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Sterilization & Disinfection

CDC sterilization, disinfection guideline

A new evidence-based guideline from the Centers for Disease Control and Prevention (CDC) provides guidance on key issues such as endoscope reprocessing, emerging pathogens, disinfection of surfaces, and susceptibility of antibiotic-resistant pathogens to disinfectants.

The new Guideline for Disinfection and Sterilization in Healthcare Facilities, in the works for a number of years, is a major advance over the CDC's previous 1985 guideline, which had only 6 pages and 7 references. The new guideline is over 150 pages with more than 1,000 references.

Authors are William Rutala, PhD, MPH, a well-known expert on sterilization and infection control; David Weber, MD, MPH; and the Healthcare Infection Control Practices Advisory Committee (HICPAC).

The recommendations are generally in line with those of AORN, the Association for the Advancement of Medical Instrumentation (AAMI), and the CDC's 1999 Guideline for Prevention of Surgical Site Infection (SSI).

Two hot topics are not addressed—the new Class 6 chemical indicators and prions. The Class 6 indicators entered the market after the guideline was finished. Prions will be addressed in a separate guideline (sidebar).

Process depends on device's intended use

The new CDC guideline follows the familiar Spaulding classification, which bases the choice of a sterilization or disinfection process on the device's intended use (sidebar). Each recommendation is rated based on the strength of the evidence.

The authors note that the Spaulding classification oversimplifies some complex issues, such as endoscope reprocessing, which are discussed in the preamble.

Here is a look at some key issues. Managers will want to review the whole document and keep it as a reference.

Cleaning

Cleaning plays a critical role in reprocessing, the guideline says. Research shows cleaning alone is effective in reducing the number of microorganisms from devices. Some key facts:

- For most surgical instruments, mechanical cleaning with a washer-disinfector is highly effective in reducing the number of microorganisms. Studies have shown more than 80% of surgical instruments have less than 100 microorganisms, and a washer-sterilizer can remove all or nearly all of them.
- Cleaning is also effective for endoscopes, which are much more heavily contaminated than surgical instru-ments—a GI endoscope can have 1 billion microorganisms. Research has found cleaning achieves approximately a 4-log reduction in microbes. That includes antibiotic-resistant pathogens such as methicillin-resistant *Staphyl-ococcus aureus* (MRSA) and vancomycin-resistant *enterococcus* (VRE).

Some data indicates enzymatic cleaners are more effective than neutral detergents, the guideline notes, but more recent studies found no difference between enzymatic and alkaline-based cleaners. Another study found no significant difference between enzymatic and nonenzymatic cleaners.

Endoscope reprocessing

More infection outbreaks have been linked to endoscopes than any other type of

device. Intricate channels and crevices make endoscopes difficult to clean and disinfect. Major reasons for infection transmission have been inadequate cleaning, not using a Food and Drug Administration (FDA)-cleared high-level disinfectant, and failing to follow recommended reprocessing steps.

For endoscopes used in mucous membranes, the guideline advises at a minimum meticulous cleaning followed by high-level disinfection using an FDA-cleared high-level disinfectant.

"If high-level disinfection is done correctly, it will achieve complete elimination of microbial contamination. If not done correctly, there is a lot of evidence that transmission has occurred, including death," Rutala said in a presentation at the 2008 AORN Congress in Anaheim.

The guideline outlines 5 general steps with 41 recommendations for high-level disinfection of endoscopes:

1. Clean.
2. High-level disinfect or sterilize.
3. Rinse with sterile water, tap water, or filtered water followed by an alcohol rinse.
4. Dry with forced air.
5. Store in a manner that prevents contamination.

Time, temperature for glutaraldehyde

An issue that took the authors time to resolve was time and temperature for high-level disinfection with 2.4% glutaraldehyde.

The FDA label claim specifies an exposure time of 45 minutes at 25° C to achieve high-level disinfection (ie, kill 100% of the resistant organism *Mycobacterium tuberculosis*). This longer time provides a margin of safety to allow for possible cleaning lapses. But studies suggest that with adequate cleaning, high-level disinfection can be achieved in 20 minutes at 20° C. Cleaning alone can reduce the bioburden by 4 logs.

