rutala WA, Weber DJ. Gastrointestinal endoscopes: a need to shift from disinfection to sterilization? *JAMA* 2014;312:1405–6.
25. Rutala WA, Weber DJ. ERCP scopes: what can we do to prevent infections? *Infect Control Hosp Epidemiol* 2015;36:643–8.
26. Tosh PK, Disbot M, Duffy JM, et al. Outbreak of *Pseudomonas aeruginosa* surgical site infections after arthroscopic procedures: Texas, 2009. *Infect Control Hosp Epidemiol* 2011;32:1179–86.
27. Rutala WA, Gergen MF, Weber DJ. Microbial contamination on used surgical instruments. *Infect Control Hosp Epidemiol* 2014;35:1068–70.
28. Rutala WA, Gergen MF, Weber DJ. Disinfection of a probe used in ultrasound-guided prostate biopsy. *Infect Control Hosp Epidemiol* 2007;28:916–9.
29. Rutala WA, Gergen MF, Bringham J, et al. Effective high-level disinfection of cystoscopes: is perfusion of channels required? *Infect Control Hosp Epidemiol* 2016;37(2):228–31.
30. Rutala WA, Gergen MF, Weber DJ. Disinfection of an infrared coagulation device used to treat hemorrhoids. *Am J Infect Control* 2012;40:78–9.
31. Weber DJ, Rutala WA. Role of environmental contamination in the transmission of vancomycin-resistant enterococci. *Infect Control Hosp Epidemiol* 1997;18:306–9.
32. Weber DJ, Rutala WA, Miller MB, et al. Role of hospital surfaces in the transmission of emerging health care-associated pathogens: norovirus, *Clostridium difficile*, and *Acinetobacter* species. *Am J Infect Control* 2010;38:S25–33.
33. Weber DJ, Rutala WA, Sickbert-Bennett EE. Outbreaks associated with contaminated antiseptics and disinfectants. *Antimicrob Agents Chemother* 2007;51:4217–24.
34. Rutala WA, Cole EC, Thomann CA, et al. Stability and bactericidal activity of chlorine solutions. *Infect Control Hosp Epidemiol* 1998;19:323–7.
35. Petersen BT, Chennat J, Cohen J, et al. Multisociety guideline on reprocessing flexible GI endoscopes: 2011. *Infect Control Hosp Epidemiol* 2011;32:527–37.
36. Society of Gastroenterology Nurses and Associates I. Standards of infection control and reprocessing of flexible gastrointestinal endoscopes. *Gastroenterol Nurs* 2013;36:293–303.
37. Muscarella LF. Risk of transmission of carbapenem-resistant Enterobacteriaceae and related “superbugs” during gastrointestinal endoscopy. *World J Gastrointest Endosc* 2014;6:457–74.
38. Ofstead CL, Wetzler HP, Doyle EM, et al. Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines. *Am J Infect Control* 2015;43:794–801.
39. Carbonne A, Thiolet JM, Fournier S, et al. Control of a multi-hospital outbreak of KPC-producing *Klebsiella pneumoniae* type 2 in France, September to October 2009. *Euro Surveill* 2010;15 [pii:19734].

40. Roberts CG. Studies on the bioburden on medical devices and the importance of cleaning. In: Rutala WA, editor. *Disinfection, sterilization and antiseptics: principles and practices in healthcare facilities*. Washington, DC: Association for Professionals in Infection Control and Epidemiology; 2000. p. 63–9.
41. Alfa MJ, Degagne P, Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. *Am J Infect Control* 1999;27:392–401.
42. Rutala WA, Weber DJ. FDA labeling requirements for disinfection of endoscopes: a counterpoint. *Infect Control Hosp Epidemiol* 1995;16:231–5.
43. Food and Drug Administration. Brief summary of the gastroenterology and urology devices panel meeting, May 14-15, 2015. Available at: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ucm445590.htm>. Accessed 18 May, 2016.
44. Pajkos AVK, Cossart Y. Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination. *J Hosp Infect* 2004;58:224.
45. Roberts CG. The role of biofilms in reprocessing medical devices. In: WA R, editor. *Disinfection, sterilization and antiseptics: principles, practices, current issues, new research, and new technologies*. Washington, DC: Association for Professionals in Infection Control and Epidemiology; 2010. p. 223–9.
