Cleaning, Disinfection, and Sterilization

Author(s): Chetan Jinadatha, MD, MPH

Department of Medicine, Central Texas Veterans Health Care System
Temple, TX
College of Medicine, Texas A&M Health Science Center
Bryan, TX

Angelia Bridges MPH, RNb CIC

Department of Research, Central Texas Veterans Healthcare System
Temple, TX

Published: February 23, 2018
Revised: December 22, 2020

Declarations of Conflicts of Interest: Chetan Jinadatha reports that he is the principal investigator on various projects that have been funded by Xenex Disinfection Services under a cooperative research and development agreement between the Department of Veterans Affairs and Xenex Disinfection Services. He is also the inventor of record for a patent pending technology named "Methods for organizing the disinfection of
one or more items contaminated with biological agents," which is owned by the Department of Veterans Affairs and has been licensed to Xenex Disinfection Services. He reports that he does not own shares, investments or partnerships in Xenex Disinfection Services or any other company relevant to the chapter. He also reports receiving funding from the National Institutes of Health/National Institute of Nursing Research, the Agency for Healthcare Research and Quality, and the Department of Veterans Affairs. Angelia Bridges reports no conflicts of interest.

Revision Note (December 2020)

On December 22, 2020, information pertaining to COVID-19 was added to this chapter; the rest of the chapter remains unchanged from the previous version. A complete chapter revision is in progress, but until we can bring that to you, we have added COVID-19 information to the following sections:

- **Coronavirus Disease 2019 (COVID-19)**

Two additional authors contributed to this update:

**Hosoon Choi, PhD**  
Department of Research, Central Texas Veterans Healthcare System  
Temple, TX

**Piyali Chatterjee, PhD**  
Department of Research, Central Texas Veterans Healthcare System  
Temple, TX

Declarations of Conflicts of Interest: Hosoon Choi reports no conflicts of interest. Piyali Chatterjee reports funding from Agency for Healthcare Research and Quality

Please note: The ongoing COVID-19 pandemic is causing evolving changes in national, state, and local guidelines related to infection prevention and control. While some of our content discusses COVID-19, please note that the APIC Text is intended as a fundamental
Abstract

All invasive procedures involve contact by a medical device or surgical instrument with a patient’s sterile tissue or mucous membranes. The level of disinfection or sterilization is dependent on the intended use of the object: critical (items that contact sterile tissue such as surgical instruments), semicritical (items that contact mucous membrane such as endoscopes), and noncritical (devices that contact only intact skin such as stethoscopes) items require sterilization, high-level disinfection, and low-level disinfection, respectively. Cleaning (the removal of foreign material) must always precede disinfection and sterilization. In addition, environmental cleaning and disinfection are also essential for maintaining a safe patient environment.

Key Concepts

- All invasive procedures involve contact by a medical device or surgical instrument with a patient’s sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic microbes leading to infection.

- The Spaulding Classification System divides medical equipment into three categories based on risk—critical, semicritical, and noncritical—and continues to be the primary principle that guides disinfection and sterilization processes. Environmental surfaces have been designated as a fourth category by the Association for the Advancement of Medical Instruments (AAMI).

- Cleaning is the removal of foreign material (e.g., soil, organic material) from objects and is required before disinfection and sterilization can occur since these materials interfere with the effectiveness of these processes.

- Failure to properly disinfect or sterilize equipment after cleaning may lead to transmission via contaminated medical and surgical devices.

- Environmental decontamination plays an important role in
decreasing bioburden, which may help lower rates of healthcare-associated infections. Environmental surfaces include noncritical items as designated by the Spaulding Classification System as well as high-touch surfaces such as countertops, bedrails, and tray tables.

- This chapter capsulizes other papers on this subject as well as provides updated information of newer sterilization (e.g., hydrogen peroxide vapor, ozone) and disinfection (e.g., ultraviolet light, improved hydrogen peroxide, copper surfaces) technologies.

Background

More than 45 years ago, Earle H. Spaulding devised a rational approach to disinfection and sterilization of patient care items and equipment. This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization. Spaulding believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into three categories based on the degree of risk of infection involved in the use of the items. The three categories he described were critical (enters sterile tissue and must be sterile), semicritical (contacts mucous membranes and requires high-level disinfection), and noncritical (comes in contact with intact skin and requires low-level disinfection). These categories and the methods to achieve sterilization, high-level disinfection, and low-level disinfection are summarized in Table 31-1.

Table 31-1 Methods for Disinfection and Sterilization of Patient-Care Items and Environmental Surfaces

<table>
<thead>
<tr>
<th>Process</th>
<th>Level of Microbial Inactivation</th>
<th>Method</th>
<th>Examples (with processing times)</th>
<th>Healthcare Application (examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization</td>
<td>Destroys all microorganisms, including bacterial spores</td>
<td>High temperature</td>
<td>Steam (~40 min), dry heat (1-6 hr depending on temperature)</td>
<td>Heat-tolerant critical (surgical instruments) and semicritical patient-care</td>
</tr>
<tr>
<td>Method</td>
<td>Sterilization Process</td>
<td>Sterilization Type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low temperature</td>
<td>Ethylene oxide gas (~15 hr), hydrogen peroxide gas plasma (28-52 min), ozone (~4 hr), hydrogen peroxide vapor (55 min)</td>
<td>Heat-sensitive critical and semicritical patient-care items</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquid immersion</td>
<td>Chemical sterilants include*: &gt;2% glut (~10 hr); 1.12% glut with 1.93% phenol (12 hr); 7.35% HP with 0.23% PA (3 hr); 8.3% HP with 7.0% PA (5 hr); 7.5% HP (6 hr); 1.0% HP with 0.08% PA (8 hr); &gt;0.2% PA (12 min at 50-56°C)</td>
<td>Heat-sensitive critical and semicritical patient-care items that can be immersed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High-level disinfection (HLD)</td>
<td>Destroys all microorganisms except high numbers of bacterial spores</td>
<td>Heat-automated Pasteurization (65-77°C, 30 min)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Liquid immersion Chemical sterilants/HLDs include*: &gt;2% glut (10-90 min); 0.55% OPA (12 min); 1.12% glut with 1.93% phenol (20 min); 7.35% HP with 0.23% PA (15 min); 7.5% HP (30 min); 1.0% HP with 0.08% PA (25 min); 650-675 ppm chlorine (10 min);</td>
<td>Heat-sensitive semicritical items (e.g., GI endoscopes, bronchoscopes, endocavitary probes)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Intermediate-level disinfection

Destroys vegetative bacteria, mycobacteria, most viruses, most fungi but not bacterial spores

<table>
<thead>
<tr>
<th>Technique</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid contact</td>
<td>EPA-registered hospital disinfectant with label claim regarding tuberculocidal activity (e.g., chlorine-based products, phenolics, improved hydrogen peroxide-exposure times at least 1 min)</td>
</tr>
<tr>
<td></td>
<td>Noncritical patient care item (blood pressure cuff or surface with visible blood)</td>
</tr>
</tbody>
</table>

## Low-level disinfection

Destroys vegetative bacteria, some fungi and viruses but not mycobacteria or spores

<table>
<thead>
<tr>
<th>Technique</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid contact</td>
<td>EPA-registered hospital disinfectant with no tuberculocidal claim (e.g., chlorine-based products, phenolics, improved hydrogen peroxide, quaternary ammonium compounds-exposure times at least 1 min) or 70-90% alcohol</td>
</tr>
<tr>
<td></td>
<td>Noncritical patient care item (blood pressure cuff or surface (bedside table with no visible blood)</td>
</tr>
</tbody>
</table>

Modified from various publications.

*Consult the FDA-cleared package insert for information about the cleared contact time and temperature, and see reference 1 for discussion on why one product is used at a reduced exposure time (2% glutaraldehyde at 20 min, 20°C). Increasing the temperature using an automated endoscope reprocess (AER) will reduce the contact time (e.g., OPA 12 min at 20°C but 5 min at 25°C in AER). Exposure temperatures for some high-level disinfectants above vary from 20°C to 25°C; check FDA-cleared temperature conditions. Tubing must be
completely filled for high-level disinfection and liquid chemical sterilization. Material compatibility should be investigated when appropriate (e.g., HP and HP with PA will cause functional damage to endoscopes).

**Abbreviations:** glut, glutaraldehyde; HP, hydrogen peroxide; PA, peracetic acid; OPA, ortho-phthalaldehyde; ppm, parts per million; EPA, Environmental Protection Agency; FDA, Food and Drug Administration; GI, gastrointestinal.

### Basic Principles

#### CLEANING

The cleaning process for critical and semicritical devices should begin as soon as possible after use. Gross debris should be removed by wiping or irrigation as indicted by the instrument manufacturer's instructions for use. Removal of gross contamination prevents the drying of blood and tissue, reduces the bioburden and nutrient material on medical instruments, and reduces the possibility of spillage or aerosolizing of contaminants into the environment. 11

Instruments opened but unused during a procedure should also be considered contaminated and reprocessed accordingly 11. If soiled materials become dried or baked onto the instruments the removal process becomes more difficult and the disinfection or sterilization process becomes less effective or ineffective. Instruments should be kept moist after the initial removal of gross contamination and prior to transport for additional cleaning, disinfection, and sterilization. This can be accomplished by using special containers, a pretreatment product, or towels moistened with water (but not saline). 11

Contaminated reusable items should be separated from single-use disposable items and medical waste and handled as little as possible to reduce the potential for hazardous exposure. Reusable items should be transported from the point of use to the reprocessing area in closable, puncture-resistant, leak-proof containers that are properly marked as a biohazard. Standard Precautions should always be adhered to when handling contaminated medical equipment. 11 12

Contaminated items should be transported to a decontamination area where they must be thoroughly cleaned and decontaminated using
water with detergents or enzymatic cleaners. Cleaning and rinsing is the most important step in the reusable medical equipment process. Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process by acting as a barrier to the sterilization agent.