Several guidelines, including the 2003 Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, say 20 minutes at 20° C is adequate for high-level disinfection with 2.4% glutaraldehyde provided adequate cleaning is done.

The new CDC guideline takes a middle ground, referring to both.

In practice, many facilities have switched to OPA (ortho-phthalaldehyde) and peracetic acid.

Endoscope controversies

Two endoscope controversies are unresolved:

- The guideline makes no recommendation about routine microbiological testing of endoscopes or the rinse water for quality assurance purposes.
- There is no recommendation about reprocessing an endoscope again immediately before use.

For rinsing other types of semi-critical devices like endocavitary probes and endotracheal tubes, the guideline recommends:

- Use sterile water, filtered water, or tap water followed by an alcohol rinse for semi-critical items that will have contact with mucous membranes of the upper respiratory tract.
- There is no recommendation to use sterile or filtered water rather than tap water for semi-critical equipment in contact with mucous membranes of the rectum or vagina. This is unresolved.

Endocavitary probes, such as vaginal and cryosurgical probes, should be cleaned and high-level disinfected even if a probe cover is used because the covers can fail, the guideline advises.

Staff training

Staff training and competency are critical to reprocessing. Recommendations include:

- providing comprehensive and intensive training for all reprocessing staff
- supervising work until competency is documented

- conducting competency testing at hire and annually
- reviewing instructions regularly to make sure staff comply with the literature and manufacturers' instructions.

Flash sterilization

On flash sterilization, the guideline is consistent with recommendations from AAMI, AORN, and the CDC SSI guideline:

- Do not flash sterilize implanted devices unless doing so is unavoidable.
- Do not use flash sterilization for convenience, as an alternative to purchasing additional instrument sets, or to save time.
- When flash sterilizing, make sure: to clean the item; prevent contamination during transport from the sterilizer to the patient; and monitor sterilizer function with mechanical (physical), chemical, and biological monitors.
- Do not use packaging materials and containers in flash sterilization cycles unless they are designed for this use.
- When necessary, use flash sterilization for processing patient-care items that cannot be packaged, sterilized, and stored before use.
- Use biological indicators for every load containing implantable items and quarantine items whenever possible until the biological indicator is negative.

When flash sterilizing an implant is unavoidable, records must be kept for tracking and to assess the reliability of the sterilization process.

Thinking on flash sterilization is evolving. Rutala says he expects the recommendations to change in the coming years. Flash sterilization has more safeguards than 30 or 40 years ago. But for now, the guideline is unchanged.

Class 6 indicator

Though the new Class 6 emulating indicators are not addressed in the guideline, Rutala said the Class 6 indicators "are not a substitute for a biological indicator." He added: "No professional organization has recommended the use of Class 6 emulating indicators as a substitute for biological indicators, and there are no data (to include our own data) that demonstrate that a Class 6 indicator mimics a biological indicator at suboptimal sterilization times."

The Class 6 indicators, offered by Steris, received FDA clearance in 2008. Steris says these indicators, which consist of a plastic strip with special yellow ink, integrate the crucial parameters of steam sterilization cycles.

Disinfecting noncritical items

In the guideline, noncritical items are divided into patient-care items and environmental surfaces. There's virtually no risk of infection transmission for noncritical devices that don't come in contact with nonintact skin or mucous membranes.

Noncritical patient care devices

For noncritical patient-care devices such as blood pressure cuffs the guideline recommends:

- using an Environmental Protection Agency (EPA)-registered hospital disinfectant and following the label's safety precautions and directions
- disinfecting these devices at a minimum when visibly soiled and on a regular basis. There is no evidence on how often; that is up to facility policy.

Most of these disinfectants have a label contact time of 10 minutes. By law, label instructions on EPA-registered products must be followed, and users who use them differently assume the liability of off-label use and could be subject to enforcement action.