46. Neves MS, daSilva MG, Ventura GM, et al. Effectiveness of current disinfection procedures against biofilm on contaminated GI endoscopes. *Gastrointest Endosc* 2016;83(5):944–53.
47. Ren-Pei W, Hui-Jun X, Ke Q, et al. Correlation between the growth of bacterial biofilm in flexible endoscopes and endoscope reprocessing methods. *Am J Infect Control* 2014;42:1203–6.
48. Agrawal D, Muscarella LF. Delayed reprocessing of endoscopes. *Gastrointest Endosc* 2011;73:853–4.
49. Rutala WA, Weber DJ. Outbreaks of carbapenem-resistant *Enteriobacteriaceae* infections associated with duodenoscopes: what can we do to prevent infections? *Am J Infect Control* 2016;44(5 Suppl):e47–51.
50. Otter JA, Yezli S, French GL. The role played by contaminated surfaces in the transmission of nosocomial pathogens. *Infect Control Hosp Epidemiol* 2011;32:687–99.
51. Boyce JM. Environmental contamination makes an important contribution to hospital infection. *J Hosp Infect* 2007;65(Suppl 2):50–4.
52. Weber DJ, Anderson DJ, Sexton DJ, et al. Role of the environment in the transmission of *Clostridium difficile* in health care facilities. *Am J Infect Control* 2013;41:S105–10.
53. Rutala WA, Weber DJ. Disinfectants used for environmental disinfection and new room decontamination technology. *Am J Infect Control* 2013;41:S36–41.
54. Stiefel U, Cadnum JL, Eckstein BC, et al. Contamination of hands with methicillin-resistant *Staphylococcus aureus* after contact with environmental surfaces and after contact with the skin of colonized patients. *Infect Control Hosp Epidemiol* 2011;32:185–7.
55. Carling P. Methods for assessing the adequacy of practice and improving room disinfection. *Am J Infect Control* 2013;41:S20–5.
56. Huang SS, Datta R, Platt R. Risk of acquiring antibiotic-resistant bacteria from prior room occupants. *Arch Intern Med* 2006;166:1945–51.
57. Shaughnessy MK, Micielli RL, DePestel DD, et al. Evaluation of hospital room assignment and acquisition of *Clostridium difficile* infection. *Infect Control Hosp Epidemiol* 2011;32:201–6.

58. Donskey CJ. Does improving surface cleaning and disinfection reduce health care-associated infections? *Am J Infect Control* 2013;41:S12–9.
59. Carling PC, Bartley JM. Evaluating hygienic cleaning in health care settings: what you do not know can harm your patients. *Am J Infect Control* 2010;38:S41–50.
60. Boyce JM, Havill NL, Dumigan DG, et al. Monitoring the effectiveness of hospital cleaning practices by use of an adenosine triphosphate bioluminescence assay. *Infect Control Hosp Epidemiol* 2009;30:678–84.
61. Hota B, Blom DW, Lyle EA, et al. Interventional evaluation of environmental contamination by vancomycin-resistant enterococci: failure of personnel, product or procedure? *J Hosp Infect* 2009;71:123–31.
62. Goodman ER, Platt R, Bass R, et al. Impact of an environmental cleaning intervention on the presence of methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococci on surfaces in intensive care unit rooms. *Infect Control Hosp Epidemiol* 2008;29:593–9.
63. Eckstein BC, Adams DA, Eckstein EC, et al. Reduction of *Clostridium difficile* and vancomycin-resistant *Enterococcus* contamination of environmental surfaces after an intervention to improve cleaning methods. *BMC Infect Dis* 2007;7:61.
64. Leas BF, SN, Han JH, et al. Environmental cleaning for the prevention of healthcare-associated infection. Technical brief No. 22 (prepared by the ECRI Institute – Penn Agency for Healthcare Research and Quality. Available at: <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1951>. Accessed 18 May, 2016.
65. Huslage K, Rutala WA, Sickbert-Bennett E, et al. A quantitative approach to defining “high-touch” surfaces in hospitals. *Infect Control Hosp Epidemiol* 2010;31:850–3.
66. Huslage K, Rutala WA, Gergen MF, et al. Microbial assessment of high-, medium-, and low-touch hospital room surfaces. *Infect Control Hosp Epidemiol* 2013;34:211–2.