Thorough cleaning is required for all equipment before high-level disinfection and sterilization.

Instrument cleaning is done manually when the use area does not have a mechanical unit (e.g., ultrasonic cleaner or washer-disinfector) or for fragile or difficult-to-clean instruments. If cleaning is done manually, the two essential components are friction and fluidics. Using friction (e.g., rubbing/scrubbing the soiled area with a brush) is an old and dependable method. Brush selection should be based on the manufacturer's instructions for use. (Refer to 108, Sterile Processing for additional information on brushes.) Fluidics (i.e., fluids under pressure) is used to remove soil and debris from internal channels after brushing and when the design does not allow the passage of a brush through a channel. When using a washer-disinfector, care should be taken as to the method of loading instruments. Hinged instruments should be opened fully to allow adequate contact with the detergent solution. The stacking of instruments in washers should be avoided. Instruments should be disassembled as much as possible.

The most common types of mechanical or automatic cleaners include ultrasonic cleaners, washer-decontaminators, washer-disinfectors, and washer-sterilizers. Ultrasonic cleaning removes soil by a process called cavitation and implosion in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces. Bacterial contamination may be present in used ultrasonic cleaning solutions (and other used detergent solutions) as these solutions generally do not make antibacterial label claims. While ultrasound alone does not cause significant inactivation of bacteria, sonication can act synergistically to increase the cidal efficacy of a disinfectant. Users of ultrasonic cleaners should be aware that the cleaning fluid could result in endotoxin contamination of surgical instruments that could cause severe inflammatory reactions. Washer-sterilizers are modified steam sterilizers that clean by filling the chamber with water and detergent.
through which steam is passed to provide agitation. Instruments are subsequently rinsed and subjected to a short steam sterilization cycle. Another washer-sterilizer employs rotating spray arms for a wash cycle followed by a steam sterilization cycle at 285°F. 1 24 25 Washer-decontaminators/disinfectors act like a dishwasher that uses a combination of water circulation and detergents to remove soil. These units sometimes have a cycle that subjects the instruments to a heat process (e.g., 93°C for 10 minutes). 26 Washer-disinfectors are generally computer-controlled units for cleaning, disinfecting, and drying solid and hollow surgical and medical equipment. In one study, cleaning (measured as 5- to 6-log reduction) was achieved on surfaces that were adequately in contact with the water flow in the machine. 27 Washer-pasteurizers expose instruments to hot water for 30 minutes at a temperature of ~70° and are typically used in the reprocessing of respiratory therapy equipment. 11

Detailed information on cleaning and preparation of supplies for terminal sterilization is provided by professional organizations and books. 28 29 30 Studies have shown that manual and mechanical cleaning of endoscopes achieves a 4- to 6-log reduction of contaminating organisms. 14 16 31 32 Thus, cleaning alone is very effective in reducing the number of microorganisms present on contaminated equipment. When manual methods were compared to automated methods for cleaning reusable accessory devices used for minimally invasive surgical procedures, the automated method was more efficient and achieved a more than 99 percent reduction in soil parameters (e.g., protein, carbohydrate, hemoglobin) in both ported and nonported laparoscopic devices. 30

The best choice for instrument cleaning is neutral or near-neutral pH detergent solutions, as these solutions generally provide the best material compatibility profile and good soil removal. Enzymes, usually proteases, are sometimes added to neutral pH solutions to assist in the removal of organic material. Enzymes in these formulations attack proteins that make up a large portion of common soil (e.g., blood, pus). Cleaning solutions can also contain lipases (enzymes active on fats) and amylases (enzymes active on starches). Enzymatic cleaners are not disinfectants and proteinaceous enzymes may be inactivated by germicides. Like all chemicals, enzymes must be rinsed from the equipment or adverse reactions (e.g., fever) could result. 31 Enzyme
solutions should be used in accordance with the manufacturer’s instructions. Detergent enzymes may be associated with asthma or other allergic effects in users. Neutral pH detergent solutions that contain enzymes are compatible with metals and other materials used in medical instruments and are the best choice for cleaning delicate medical instruments, especially flexible endoscopes. Alkaline-based cleaning agents are used for processing medical devices as they dissolve protein and fat residues efficiently; however, they may be corrosive. Some data demonstrate that enzymatic cleaners are more effective cleaners than neutral detergents in removing microorganisms from surfaces but two studies found no difference in cleaning efficiency between enzymatic and alkaline-based cleaners.

A new nonenzyme, hydrogen peroxide-based formulation was as effective as an enzymatic cleaner in removing protein, blood, carbohydrate, and endotoxin from surface test carriers. In addition, this product was able to affect a 5-log reduction in microbial loads with a 3-minute exposure at room temperature. Validation of the cleaning processes in a laboratory testing program is possible by microorganism detection, chemical detection for organic contaminants (e.g., protein), radionuclide tagging, and chemical detection for specific ions. Data have been published describing the use of an artificial soil, protein, endotoxin, x-ray contrast medium, or blood to verify the manual or automated cleaning process and adenosine triphosphate (ATP) bioluminescence, fluorescence, and microbiologic sampling to evaluate the effectiveness of environmental surface cleaning. Although ATP has been used to assess manual cleaning adequacy of flexible endoscope channels, it has not been supported by epidemiological data to reduce infection risk or levels of microbial contamination that can cause disease. Rapid indicator testing can be incorporated into a quality assurance program; however manufacturers of ATP devices use varying scales for measuring and benchmarking effectiveness. At a minimum, all instruments should be individually inspected and be visibly clean prior to high-level disinfection or sterilization.

CRITICAL ITEMS

Critical items are objects or instruments that must be free of any microorganisms, including bacterial spores, when they enter sterile
tissue, bone, or the vascular system in order not to introduce microorganisms into the site resulting in an infection or disease. Thus, it is critical that objects that enter sterile tissue or the vascular system are sterile because any microbial contamination could result in disease transmission. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. The items in this category should be purchased as sterile or be steam sterilized prior to use. Steam sterilization under pressure is one of the oldest and most effective methods for sterilization and is the preferred method for the sterilization of critical medical equipment. If the item is heat-sensitive and cannot be steam sterilized, the object may be sterilized with ethylene oxide (ETO), hydrogen peroxide gas plasma, ozone, vaporized hydrogen peroxide, or liquid chemical sterilants. Tables 31-1, 31-2, and 31-3 list sterilization processes and liquid chemical sterilants as recommended by the manufacturer’s instructions for use.

Liquid chemical sterilants, with the exception of 0.2 percent peracetic acid (12 minutes at 50 to 56°C) have indicated exposure times that range from 3 to 12 hours. After effective cleaning eliminating organic and inorganic material, liquid chemical sterilants can be relied upon to produce sterility only if cleaning under proper guidelines as to concentration, contact time, temperature, and pH is performed. Another limitation to the use of liquid chemical sterilants is that the devices cannot be wrapped during processing, creating a challenge for maintaining sterility after processing and during storage. Furthermore, devices require rinsing following processing with liquid chemical sterilants. The type of water, either sterile or filtered, should be determined by the manufacturer’s instructions for use with both the device and the liquid chemical being used. Therefore, due to the inherent limitations of using liquid chemical sterilants for sterilization, their use should be restricted to reprocessing critical devices that are heat-sensitive and incompatible with other sterilization methods.

Table 31-2 Summary of Advantages and Disadvantages of Chemical Agents Used as Chemical Sterilants* or as High-level Disinfectants

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| Peracetic acid/hydrogen peroxide | • No activation required  
|                               | • Odor or irritation not significant               | • Material compatibility concerns (lead, brass, copper, zinc) both cosmetic and functional  
<p>|                               |                                                   | • Limited clinical                                           |</p>
<table>
<thead>
<tr>
<th>Chemical</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>- Numerous use studies published</td>
<td>- Respiratory irritation from glutaraldehyde vapor</td>
</tr>
<tr>
<td></td>
<td>- Relatively inexpensive</td>
<td>- Pungent and irritating odor</td>
</tr>
<tr>
<td></td>
<td>- Excellent material compatibility</td>
<td>- Relatively slow mycobactericidal activity (unless other disinfectants added such as phenolic, alcohol)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Coagulates blood and fixes tissue to surfaces</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Allergic contact dermatitis</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>- No activation required</td>
<td>- Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional</td>
</tr>
<tr>
<td></td>
<td>- May enhance removal of organic matter and organisms</td>
<td>- Serious eye damage with contact</td>
</tr>
<tr>
<td></td>
<td>- No disposal issues</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- No odor or irritation issues</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Does not coagulate blood or fix tissues to surfaces</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Inactivates Cryptosporidium</td>
<td></td>
</tr>
<tr>
<td>Ortho-phthalaldehyde (OPA)</td>
<td>- Fast acting high-level disinfectant</td>
<td>- Stains protein gray (e.g., skin, mucous membranes, clothing, and environmental surfaces)</td>
</tr>
<tr>
<td></td>
<td>- No activation required</td>
<td>-Limited clinical experience</td>
</tr>
<tr>
<td></td>
<td>- Odor not significant</td>
<td>- More expensive than glutaraldehyde</td>
</tr>
<tr>
<td></td>
<td>- Excellent materials compatibility claimed</td>
<td>- Eye irritation with contact</td>
</tr>
<tr>
<td></td>
<td>- Does not coagulate blood or fix tissues to surfaces claimed</td>
<td>- Slow sporicidal activity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Anaphylactic reactions to OPA in bladder cancer patients with repeated exposure to OPA through cystoscopy</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>- Rapid sterilization cycle time (30-45 min)</td>
<td>- Potential material incompatibility (e.g., aluminum anodized coating becomes dull)</td>
</tr>
<tr>
<td></td>
<td>- Low temperature (50-55°C) liquid immersion sterilization</td>
<td>- Used for immersible instruments only</td>
</tr>
<tr>
<td></td>
<td>- Environmental friendly by-products (acetic acid, O₂,</td>
<td>- Biological indicator may</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
H₂O₂
- Fully automated
- Single-use system eliminates need for concentration testing
- Standardized cycle
- May enhance removal of organic material and endotoxin
- No adverse health effects to operators under normal operating conditions
- Compatible with many materials and instruments
- Does not coagulate blood or fix tissues to surfaces
- Sterilant flows through scope facilitating salt, protein, and microbe removal
- Rapidly sporicidal
- Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)