67. Memarzadeh F, Olmsted RN, Bartley JM. Applications of ultraviolet germicidal irradiation disinfection in health care facilities: effective adjunct, but not stand-alone technology. *Am J Infect Control* 2010;38:S13–24.
68. Nerandzic MM, Thota P, Sankar CT, et al. Evaluation of a pulsed xenon ultraviolet disinfection system for reduction of healthcare-associated pathogens in hospital rooms. *Infect Control Hosp Epidemiol* 2015;36:192–7.
69. Rutala WA, Gergen MF, Weber DJ. Room decontamination with UV radiation. *Infect Control Hosp Epidemiol* 2010;31:1025–9.
70. Rutala WA, Gergen MF, Tande BM, et al. Room decontamination using an ultraviolet-C device with short ultraviolet exposure time. *Infect Control Hosp Epidemiol* 2014;35:1070–2.
71. Nerandzic MM, Cadnum JL, Pultz MJ, et al. Evaluation of an automated ultraviolet radiation device for decontamination of *Clostridium difficile* and other healthcare-associated pathogens in hospital rooms. *BMC Infect Dis* 2010;10:197.
72. Boyce JM, Havill NL, Moore BA. Terminal decontamination of patient rooms using an automated mobile UV light unit. *Infect Control Hosp Epidemiol* 2011;32:737–42.
73. Boyce JM, Havill NL, Otter JA, et al. Impact of hydrogen peroxide vapor room decontamination on *Clostridium difficile* environmental contamination and transmission in a healthcare setting. *Infect Control Hosp Epidemiol* 2008;29:723–9.

74. French GL, Otter JA, Shannon KP, et al. Tackling contamination of the hospital environment by methicillin-resistant *Staphylococcus aureus* (MRSA): a comparison between conventional terminal cleaning and hydrogen peroxide vapour decontamination. *J Hosp Infect* 2004;57:31–7.
75. Bartels MD, Kristoffersen K, Slotsbjerg T, et al. Environmental methicillin-resistant *Staphylococcus aureus* (MRSA) disinfection using dry-mist-generated hydrogen peroxide. *J Hosp Infect* 2008;70:35–41.
76. Hall L, Otter JA, Chewins J, et al. Use of hydrogen peroxide vapor for deactivation of *Mycobacterium tuberculosis* in a biological safety cabinet and a room. *J Clin Microbiol* 2007;45:810–5.
77. Hardy KJ, Gossain S, Henderson N, et al. Rapid recontamination with MRSA of the environment of an intensive care unit after decontamination with hydrogen peroxide vapour. *J Hosp Infect* 2007;66:360–8.
78. Johnston MD, Lawson S, Otter JA. Evaluation of hydrogen peroxide vapour as a method for the decontamination of surfaces contaminated with *Clostridium botulinum* spores. *J Microbiol Methods* 2005;60:403–11.
79. Heckert RA, Best M, Jordan LT, et al. Efficacy of vaporized hydrogen peroxide against exotic animal viruses. *Appl Environ Microbiol* 1997;63:3916–8.
80. Klapes NA, Vesley D. Vapor-phase hydrogen peroxide as a surface decontaminant and sterilant. *Appl Environ Microbiol* 1990;56:503–6.
81. Bates CJ, Pearce R. Use of hydrogen peroxide vapour for environmental control during a *Serratia* outbreak in a neonatal intensive care unit. *J Hosp Infect* 2005; 61:364–6.
82. Shapay S, Machin K, Levi K, et al. Activity of a dry mist hydrogen peroxide system against environmental *Clostridium difficile* contamination in elderly care wards. *J Hosp Infect* 2008;70:136–41.
83. Falagas ME, Thomaidis PC, Kotsantis IK, et al. Airborne hydrogen peroxide for disinfection of the hospital environment and infection control: a systematic review. *J Hosp Infect* 2011;78:171–7.
84. Weber DJ, Rutala W, Anderson DJ, et al. Effectiveness of UV devices and hydrogen peroxide systems for terminal room decontamination: focus on clinical trials. *Am J Infect Control*, 2016.;44(5 Suppl):e77–e84.