<table>
<thead>
<tr>
<th>Improved hydrogen peroxide (2.0%)</th>
<th>Material compatibility concerns due to limited clinical experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>No activation required</td>
<td>Organic material resistance concerns due to limited data</td>
</tr>
<tr>
<td>No odor</td>
<td></td>
</tr>
<tr>
<td>Non-staining</td>
<td></td>
</tr>
<tr>
<td>No special venting requirements</td>
<td></td>
</tr>
<tr>
<td>Manual or automated applications</td>
<td></td>
</tr>
<tr>
<td>12-month shelf life, 14-day reuse</td>
<td></td>
</tr>
<tr>
<td>8 min at 20°C high-level disinfectant claim</td>
<td></td>
</tr>
</tbody>
</table>

Modified from several papers. 1 3 4

*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 above characteristics are documented in the literature; contact the manufacturer of the instrument and sterilant for additional information. All products listed above are FDA-cleared as chemical sterilants except OPA, which is an FDA-cleared high-level disinfectant.
**SEMICRITICAL ITEMS**

Semicritical items are those that come in contact with mucous membranes or nonintact skin. This category includes respiratory therapy and anesthesia equipment, gastrointestinal endoscopes, bronchoscopes, laryngoscopes, esophageal manometry probes, anorectal manometry catheters, endocavitary probes (e.g., rectal and vaginal probes), prostate biopsy probes, infrared coagulation devices, and diaphragm fitting rings. These medical devices should be free of all microorganisms (i.e., 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, generally are resistant to infection by common bacterial spores but are susceptible to other organisms such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, improved hydrogen peroxide, peracetic acid with hydrogen peroxide, and chlorine-based products are cleared by the U.S. Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the correct parameters for time and temperatures are met (Tables 31-1 and 31-2). The exposure time for most high-level disinfectants varies from 8 to 45 minutes at 20° to 25°C. (Refer to 56. Endoscopy for additional information on reprocessing of endoscopes.)

Since semicritical equipment has been associated with reprocessing errors resulting in patient lookback and patient notifications, it is essential that control measures be instituted to prevent patient exposures. Before new equipment is used for patient care on more than one patient, reprocessing procedures for that equipment should be developed. Staff should receive competency training and evaluation on the safe use and reprocessing of the equipment. Infection prevention rounds or audits should be conducted at least annually in all clinical areas that reprocess critical and semicritical devices to ensure adherence to the reprocessing standards and policies. The Infection Prevention and Control Assessment Tool for Acute Care Hospitals created by the Centers for Disease Control and

---

**Abbreviations:** AER, automated endoscope reprocessor; FDA, U.S. Food and Drug Administration; HLD, high-level disinfectant.
Prevention (CDC) contains a comprehensive section on evaluating a device reprocessing program. This document can be accessed at: https://www.cdc.gov/infectioncontrol/pdf/icar/hospital.pdf.

Results of infection prevention rounds should be provided to the unit managers, deficiencies in reprocessing should be corrected, and the corrective measures should be documented to infection prevention within a few days after rounding based on facility policy and procedure.

Table 31-3 Summary of Advantages and Disadvantages of Commonly Used Sterilization Technologies

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>● Nontoxic to patient, staff, environment</td>
<td>● Deleterious for heat-sensitive instruments</td>
</tr>
<tr>
<td></td>
<td>● Cycle easy to control and monitor</td>
<td>● Microsurgical instruments damaged by repeated exposure</td>
</tr>
<tr>
<td></td>
<td>● Rapidly micobicidal</td>
<td>● May leave instruments wet, causing them to rust</td>
</tr>
<tr>
<td></td>
<td>● Least affected by organic/inorganic soils among sterilization processes listed</td>
<td>● Potential for burns</td>
</tr>
<tr>
<td></td>
<td>● Rapid cycle time</td>
<td></td>
</tr>
<tr>
<td></td>
<td>● Penetrates medical packing, device lumens</td>
<td></td>
</tr>
<tr>
<td>Hydrogen peroxide gas plasma</td>
<td>● Safe for the environment</td>
<td>● Cellulose (paper), linens, and liquids cannot be processed</td>
</tr>
<tr>
<td></td>
<td>● Leaves no toxic residuals</td>
<td>● Endoscope or medical device restrictions based on lumen internal diameter and length (see manufacturer’s recommendations)</td>
</tr>
<tr>
<td></td>
<td>● Cycle time is ≥28 minutes and no aeration necessary</td>
<td>● Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and special container tray</td>
</tr>
<tr>
<td></td>
<td>● Used for heat- and moisture-sensitive items since process temperature &lt;50°C</td>
<td>● Hydrogen peroxide may be toxic at levels greater than 1 ppm TWA</td>
</tr>
<tr>
<td></td>
<td>● Simple to operate, install (208 V outlet), and monitor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>● Compatible with</td>
<td></td>
</tr>
<tr>
<td>Method</td>
<td>Advantages</td>
<td>Disadvantages</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>100% Ethylene oxide (ETO)</td>
<td>- Penetrates packaging materials, device lumens</td>
<td>- Requires aeration time to remove ETO residue</td>
</tr>
<tr>
<td></td>
<td>- Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure</td>
<td>- ETO is toxic, a carcinogen, and flammable</td>
</tr>
<tr>
<td></td>
<td>- Simple to operate and monitor</td>
<td>- ETO emission regulated by states but catalytic cell removes 99.9% of ETO and converts it to CO₂ and H₂O</td>
</tr>
<tr>
<td></td>
<td>- Compatible with most medical materials</td>
<td>- ETO cartridges should be stored in flammable liquid storage cabinet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Lengthy cycle/aeration time</td>
</tr>
<tr>
<td>ETO mixtures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.6% ETO/91.4% HCFC</td>
<td>- Penetrates medical packaging and many plastics</td>
<td>- Some states (e.g., CA, NY, MI) require ETO emission reduction of 90-99.9%</td>
</tr>
<tr>
<td>10% ETO/90% HCFC</td>
<td>- Compatible with most medical materials</td>
<td>- CFC (inert gas that eliminates explosion hazard) banned in 1995</td>
</tr>
<tr>
<td>8.5% ETO/91.5% CO₂</td>
<td>- Cycle easy to control and monitor</td>
<td>- Potential hazards to staff and patients</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Lengthy cycle/aeration time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- ETO is toxic, a carcinogen, and flammable</td>
</tr>
<tr>
<td>Vaporized hydrogen peroxide</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Safe for the environment and health care worker</td>
<td>- Medical devices restrictions based on lumen internal diameter and length—see manufacturer’s recommendations, e.g., stainless steel lumen 1 mm diameter, 125 mm length</td>
</tr>
<tr>
<td></td>
<td>- It leaves no toxic residue; no aeration necessary</td>
<td>- Not used for liquid, linens, powders, or any cellulose materials</td>
</tr>
<tr>
<td></td>
<td>- Fast cycle time, 55 min</td>
<td>- Requires synthetic packaging (polypropylene)</td>
</tr>
<tr>
<td></td>
<td>- Used for heat and moisture sensitive items (metal and nonmetal devices)</td>
<td>- Limited materials compatibility data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Limited clinical use and comparative microbicidal efficacy data</td>
</tr>
<tr>
<td>Ozone</td>
<td>- Used for moisture and heat-sensitive</td>
<td>- Limited clinical use (no published data on material)</td>
</tr>
</tbody>
</table>
Noncritical patient care 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." Noncritical items can be divided into two categories: noncritical patient care equipment such as stethoscopes, bedpans, blood pressure cuffs, crutches, bed rails, poles, monitors, wheelchairs, and linens; and noncritical environmental surfaces such as counters, sinks, bedside tables, patient furniture, and floors. In contrast to critical and some semicritical items, most noncritical reusable patient care items may be cleaned and disinfected where they are used and do not need to be transported to a central processing area. Although there is virtually no documented risk of transmitting infectious agents to patients via noncritical items when they are used as noncritical items and do not contact nonintact skin and/or mucous membranes, several studies have shown that portable noncritical patient care equipment such as stethoscopes and blood pressure cuffs may be contaminated with a concerning level of pathogenic organisms.  

Similarly, contamination has been found on noncritical high-touch environmental surfaces (e.g., bedside tables, computers) even after environmental cleaning. These items could potentially contribute to secondary transmission by direct contact between patients and the equipment.
or by contaminating hands of healthcare personnel that subsequently come in contact with the equipment and multiple patients. 56 57 58 60

Noncritical reusable medical equipment should be cleaned on a regular schedule with an approved low-level disinfectant based on the manufacturer’s recommendations for use including dwell or contact time. 1 Table 31-1 lists several low-level disinfectants that may be used for noncritical items.