85. Rutala WA, Weber DJ. Selection of the ideal disinfectant. *Infect Control Hosp Epidemiol* 2014;35:855–65.
86. Weber DJ, Rutala WA. Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Am J Infect Control* 2013;41:S67–71.
87. Meyers J, Ryndock E, Conway MJ, et al. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. *J Antimicrob Chemother* 2014;69(6): 1546–50.
88. Ryndock E, Robison R, Meyers C. Susceptibility of HPV 16 and 18 to high-level disinfectants indicated for semi-critical ultrasound probes. *J Med Virol* 2015; 88(6):1076–80.
89. Rutala WA, Gergen MF, Sickbert-Bennett EE. Effectiveness of a hydrogen peroxide mist (Tropon®) system in inactivating healthcare pathogens on surface and endocavitary probes. *Infect Control Hosp Epidemiol* 2016;37(5):613–4.
90. Vickery K, Gorgis VZ, Burdach J, et al. Evaluation of an automated high-level disinfection technology for ultrasound transducers. *J Infect Public Health* 2014;7:153–60.
91. Bringhurst J. Disinfection and sterilization in physician practices and specialty clinics. *Am J Infect Control* 2016;44:e63–7.

92. Rutala WA, Weber DJ. Reprocessing semicritical items: current issues and new technologies. *Am J Infect Control* 2016;44(5 Suppl):e53–62.
93. Anonymous. McGrath MAC video laryngoscope operator's manual. Available at: [https://www.physio-control.com/uploadedFiles/Physio85/Contents/Emergency\\_Medical\\_Care/Products/PreHospital/MAC%20EMS%20IFU.pdf](https://www.physio-control.com/uploadedFiles/Physio85/Contents/Emergency_Medical_Care/Products/PreHospital/MAC%20EMS%20IFU.pdf). Access 18 May, 2016.
94. Wendelboe AM, Bauchman J, Blossom DB, et al. Outbreak of cystoscopy related infections with *Pseudomonas aeruginosa*: New Mexico, 2007. *J Urol* 2008;180:588–92.
95. Muscarella LF. Recommendations to resolve inconsistent guidelines for the reprocessing of sheathed and unsheathed rigid laryngoscopes. *Infect Control Hosp Epidemiol* 2007;28:504–7.
96. Muscarella LF. Prevention of disease transmission during flexible laryngoscopy. *Am J Infect Control* 2007;35:536–44.
97. Muscarella LF. Reassessment of the risk of healthcare-acquired infection during rigid laryngoscopy. *J Hosp Infect* 2008;68:101–7.
98. Call TR, Auerbach FJ, Riddell SW, et al. Nosocomial contamination of laryngoscope handles: challenging current guidelines. *Anesth Analg* 2009;109:479–83.
99. Williams D, Dingley J, Jones C, et al. Contamination of laryngoscope handles. *J Hosp Infect* 2010;74:123–8.
100. Phillips RA, Monaghan WP. Incidence of visible and occult blood on laryngoscope blades and handles. *AANA J* 1997;65:241–6.
101. Anonymous. GlideScope. Available at: <http://www.verathon.com/assets/0900-4200-02-60.pdf>. Accessed 18 May, 2016.
102. Cook BWM, Cutts TA, Nikiforuk AM, et al. Evaluating environmental persistence and disinfection of the Ebola virus Makona variant. *Viruses* 2015;7:1975–86.
103. Klein M, DeForest A. The inactivation of viruses by germicides. *Chem Specialists Manuf Assoc Proc* 1963;49:116–8.
104. Rutala WA, Gergen MF, Weber DJ. Sporidicidal activity of a new low-temperature sterilization technology: the Sterrad 50 sterilizer. *Infect Control Hosp Epidemiol* 1999;20:514–6.
105. Rutala WA, Stiegel MM, Sarubbi FA, et al. Susceptibility of antibiotic-susceptible and antibiotic-resistant hospital bacteria to disinfectants. *Infect Control Hosp Epidemiol* 1997;18:417–21.
106. Anderson RL, Carr JH, Bond WW, et al. Susceptibility of vancomycin-resistant enterococci to environmental disinfectants. *Infect Control Hosp Epidemiol* 1997;18:195–9.
107. Rutala WA, Barbee SL, Aguiar NC, et al. Antimicrobial activity of home disinfectants and natural products against potential human pathogens. *Infect Control Hosp Epidemiol* 2000;21:33–8.