**Special Considerations for Sterilization and Disinfection**

**HOW CLEAN IS CLEAN?**

The Association for the Advancement of Medical Instrumentation (AAMI) has proposed the use of < 6.4 µg/cm² as the benchmark for residual protein on medical and surgical instruments following cleaning of an instrument prior to sterilization. 2 11 Additional benchmarks for flexible endoscopes are: protein, < 6.4ug/cm²; carbohydrate, < 1.8 ug/cm²; hemoglobin, < 2.2 ug.cm²; sodium ion, < 1 µmole/cm²; endotoxin, < 2.2.EU/cm²; and ATP, 200 relative light units (RLU include 1.8ug/cm2, however ATP levels vary by manufacturer). 11 While there have been experiments that demonstrate the effectiveness of cleaning in eliminating or reducing many components of soil (e.g., protein, carbohydrate, hemoglobin, endotoxin, microorganisms), investigators have not assessed if the components of soil (e.g., protein) that remain on the instrument interferes with sterilization or poses a risk of infection to patients. 37

In addition, there are no "real time" tests that can be performed in central processing areas that reliably determine a certain protein load (< 6.4 µg/cm²). While the presence of residual protein can be quantitatively assessed by many methods (e.g., ninhydrin, OPA method, chemical analysis, micro bicinchoninic acid test kit) none of these methods can be easily applied to determine protein residues in central processing by staff. 19

Additionally, before a test soil component (e.g., protein) is accepted as a good component for monitoring the cleaning efficacy of manual and automated washers, three other criteria should be met. First, the soil component cleaning criteria should be achievable using standard
cleaning protocols and manufacturer's instructions for use using a wide range of surgical instruments. Very few studies have measured the soil load on surgical instruments and the studies done have been done in a research setting by research staff. This is a significant consideration because North American hospitals do not conduct analytical monitoring of cleaning efficacy of instruments and do not know if the criteria set for soil are achievable. Second, the soil load on surgical instruments has not been sufficiently characterized to assess both the concentration and whether another component of soil is a better marker of cleaning efficacy and sterilization failure. For example, Alfa and colleagues found that the level of carbohydrate and endotoxin on instruments post cleaning was higher than that detected immediately after the patient procedure before cleaning. Is protein the best marker of cleaning adequacy, or are endotoxin, total organic carbon, carbohydrate, and/or hemoglobin more relevant parameters? Third, there are no scientific studies that demonstrate that protein load greater than 6.4 µg/cm² interferes with steam sterilization or poses an infection risk to patients. Further studies are needed to answer these important questions.

CLEANING THROUGH LOCAL VERSUS CENTRAL REPRESSING AREAS

The cleaning stage of instrument reprocessing has come under increased scrutiny due to the complexity of surgical instruments and the recognition that cleaning in local decontamination units may not be comparable to reprocessing in central processing areas. In general, central processing areas offer several advantages to include validated and specialized reprocessing equipment (e.g., washer-disinfectors) and persons that specialize in instrument reprocessing (preferably certified instrument reprocessing technicians). Local reprocessing offers the advantages of faster instrument turnaround, less instrument loss, and lower instrument inventory. In one study, instruments reprocessed by the central decontamination unit (median 21 µg/instrument) had significantly less residual protein than instruments reprocessed by the local decontamination unit (median 117 µg/instrument). Periodic inspections for quality and infection prevention purposes are recommended for all areas where equipment is reprocessed.

BIOFILMS
Microorganisms may be protected from disinfectants due to the production of thick masses of cells and extracellular materials or biofilms. Biofilms are microbial masses attached to surfaces that are immersed in liquids. Once these masses are formed, microbes may be resistant to the disinfectants by multiple mechanisms including higher resistance of older biofilms, genotypic variation of the bacteria, microbial production of neutralizing enzymes, and physiologic gradients within the biofilm (e.g., pH). Bacteria within biofilms are up to 1,000 times more resistant to antimicrobials than the same bacteria in suspension. Although new decontamination methods are being investigated for removal of biofilms, chlorine and monochloramines are effective for inactivation of biofilm bacteria.

Investigators have hypothesized that the glycocalyx-like cellular masses on the interior walls of polyvinyl chloride pipe would protect embedded organisms from some disinfectants and serve as a reservoir for continuous contamination. Biofilms have been found in whirlpools, dental unit waterlines, and numerous medical devices (e.g., contact lenses, pacemakers, hemodialysis systems, urinary catheters, central venous catheters, endoscopes). Their presence may have serious implications for immunocompromised patients and patients with indwelling medical devices. Some enzymes and detergents can be used for the degradation of biofilms or reduction in viable bacterial numbers, but no products are registered by the Environmental Protection Agency (EPA) or cleared by the FDA for this purpose. One study evaluating the clearance effect of enzymatic and nonenzymatic detergents against Escherichia coli biofilms on the inner surface of gastrosopes found that nonenzymatic detergents and high-speed lavage (250 mL/min) are both important in temporal-formed biofilm elimination. In general, the available data suggest that by ensuring prompt device cleaning and reprocessing by either high-level disinfection or sterilization, biofilms will not have a chance to form. However, biofilms can develop inside channels if established protocols are not met and these biofilms can be difficult to remove.
TOXIC ANTERIOR SEGMENT SYNDROME (TASS)

Toxic anterior segment syndrome (TASS) is an acute, noninfectious inflammatory reaction of the anterior chamber or segment of the eye that typically occurs 12-48 hours after an uneventful cataract surgery. Common symptoms include blurry vision, redness of the eye, ocular pain, corneal edema, and severe inflammation that is limited to the anterior segment. Symptoms often mimic those of infectious bacterial endophthalmitis; however TASS symptoms improve after the administration of topical or oral steroids. A variety of substances that can enter the eye during or after surgery as well as breaches in sterilization and disinfection of intraocular surgical instruments have been implicated as causes of TASS. These substances include detergent residues, topical ophthalmic ointments and salt solutions, anti-septic agents, talc from gloves, water bath contaminates, impurities of autoclave steam, heat stable endotoxin, and irritants on the surfaces of intraocular surgical instruments. (Refer to Ophthalmology Services for more information on TASS). The American Society of Cataract and Refractive Surgery and the American Society of Ophthalmic Registered Nurses recommend that the cleaning and sterilization of intraocular surgical instruments follow the manufacturer's directions for use with strict adherence to the instructions for sterilizers, chemicals, detergents, rinsing solutions, and time requirements for intraocular instruments. Viscosurgical device solutions used during ophthalmic procedures can dry and harden quickly; therefore the recommendations include keeping used intraocular surgical instruments moist to avoid the drying of debris until the cleaning process begins. Intraocular instruments should be cleaned separately from other surgical instruments and a dedicated cleaning area is recommended. Prior to use, intraocular surgical instruments should be verified for cleanliness and functional integrity by the surgical staff. Administrative controls such as written policies and procedures should be updated annually and education regarding TASS should be provided to staff involved in the cleaning and disinfection process on hire, with updates provided periodically. Early identification of TASS for single cases, as well as outbreaks, requires the implementation of a surveillance system involving surgical staff, infection prevention, and cleaning and sterilization personnel. Communication of cases facilitates rapid identification of breeches in cleaning and sterilization processes and surgical equipment degradation and aids in outbreak management. A reporting mechanism for TASS has not been established; however the United
States Food and Drug Administration accepts reports of TASS associated with a specific product through the MedWatch online reporting system. Reports to other public health agencies should follow local guidelines for reporting outbreaks or unusual conditions.  

**Human Papilloma Virus (HPV)**

Emerging pathogens are of growing concern to the general public and infection prevention and control professionals. Human papilloma virus (HPV) is an extremely common sexually acquired infection and is considered the cause of cervical cancer, with approximately 70% of cervical cancers being attributed to two types of HPV: HPV-16 and HPV-18. A recent study showed that a considerable number of endovaginal ultrasound probes were contaminated with HPV (28 percent pre-examination). Endovaginal ultrasound probes are semicritical items (even if covered with a sheath or probe cover) and require high-level disinfection; HPV contamination of endovaginal probes can occur regardless of sheath or probe cover usage.

Limited data exist regarding the inactivation of HPV by disinfectants because in vitro replication of complete virions requires a specific culture system which has only been recently achieved. A 2016 study by Ryndock, Robinson, and Meyers, compared commonly recommended aldehyde-based disinfectants such as orthophthalaldehyde and glutaraldehyde with 35% sonicated hydrogen peroxide on HPV-contaminated plastic carriers. The study results indicated minimal activity demonstrated against HPV-16 and HPV-18 when using the aldehyde-based high level disinfectants as recommended by the manufacturer; however, the 35% sonicated hydrogen peroxide completely inactivated both types of HPV.

Immersion in the manufacturer’s recommended FDA-approved chemical disinfectant is the most common high-level disinfection method; however an alternative system that utilizes a proprietary hydrogen peroxide mist is also available. This type of system, also approved by the FDA, utilizes a 35% hydrogen peroxide solution at 56°C and generally disinfects the entire probe, not just the part that contacts mucous membranes.

**Inactivation of Creutzfeldt-Jakob Disease Agent (CJD)**

Creutzfeldt-Jakob disease (CJD) is a degenerative neurologic disorder.
of humans with an incidence in the United States of approximately 1 to 1.5 cases/million population/year. 93 94 CJD is thought to be caused by a proteinaceous infectious agent or prion. CJD is related to other human transmissible spongiform encephalopathies (TSEs) that include kuru (0 incidence, now eradicated), Gerstmann-Sträussler-Scheinker (GSS) syndrome (1/40 million), and fatal insomnia syndrome (FFI) (< 1/40 million). The agents of CJD and other TSEs exhibit an unusual resistance to conventional chemical and physical decontamination methods. Since the CJD agent is not readily inactivated by conventional disinfection and sterilization procedures and because of the invariably fatal outcome of CJD, the procedures for disinfection and sterilization of the CJD prion have been both conservative and controversial for many years. 11 95 96 It should be noted that the FDA does not recognize or regulate methods for the reduction of prion activity and does not permit manufacturers to make statements regarding CJD decontamination on device labels. 11

The current recommendations consider inactivation data but also use epidemiological studies of prion transmission, infectivity of human tissues, and efficacy of removing proteins by cleaning. 93 95 97 On the basis of scientific data, only critical (e.g., surgical instruments) and semicritical devices contaminated with high-risk tissue (e.g., brain, spinal cord, and eye tissue) from high-risk patients (e.g., known or suspected infection with CJD or other prion disease) require special prion reprocessing. A moist environment post contamination reduces the attachment of both protein and prion amyloid to the stainless steel surface, so maintaining moist conditions at the point of use is critical. 98 After the device is clean, it should be sterilized by either steam sterilization or using a combination of sodium hydroxide and autoclaving using one of the following options: (1) steam sterilize at 134°C for 18 minutes in a prevacuum sterilizer; (2) steam sterilize at 132°C for 1 hour in a gravity displacement sterilizer; (3) immerse in 1N NaOH for 1 hour, remove and rinse in water, then transfer to an open pan and steam sterilize (121°C gravity displacement or 134°C porous or prevacuum sterilizer for 1 hour); or (4) immerse in 1N NaOH for 1 hour and heat in a gravity displacement at 121°C for 30 minutes, then clean and subject to routine sterilization. 1 93 99 100

Instruments should never be placed in NaOH and then steam sterilized; this could be hazardous to staff and may damage sterilizers and equipment. 11 Some data suggest the temperature should not
exceed 134°C since the effectiveness of steam sterilization may
decline as the temperature is increased (e.g., 136°C, 138°C). 101

Prion-contaminated medical devices that are impossible or difficult to
clean should be discarded. To minimize environmental contamination,
noncritical environmental surfaces should be covered with plastic-
backed paper, and when contaminated with high-risk tissues, the
paper should be properly discarded. Noncritical environmental
surfaces (e.g., laboratory surfaces) contaminated with high-risk tissues
should be cleaned and then spot decontaminated with a 1:10 dilution
of hypochlorite solutions. 93

**IMPROVED HYDROGEN PEROXIDE (HP)**

An improved hydrogen peroxide-based technology has been
introduced into healthcare for disinfection of noncritical environmental
surfaces and patient equipment and high-level disinfection of
semicritical equipment such as endoscopes. 96 102 103 104 Improved
hydrogen peroxide contains very low levels of anionic and/or nonionic
surfactants in an acidic product that acts with hydrogen peroxide to
produce microbicidal activity. This combination of ingredients speeds
the antimicrobial activity of hydrogen peroxide and cleaning
efficiency. 103 104 Improved hydrogen peroxide is considered safe
for humans and equipment and benign for the environment. In fact,
improved hydrogen peroxide has the lowest EPA toxicity category
(i.e., category IV) based on its oral, inhalation, and dermal toxicity,
which means it is practically nontoxic and is not an irritant. 102 103 It
is prepared and marketed by several companies in various
concentrations (e.g., 0.5 to 7 percent) and different companies may
use different terminology for these products, such as "accelerated" or
"activated." Lower concentrations (e.g., 0.5 percent, 1.4 percent) are
designed for the low-level disinfection of noncritical environmental
surfaces and patient care objects while the higher concentrations
(e.g., 2 percent) can be used as high-level disinfectants for
semicritical medical devices (e.g., endoscopes).

A recent study compared the bactericidal activity of a quaternary
ammonium compound to two new improved hydrogen peroxide
products for environmental surfaces. The improved hydrogen peroxide
products were superior, or similar, to the quaternary ammonium
compound tested. When the two improved hydrogen peroxide
products were compared to standard 0.5, 1.4, and 3 percent
hydrogen peroxide formulations, the improved hydrogen peroxide-based environmental surface disinfectants proved to be more effective (> 6-log reduction) and faster-acting (1 minute) microbicides in the presence of a soil load (to simulate the presence of body fluids) than commercially available hydrogen peroxide. Only 1 minute contact time was studied because longer contact times (e.g., 10 minutes) are not achievable in clinical practice. Additionally, the improved hydrogen peroxide products have an EPA-registered contact time that is substantially less (e.g., 30 seconds, 1 minute for bacteria) than most EPA-registered low-level disinfectants. Another recent study also tested improved hydrogen peroxide for environmental decontamination of hospital privacy curtains. The study results indicated that a 1.4 percent activated hydrogen peroxide solution effectively reduced microbial contamination of hospital privacy curtains. The activated hydrogen peroxide completely eliminated contamination with methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE) and resulted in a 98.5 percent reduction in microbes (only *Bacillus* spp. recoverable). As a result, privacy curtains in the facility where the study was conducted (University of North Carolina Health Care) are being disinfected at the grab area by spraying the grab area of the curtain three times with activated hydrogen peroxide at discharge cleaning.

**Reprocessing of Endoscopes**

Physicians use endoscopes to diagnose and treat numerous medical disorders. While endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with use has been reported as very low (about 1 in 1.8 million procedures), some investigators believe that number is inaccurate and based on flawed methodology. More healthcare-associated outbreaks have been linked to contaminated endoscopes than to any other medical or surgical device. In order to prevent the spread of healthcare-associated infections, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, nasopharyngoscopes) must be properly cleaned and at a minimum subjected to high-level disinfection following each use. High-level disinfection can be expected to destroy all microorganisms; however, 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. Unfortunately, audits have shown that personnel do not adhere to guidelines on reprocessing and outbreaks of infection continue to occur. In order to 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. Automated endoscope reprocessors can automate and standardize several important reprocessing steps, reduce the likelihood that an essential reprocessing step will be skipped, and reduce personnel exposure to high-level disinfectants.

In general, endoscope disinfection or sterilization with a liquid chemical sterilant or high-level disinfectant involves five steps after leak testing: (1) clean, mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and an enzymatic cleaner; (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 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 (e.g., hung vertically).

Unfortunately, there is poor compliance with the recommendations for reprocessing endoscopes, which may result in patient exposure to bloodborne pathogens and drug resistant organisms (i.e. Carbapenem-resistant Enterobacteriaceae). In addition, there are rare instances where the scientific literature and recommendations from professional organizations regarding the use of disinfectants and sterilants may differ from the manufacturer's label claim. One example is the contact time used to achieve high-level disinfection with 2 percent glutaraldehyde. Based on FDA requirements (FDA regulates liquid sterilants and high-level disinfectants used on critical and semicritical medical devices), manufacturers test the efficacy of their
germicide formulations under worse-case conditions (i.e., minimum recommended concentration of the active ingredient) and in the presence of organic soil (typically 5 percent serum). The soil is used to represent the organic loading to which the device is exposed during actual use and that would remain on the device in the absence of cleaning. These stringent test conditions are designed to provide a margin of safety by assuring that the contact conditions for the germicide provide complete elimination of the test bacteria (e.g., $10^5$ to $10^6$ M. tuberculosis in organic soil and dried on a scope) if inoculated into the most difficult areas for the disinfectant to penetrate and in the absence of cleaning. However, the scientific data demonstrate that M. tuberculosis levels can be reduced by at least 8-log with cleaning (4-log) followed by chemical disinfection for 20 minutes at 20°C (4- to 6-log). Because of these data, professional organizations (at least 14 professional organizations worldwide) that have endorsed an endoscope reprocessing guideline recommend contact conditions of 20 minutes at 20°C (or less than 20 minutes outside the United States) with 2 percent glutaraldehyde to achieve high-level disinfection that differs from that of the manufacturer’s label.

It is important to emphasize that the FDA tests do not include cleaning, a critical component of the disinfection process. Therefore, when cleaning has been included in the test methodology, 2 percent glutaraldehyde for 20 minutes has been demonstrated to be effective in eliminating all vegetative bacteria.

The CDC Healthcare Infection Control Practices Advisory Committee (HICPAC) recommends that all facilities performing endoscopic procedures develop a reliable, high-quality infrastructure that includes, in addition to annual training and competencies, the essential steps for endoscope reprocessing: pre-cleaning, leak testing, manual cleaning, visual inspection, disinfection or sterilization per manufacturer’s instructions for use, transportation, and storage.

Facility polices should also address the management of “loaner” instruments from other healthcare facilities or manufacturers for temporary use. Developing a system for documenting endoscopes used during procedures, to include patient identifiers, is recommended to aid in identification of patients who may have been affected by a product recall or a reprocessing failure. Periodic quality assurance audits of the endoscope program should be conducted to ensure that all aspects of the program are maintained per current
standards. (Refer to 56. Endoscopy for additional information on reprocessing of endoscopies.) Unfortunately, studies have shown that contamination can persist in endoscopes even if strict adherence to the guidelines for cleaning and disinfection are followed. A recent study by Ofstead et al. showed that rapid indicator tests for blood, protein, and carbohydrates indicated persistent contamination (p < 0.5) in the absence of visible residue after high-level disinfection, even when processes were strictly followed. Incorporating rapid indicator testing into a quality assurance program for endoscope reprocessing was recommended.

ENVIRONMENTAL CLEANING AND SURFACE DISINFECTION

Role of Environmental Surfaces in Disease Transmission

There is excellent evidence in the scientific literature that environmental contamination plays an important role in the transmission of several key healthcare-associated pathogens including MRSA, VRE, Acinetobacter, norovirus, and Clostridium difficile. Candida auris recently joined the club of environmental transmissible pathogens. 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 healthcare personnel, be transmitted by healthcare personnel, and cause outbreaks in which environmental transmission was deemed to play a role. Importantly, a recent study by Stiefel and colleagues demonstrated that contact with the environment was just as likely to contaminate the hands of healthcare personnel as was direct contact with the patient. 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 the newly admitted patient to develop colonization or infection.

Contact Time for Disinfection of Noncritical Patient Care Equipment and Environmental Surfaces
CDC guidelines discuss contact time (i.e., wet time) of least a 1-minute for low-level disinfection of noncritical environmental surfaces and patient care equipment. To obtain EPA clearance for the CDC guidelines it was necessary to insert the following disclaimer: “By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA.”

There are several points that should be made about this apparent disconnect between label instructions and what scientific studies demonstrate, to include: (1) Multiple scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens causing healthcare-associated infections with a contact time of at least 1 minute; (2) There are no data that demonstrate improved infection prevention by a 10-minute contact time versus a 1-minute contact time. Further, the only way an institution can achieve a contact time of 10 minutes is to reapply the surface disinfectant multiple times to the surface, which is unlikely, as the typical dry time for a water-based disinfectant is 1.5 to 2 minutes. Lastly, as important as disinfectant contact time is to surface disinfection, nothing is more important than the thoroughness of cleaning/disinfecting all hand contact surfaces (e.g., environmental surfaces or patient care equipment), as current studies demonstrate that less than 50 percent of high-risk objects are cleaned/disinfected at terminal cleaning.

Wiping all "hand contact" or "touchable" surfaces/equipment, and not just perceived “high-risk” surfaces/equipment, is essential because “high-risk” surfaces/equipment have not been epidemiologically defined. In addition, “high touch” surfaces have only recently been defined but there was no significant difference in microbial contamination of “high,” “medium,” and “low” touch surfaces. If an institution chooses to use a product with a nonachievable label claim (e.g., 10 minutes), it should prepare a formal risk assessment (see Supplemental Resources for an example of a Risk Assessment) to be presented to surveyors (e.g., The Joint Commission) when challenged. Alternatively, the hospital could purchase and use an EPA-registered disinfectant with an achievable contact time such as a disinfectant with a 30-second to 2-minute bactericidal claim for low-level disinfection of noncritical surfaces and patient care equipment.

Studies have found that monitoring cleanliness, while it might
esthetically improve the cleanliness of the room, did not correlate with decreased bacterial colony counts. 137 138 Appropriate application of disinfection products has been demonstrated to reduce the environmental contamination with VRE, MRSA, and C. difficile. 139 140

Determining which pathogen on the disinfectant label should be used to identify contact time (e.g., bacteria, Candida, mycobacteria, spores) for surfaces in healthcare facilities is another issue. The CDC guidelines base the 1-minute contact time on demonstration of bactericidal activity for vegetative bacteria such as S. aureus, Enterococcus, E. coli, coagulase-negative Staphylococcus, Pseudomonas aeruginosa, Klebsiella spp., Enterobacter spp., etc. These vegetative bacteria are the pathogens responsible for the vast majority of healthcare-associated infections (HAIs) (85 to 90 percent). 142 143 Further, contaminated surfaces with organisms such as Candida, nontuberculous mycobacteria, and other fungi were rarely, if ever, considered risk factors for HAIs. But, recent emergence of Candida auris as an environmentally transmitted pathogen has challenged this prior thinking. 130 Exceptions to this principle are the use of EPA-registered sporicidal disinfectants effective against C. difficile spores or norovirus for disinfecting the rooms of patients with one of these pathogens.

ADEQUACY OF ROOM CLEANING AND DISINFECTION USING CHEMICAL GERMICIDES

It has long been recommended in the United States that environmental surfaces in patient rooms be cleaned and disinfected on a regular basis (e.g., daily, three times per week), when surfaces are visibly soiled, and following patient discharge (terminal cleaning). 1

Disinfection is generally performed using an EPA-registered hospital disinfectant such as a quaternary ammonium compound. Recent studies have demonstrated that adequate environment cleaning is frequently lacking. For example, Carling and coworkers assessed the thoroughness of terminal cleaning in the patient’s immediate environment in 23 acute care hospitals (1,119 patient rooms) by using a transparent, easily cleaned, stable solution that fluoresces when exposed to handheld ultraviolet (UV) light. 144 The overall thoroughness of cleaning, expressed as a percent of surfaces
evaluated, was 49 percent (range for all hospitals, 35 to 81 percent). Using a similar design, Carling and associates assessed the environmental cleaning in intensive care unit rooms in 16 hospitals (2,320 objects) and demonstrated that only 57.1 percent of sites were cleaned following discharge of the room’s occupant. A recent study using ATP bioluminescence assays and aerobic cultures demonstrated that medical equipment frequently had not been disinfected as per protocol.

FACTORS THAT AFFECT THE MANUAL DISINFECTION PROCESS

Factors that affect the manual disinfection process can be broadly classified into two categories: product-related issues and/or process-related issues. Product-related considerations include: (i) differing efficacies of disinfectants against organisms with many products having no activity against spores; (ii) varying disinfectant contact times based on chemical ingredients and by organism type; (iii) the ability of a disinfectant to work on environmental surfaces may be decreased in the presence of organic material, similar to the decreased effectiveness of high-level disinfectants on poorly cleaned endoscopes; (iv) concerns about organisms developing potential resistance against disinfectants similar to antimicrobials due to mutations or the incorporation of genetic material into the organism. However, changes in antibiotic susceptibility do not correlate with a resistance to disinfectants as chemical concentrations exceed the bactericidal level of the organisms. Currently, there are no data that indicate multidrug-resistant organisms are less susceptible to currently used environmental disinfectants. Process-related considerations include: (i) factors that affect disinfection application such as methods for distribution of the disinfectant (microfiber vs rags) and assurance of contact time; (ii) variations in formulation (dilution of disinfectants from a concentrate bottle) by environmental management staff; (iii) number of rooms the same solution can be used in prior to changing, (iv) how often the disinfectant-containing bucket is cleaned; (v) the time allotted for disinfection and distribution of cleaning duties between environmental management staff and other facility employees such as nurses.

Hospitals may choose several disinfectants for reasons other than disinfection properties. There may be environmental considerations or
regulations, material compatibility with existing hospital equipment, and serious hazards classification with exposure to eyes, skin and inhalation. Some effective disinfectants may not adequately remove greasy or organic material since they lack a strong detergent component. Furthermore, certain disinfectant wipes may leave an undesirable white residue over specialized equipment surfaces such as touch screens, and repeated use may damage equipment and void manufacturer warranties.

Improving Room Cleaning and Disinfection

Investigators have reported that intervention programs aimed at environmental services workers resulted in significant improvement in cleaning practices. Improved environmental disinfection has been demonstrated to reduce the environmental contamination with VRE, MRSA, and Clostridioides difficile. Such interventions have generally included multiple activities: improved education, monitoring the thoroughness of cleaning (e.g., by use of ATP assays or fluorescent dyes) with feedback of performance to the environmental service workers, and/or use of cleaning checklists. Some studies have not been able to correlate the esthetical improvement in the cleanliness of the room with reduction in bacterial colony counts. This could be due to inadequate application of appropriate quantity or concentration of a disinfectant or lack of use of a disinfectant or resistance of organism to disinfectants. Assignment of cleaning responsibility (e.g., patient care equipment to be cleaned by nursing; environmental surfaces to be cleaned by environmental management services) is also important to ensure all objects and surfaces are decontaminated, especially the surfaces of noncritical patient care equipment (e.g., cardiac monitors). Importantly, no study has reported in the postintervention period proper cleaning of more than 85 percent of objects. 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.
NEW TECHNOLOGIES FOR ENVIRONMENTAL SURFACE DISINFECTION

Continued improvements in technologies for disinfection and sterilization may result in reduced risks from surfaces or instruments. Several promising new technologies are under examination, including self-disinfecting surfaces that are created by impregnating or coating surfaces with heavy metals (e.g., silver or copper), germicides (e.g., triclosan), or miscellaneous methods (e.g., light-activated antimicrobials). Similarly, development of new technologies for sterilization (e.g., ozone with hydrogen peroxide vapor) and disinfection will continue as the search for processes that improve the compatibility of instruments and faster instrument turnaround progresses. Lastly, the intricate design of instruments, configuration of instrument trays, etc. has resulted in complicated reprocessing instructions to include extended cycle times, weight limits for instrument trays, wet packs, a variety of packaging systems, and loaned instruments for specialty operative procedures (e.g., orthopedic, spinal surgeries). These issues warrant further exploration into new methods and technologies for disinfection and sterilization.

“NO TOUCH” METHODS FOR ROOM DECONTAMINATION

As noted, multiple studies have demonstrated that environmental surfaces and objects in rooms are frequently improperly cleaned and these surfaces may be important in transmission of healthcare-associated pathogens. Further, while 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 if first properly cleaned. These systems use one of two methods, either UV light or hydrogen peroxide. These technologies supplement, but do not replace, standard cleaning and disinfection, because surfaces must be physically cleaned of dirt and debris before deploying these no-touch disinfection systems.

ULTRAVIOLET (UV) LIGHT FOR ROOM DECONTAMINATION
UV irradiation has been used for the control of pathogenic microorganisms in a variety of applications, such as control of *Legionella* in water, as well as disinfection of air, surfaces, and instruments. At certain wavelengths, UV light will break the molecular bonds in DNA, thereby destroying the organism. UV-C has a characteristic wavelength of 200 to 270 nm (e.g., 254 nm), which lies in the germicidal active portion of the electromagnetic spectrum of 200 to 320 nm. The efficacy of UV irradiation is a function of many different parameters such as intensity, exposure time, lamp placement (distance from the object), presence or absence of reflective material, and air movement patterns/humidity.

Automated mobile UV-C units have been shown to eliminate pathogens such as MRSA, VRE, CRE, and *Acinetobacter baumannii*, and to reduce *C. difficile* seeded onto Formica surfaces in experimentally contaminated patient rooms.

Additional studies have also reported the results of assessing the effectiveness of UV-C units to reduce environmental contamination with vegetative bacteria (measured using aerobic colony counts), MRSA, VRE and *C. difficile* inoculated onto stainless steel carrier disks in addition to the environment. Room decontamination with UV systems resulted in significant reductions in aerobic bacteria and *C. difficile* counts on “high-touch” surfaces and demonstrated that a UV-C system is capable of reducing vegetative bacteria inoculated on carrier disks by >3- to 4-log in 15 to 20 minutes and *C. difficile* by >1.7- to 4-log in 35 to 100 minutes. However, studies also demonstrated reduced effectiveness when surfaces were not in the direct line of sight.

Investigators have also demonstrated the effectiveness of an automated UV-C emitter against VRE, MRSA, *Acinetobacter* spp., and *C. difficile* in patient rooms and the use of a nanostructured UV-reflective wall coating that significantly reduced the time (from 25 minutes to 5 minutes for MRSA and from 44 minutes to 9 minutes for *C. difficile* spores) necessary to decontaminate a room using a UV-C-emitting device. A handheld UV radiation device was also tested and found to rapidly kill *C. difficile* spores and other healthcare-associated pathogens on surfaces. However, the presence of organic matter reduces the efficacy of far UV.

**Hydrogen Peroxide (HP) Systems for Room Decontamination**

Several systems that produce hydrogen peroxide (e.g., Hydrogen peroxide vapor [HP vapor], aerosolized dry mist HP) have been studied for their ability to decontaminate environmental surfaces and objects in hospital rooms. HP vapor has been used increasingly for the decontamination of rooms in healthcare. Investigators found that HP systems are a highly effective method for eradicating various pathogens (e.g., MRSA, *M. tuberculosis*, *Serratia*, *C. difficile* spores, *Clostridium botulinum* spores) from rooms, furniture, and equipment. Using a before-after study design, Boyce and coworkers demonstrated that the use of HP vapor was associated with a significant reduction in the incidence of *C. difficile* infection on five high-incidence wards. A recent paper by Passaretti and colleagues demonstrated that environmental decontamination with HP vapor reduced the risk of a patient admitted to a room previously occupied by a colonized or infected patient with a multidrug-resistant organism (MDRO) from acquiring an MDRO by 64 percent compared to using standard disinfection methods. However, HP system decontamination was shown to take more than four times longer to complete than conventional cleaning, thus resulting in prolonged bed turn-over time.

**Copper Surface Technology**

The intrinsic antimicrobial properties of copper and copper alloys that interrupt the cellular metabolic activity of microorganisms and inhibit growth have been well documented. The United States Environmental Protection Agency registered copper and copper alloys as antimicrobial materials in 2008 resulting in the development and manufacturing of copper infused and copper coated surfaces marketed for use in healthcare environments. Studies have shown that copper-infused surfaces can inhibit bacterial growth on environmental surfaces as well as decrease the accumulated bioburden over time in occupied patient rooms. Unlike UV or HP systems, surfaces that contain copper provide continuous environmental disinfection on the surfaces they cover. This continuous reduction of environmental pathogens on copper-impregnated surfaces may contribute to reducing the risk of environmental pathogens; however, additional studies are needed to determine if this translates into reducing the risk of health-care associated infections.
Comparison of Ultraviolet (UV) Irradiation versus Hydrogen Peroxide (HP) versus Copper Surfaces

Ultraviolet irradiation devices, hydrogen peroxide systems, and copper surfaces all have advantages and disadvantages (see Table 31-4) and there is evidence that these “no touch” systems can reduce environmental contamination with healthcare-associated pathogens. However, each specific system should be studied and its efficacy demonstrated before being introduced into healthcare facilities. The main advantage of both UV and HP units is their ability to achieve substantial reductions in vegetative bacteria. As noted previously, manual cleaning has been demonstrated to be suboptimal as many environmental surfaces are not cleaned. Another advantage is their ability to substantially reduce *C. difficile* as low-level disinfectants (e.g., quaternary ammonium compounds) have only limited or no measurable activity against spore-forming bacteria. Both UV and HP systems are residual and they decontaminate all exposed surfaces and equipment in the room. In comparison, copper surfaces offer continuous surface decontamination without additional equipment; however this effect is limited to the surfaces that the copper covers rather than to the entire room. Also, the log kill might be less with copper than UV and hydrogen peroxide. Further, the antibacterial activities of copper are over hours, as compared to minutes for UV and hydrogen peroxide.

The major disadvantages of these decontamination systems are the substantial capital equipment or remodeling costs. In order to utilize the UV-C and HP systems, personnel and patients must be removed from the room, thus limiting their use to terminal room disinfection (to prevent/minimize exposure to UV and HP). Another disadvantage involves the staff time needed to transport the systems to the rooms to be decontaminated and to monitor their use, in addition to physically cleaning the room of dust and debris.

There are also several important differences between the two systems. The UV-C system offers faster decontamination than the HP system, which reduces the “down” time of the room before another patient can be admitted, while the HP system has demonstrated
greater effectiveness in eliminating spore-forming organisms.  

Whether this improved sporicidal activity is clinically important is unclear as studies have demonstrated that although environmental contamination is common in the rooms of patients with C. difficile infection, the level of contamination is relatively low (also true for MRSA, VRE). Finally, the HP system demonstrated the ability to reduce C. difficile or MDRO incidence in clinical studies, while similar studies with the UV-C system have not been published. In contrast, copper surfaces become part of the permanent fixtures in the patient care environment, thus eliminating the movement of equipment; however specialized training for the care and maintenance of the materials may be required. If additional studies continue to demonstrate a benefit, then widespread adoption of these technologies should be considered for installation and/or for terminal room disinfection of certain patient rooms (e.g., Contact Precautions) in healthcare facilities.

There are other technologies that are currently in nascent stage of development or lack efficacy trials for wide spread use: Light-activated photosensitizers (nanosized titanium dioxide coated surfaces that get activated using UV light and generate reactive oxygen species), high-intensity narrow-spectrum light (visible violet-blue light in the range of 405 nm) and organosilane compounds.

### Table 31-4 Advantages and Disadvantages of Room Decontamination by Ultraviolet Irradiation and Hydrogen Peroxide

<table>
<thead>
<tr>
<th>Decontamination by Ultraviolet Irradiation</th>
<th>Decontamination by Hydrogen Peroxide (HP) Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages</strong></td>
<td><strong>Advantages</strong></td>
</tr>
<tr>
<td>* Reliable biocidal activity against a wide range of healthcare-associated pathogens*</td>
<td>* Reliable biocidal activity against a wide range of healthcare-associated pathogens*</td>
</tr>
<tr>
<td>* Room surfaces and equipment decontaminated*</td>
<td>* Room surfaces and equipment decontaminated*</td>
</tr>
<tr>
<td>* Room decontamination is rapid (15-25 minutes) for vegetative bacteria*</td>
<td>* Effective against Clostridium difficile*</td>
</tr>
<tr>
<td>* Effective against Clostridium difficile, although requires longer exposure (~50 minutes)*</td>
<td>* Useful for disinfecting complex equipment and furniture*</td>
</tr>
<tr>
<td>* HVAC (heating, ventilation and air conditioning) system does not need to be disabled and the room does not need to be sealed*</td>
<td>* Does not require that furniture and equipment be moved away from the walls*</td>
</tr>
<tr>
<td></td>
<td>* HP is residual free and does not give rise to health or safety concerns (aeration unit converts HP into oxygen and water)*</td>
</tr>
</tbody>
</table>
DOES IMPROVED SURFACE CLEANING AND DISINFECTION REDUCE HEALTHCARE-ASSOCIATED INFECTIONS?

Donskey recently performed a systematic review of the impact of environmental surface disinfection interventions on the incidence of...
healthcare-associated infections. He concluded that during the past
decade a growing body of evidence has accumulated suggesting that
improvements in environmental disinfection (e.g., product
substitutions; education plus monitoring and feedback; enhanced
cleaning, such as twice daily) may prevent transmission of pathogens
and reduce healthcare-associated infections. Although the quality of
much of the evidence remains suboptimal, a number of high-quality
investigations now support environmental disinfection as a control
strategy. 182 159 194 195 196

ASSESSING RISK TO PATIENTS FROM DISINFECTION AND STERILIZATION FAILURES
Disinfection and sterilization are critical components of infectiotion
control. Unfortunately, breaches of disinfection and sterilization
guidelines are not uncommon. A 15-step algorithm has been
constructed to aid infection prevention and control professionals in
the evaluation of potential disinfection and sterilization failures. 49 50

Patient notifications due to improper reprocessing of semicritical
(e.g., endoscopes) and critical medical instruments have occurred
regularly. 49 This article also provides a method for assessing patient
risk for adverse events, especially infection. Use of an algorithm
(Table 31-5) can guide an institution in managing potential disinfection
and sterilization failures.

Table 31-5 Protocol for Exposure Investigation after the Failure to
Follow Disinfection and Sterilization Principles

<table>
<thead>
<tr>
<th>Step</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Confirm disinfection or sterilization reprocessing failure</td>
</tr>
<tr>
<td>Step 2</td>
<td>Immediately embargo any improperly disinfected or sterilized items</td>
</tr>
<tr>
<td>Step 3</td>
<td>Do not use the questionable disinfection or sterilization unit (e.g., sterilizer) until functioning has been assured</td>
</tr>
<tr>
<td>Step 4</td>
<td>Inform key stakeholders</td>
</tr>
<tr>
<td>Step 5</td>
<td>Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure</td>
</tr>
<tr>
<td>Step 6</td>
<td>Prepare a line listing of potentially exposed patients</td>
</tr>
<tr>
<td>Step 7</td>
<td>Assess whether disinfection or sterilization failure increases patient risk for infection</td>
</tr>
</tbody>
</table>
Coronavirus Disease 2019 (COVID-19)

NOTE: THIS SECTION WAS ADDED IN DECEMBER 2020.

BACKGROUND

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged in Wuhan, China as a high-consequence infectious disease (HCID) in late 2019. COVID-19 shares characteristics with other HCID coronaviruses: SARS-CoV-1 which also emerged in China in 2003 and the Middle Eastern Respiratory Syndrome (MERS-CoV) which emerged in the Arabian Peninsula in 2013. COVID-19 is easily transmittable leading to the global spread of the virus with cases and related deaths ever rising. World Health Organization declared it a pandemic on March 11, 2020. 197 198

TRANSMISSION
Droplet transmission is the main mode of spread for COVID-19. Contact with respiratory droplets generated by infected people is considered the most common mode of transmission; however indirect modes of transmission through contact with contaminated hands and surfaces is also considered a factor in the rapid spread of the virus. In addition to respiratory samples, COVID-19 has been isolated by reverse transcription polymerase chain reaction in blood, saliva, and feces. Several medical procedures such as bronchoscopy, intubation, tracheostomy, cardiopulmonary resuscitation, and others are considered aerosol generating procedures and may be associated with high risk of SARS-CoV-2 infection.

Studies indicate that SARS-CoV-2 replicates in the upper respiratory tract and has been detected in the throat of infected individuals for up to 5 days after symptom onset. SARS-CoV-2 has also been isolated from asymptomatic individuals indicating that the rapid spread of COVID-19 can partially be attributed to individuals with no signs of illness.

SURFACE VIABILITY
Coronavirus surface viability has been studied since the emergence of SARS-CoV-1 in 2003. Coronaviruses such as SARS-CoV-1, MERS-CoV, and SARS-CoV-2 can survive on several commonly used hospital surfaces including metal and plastic. Studies indicate that surface contamination can persist for days. Frequent contact between infectious patients and contaminated surfaces by healthcare workers can contribute to transmission in the hospital setting. The length of survival depends on the porosity of the surfaces with plastic having the longest length of viability and metals having the shortest. In addition to porosity, other factors such as temperature, humidity, and dust contribute for the length of time that the virus stays viable on surfaces.

ENVIRONMENTAL CONTAMINATION
Viral shedding occurs in both symptomatic and asymptomatic patients. Severely symptomatic individuals shed more viral particles within the first week of hospitalization, particularly on high touch surfaces. Droplet contamination can occur within 2-6 m from an infected person whereas aerosolized particles generated during procedures such as suctioning, nebulizer treatments, and intubation
can circulate in the air leading to further areas of contamination. 208

High-touch surfaces are frequently touched by both patients and healthcare workers and include bed rails, over the bed tables, sinks, and portable medical equipment. 209 210 In addition to high-touch surfaces, COVID-19 viral particles have also been isolated from floors, air vents, and bathrooms, including on toilets, sinks, and door handles. 211

**CLEANING AND DISINFECTION**

Studies after the emergence of SARS-CoV-1 in 2003 demonstrated that coronaviruses were easily killed on hard, non-porous contaminated surfaces. The Environmental Protection Agency (EPA) lists approved disinfection products that are effective for use against coronaviruses. 212 Current information on approved cleaning and disinfecting agents can be found in List N: Disinfectants for Coronavirus (COVID-19) located on the EPA website: [https://www.epa.gov/pesticide-registration/list-n-disinfectants-coronavirus-covid-19](https://www.epa.gov/pesticide-registration/list-n-disinfectants-coronavirus-covid-19). List N can be searched based on a product’s EPA Registration Number; the active ingredient; contact time; and locations for use in healthcare, industrial facilities, and homes. 213

Both SARS-CoV-1 and MERS-CoV are killed within 30 seconds after the application of an 80% ethanol solution. 214 Hydrogen peroxide and quaternary ammonium-based disinfectants have also shown efficacy as surface disinfectants, with contact times ranging from less than 1 minute to less than 30 minutes after application. The EPA List N provides information on agents with extended contact times in the event of a shortage of quick-acting products. The CDC has also approved the use of a 70% alcohol solution as well as a bleach solution of 1/3 cup of bleach added to a gallon of water in the event of a shortage of EPA-approved disinfectants. Studies show that agents effective for harder-to-kill viruses such as adenovirus type 5 should be effective against coronaviruses. 213 215

Regardless of the cleaning agent used, hospitals should adhere to an environmental cleaning policy that ensures the correct use of cleaning products and contact times on a routine basis. Environmental cleaning policies should enforce the rigorous cleaning and disinfection of high touch environmental surfaces on a daily basis. Portable
medical equipment should be cleaned according to the manufacturer’s instructions for use (IFU) following the standards outlined in the CDC’s "Guideline for Disinfecting and Sterilization in Healthcare Facilities 2008." One study demonstrated that environmental surface samples taken after cleaning did not recover any COVID-19 viral particles that had been recovered on the surface prior to cleaning. 216

In addition to environmental cleaning, wearing appropriate personal protective equipment (PPE) and frequent hand hygiene are key components in decreasing spread of the virus. 197 198

EMERGENCY USE AUTHORIZATION FOR PERSONAL PROTECTIVE EQUIPMENT

The rapid emergence and spread of COVID-19 prompted the secretary of the United States Department of Health and Human Services to declare that justification existed for emergency use authorizations (EUA) for use during a public health emergency. 216 217 218

Emergency use authorizations allowed the Food and Drug Administration to approve the expanded use of approved and unapproved products to increase supplies during the pandemic. In response to COVID-19, EUAs were issued for the expanded use PPE, testing swabs, diagnostic methods, industrial N95 respirators, and other critical medical devices. Guidance was also issued for the reprocessing of single used N95 respirators in the event of a shortage. EUAs are temporary measures that can be extended by the FDA if needed; frequent checking for changes in the FDA guidance is recommended. 216 217

Single use disposable PPE is the best option for healthcare workers; however, National Institute for Occupational Safety and Health approved reusable non-powered air-purifying facepiece masks, full face or half face, and powered air purifying respirators, especially during aerosolizing procedures. Fit testing of respirators should follow the manufacturer’s IFU. Thorough cleaning and disinfection of these devices should also be based on manufacturer’s IFU and should be done on a frequent basis, especially between patient interactions. Rigorous cleaning and disinfection can increase the potential for damage so routine inspection is also advised. 219 220 221 222

Healthcare facilities should develop contingency plans for tracking inventory and the rate of use. In the event of a severe shortage of
disposable N95 respirators, decontamination and limited re-use can occur; however special care should be taken to inspect these respirators for any damage that may affect its fit. As of publication, few studies have been done on the effectiveness of disposable PPE decontamination; however one study shows that vaporized hydrogen peroxide, and UV light, can inactivate COVID viral particles on disposable N95 respirators. 

NO-TOUCH DISINFECTION & OTHER SURFACE DECONTAMINATION TECHNOLOGIES

At the time of publication studies are limited regarding the use of UV light against COVID-19; however, UV has been shown to be effective against MERS-CoV (Perlman et.al.) No detectable levels of MERS-CoV were found on surfaces after five minutes of exposure to a whole room UV-C device. Due to the similarities between SARS-CoV-1, MERS-CoV, and SARS-CoV-2, the same level of effectiveness of UV light would apply to all three strains of coronaviruses (New reference 209). Interestingly, a recent study by Simmons et al. demonstrates pulsed-xenon UV was effective in reducing SARS-CoV-2 viral load (>4 log-kill reduction) on both the surfaces and N95 respirators. 

Log reduction is commonly used to determine a ratio that compares the number of bacteria or virus on a surface before and after decontamination; for example a log reduction of >4 indicates a difference of more than 10,000 organisms after application of a disinfection product compared to before. According to current EPA standards disinfectants require > 6 log reduction (1,000,000 organisms) whereas technologies such as UV disinfection or hydrogen peroxide have no such requirement for reduction as these are not regulated by EPA or FDA.

Non-porous biocidal surfaces such as copper and copper-based alloys have consistently demonstrated a decrease in the survival time of coronaviruses. The percentage of copper contained in the surface material has shown to be in proportion to the degree of inactivation of the virus. Continued studies on copper and other metals indicate the potential for future use in PPE. 

Hydrogen peroxide works as broad-spectrum disinfectant by generating hydroxyl free radicals. Airborne hydrogen peroxide in vapor or dry mist formulations was shown to be an effective method of disinfection of the hospital environment. Hydrogen peroxide vapor
has a virucidal effect and a minimum of 4-log reduction in various structurally distinct viruses including endemic coronavirus HCoV-229E.

While other technologies are being used to contain the spread of SARS-CoV-2 in various settings, systematic studies to demonstrate their effectiveness are still lacking and broader recommendations for their use cannot be made at this time.

SUMMARY

The rapid spread of COVID-19 and ever-evolving knowledge of the virus have resulted in frequent changes to the COVID-19 management guidance. However, the recommendation for a rigorous cleaning and disinfection process has remained consistent in healthcare settings and its effectiveness in containing the spread of SARS-CoV-2 is undeniable. Continued review for updates, studies, and changes to guidelines is imperative as the COVID-19 pandemic evolves.

For more general information on COVID-19, see 74. Coronavirus Disease 2019 (COVID-19).

Conclusions

When properly used, disinfection and sterilization can ensure the safe use of invasive and noninvasive medical devices. Cleaning should always precede high-level disinfection and sterilization. Environmental cleaning and disinfection are also an important patient safety component. Various cleaning and disinfection agents as well as no-touch disinfection technologies and newer self-sanitizing surfaces provide options for healthcare facilities. Developing processes that promote and assure strict adherence to the manufacturer’s instructions for use and to current disinfection and sterilization guidelines is essential in preventing patient infections and exposures to infectious agents.

Acknowledgements

Thank you to William A. Rutala, PhD, MPH and David J. Weber, MD, MPH, who wrote the previous version of this chapter (published February 25, 2016).
References


[12] United States Department of Labor Occupational Safety and


[36] Alfa MJ, Jackson M. A new hydrogen peroxide-based medical-device detergent with germicidal properties: Comparison with enzymatic...


31. Cleaning, Disinfection, and Sterilization | Basic Principles of Infection Prevention Practice | Table of Contents | APIC


Jackson FW, Ball MD. Correction of deficiencies in flexible fiberoptic sigmoidoscope cleaning and disinfection technique in family practice and


Feedback form

If you have questions or concerns about the contents of this chapter, please let us know. You can enter your comments for the editor in the form below or email us at products@apic.org.

**Comment (Required)**

Name (Required)  Shazia Irum

Email (Required)  shehziirum@gmail.com

SEND YOUR FEEDBACK