The CDC guideline had to include this information to be approved by the EPA. Yet multiple studies have shown these disinfectants are effective against pathogens with a contact time of at least of 1 minute.

Why the disconnect?

Rutala noted several points:

- The only way to achieve a contact time of 10 minutes is to reapply the disinfectant 5 or 6 times because the typical dry time for a water-based disinfectant is 1.5

to 2 minutes. He said facilities such as his own, University of North Carolina Health Care, are achieving surface disinfection with one application of a disinfectant, requiring at least 1 minute of dry time.

- Equally important, he says, is to be sure all contaminated surfaces and noncritical patient care equipment are actually wiped—studies show only about 50% of high-risk objects are cleaned during terminal cleaning.
- No data show that infection prevention is improved by a 10-minute versus a 1-minute contact time.

He is not aware of enforcement against health care facilities for off-label use of a surface disinfectant.

"Thus, we believe the guideline allows us to continue use of low-level disinfectants for noncritical environmental surfaces and patient-care equipment with a 1-minute contact time," he says.

He emphasizes the need to make sure all contaminated surfaces are wiped.

Environmental surfaces

Surfaces such as bed rails, bedside tables, and furniture frequently touched by patients could contaminate health care workers' hands or medical equipment, the guideline notes. There are 19 recommendations for disinfecting surfaces. A few are:

- Clean housekeeping surfaces, such as floors and tabletops regularly, when spills occur, and when these surfaces are visibly soiled.
- Disinfect (or clean) environmental surfaces regularly and when surfaces become soiled. How often is up to facility policy.
- Use an EPA-registered hospital disinfectant designed for housekeeping purposes in patient care areas where the nature of the soil is uncertain (eg, blood or body fluid vs dust or dirt) or the presence of multidrug-resistant organisms is uncertain.
- Specific steps are recommended for cleaning spills of blood and other potentially infectious materials.
- In units with high rates of *Clostridium difficile* infection, use diluted solutions of 5.25% to 6.15% sodium hypochlorite (eg, 1:10 solution of household bleach) for routine disinfection. No products are currently EPA-registered specifically for this purpose.

Antibiotic-resistant bacteria, emerging pathogens

Standard sterilization and disinfection procedures are adequate, and no changes are needed for bloodborne pathogens, antibiotic-resistant bacteria, and emerging pathogens (such as *Cryptosporidium*, *Clostridium difficile*, or *Coronavirus*), or bioterrorist agents like anthrax, the guideline says. The exception is prions, which require a special process.

Does use of antiseptics or disinfectants contribute to antibiotic resistance? Though there is evidence of enhanced tolerance, the guideline says this is low, not clinically important, and unlikely to compromise the effectiveness of disinfectants, which are used in high concentrations.

Reuse of single-use devices

If reusing single-use devices, the guideline recommends following the FDA guidance, which says any organization reprocessing single-use devices must meet the same standards as the original manufacturer. As a practical matter, hospitals that reuse single-use devices today use third-party reprocessors, which must meet the FDA standards. ❖

—Pat Patterson

Reference

Rutala W A, Weber D J, Healthcare Infection Control Practices Advisory Committee. *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.* Atlanta: Centers for Disease Control and Prevention. www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf

Spaulding classification

Items are classified according to their intended use when selecting a sterilization and disinfection method:

Critical

Items that enter normally sterile tissue or the vascular system or [enter tissue] through which a sterile body fluid flows should be sterile. *Examples: Surgical instruments, cardiac catheters, and implants.*

Semi-critical

Items that touch mucous membranes or nonintact skin require a high-level disinfection process that kills all microorganisms except high-levels of bacterial spores. *Examples: GI endoscopes, endotracheal tubes.*

Noncritical

Items that touch only intact skin require low-level disinfection (or a nongermicidal detergent). *Examples: blood pressure cuffs, bed rails.*

Prion advice in separate guideline

Prions will be addressed in a separate guideline. The CDC guideline originally had a prion section, but it was removed after CDC experts objected to the recommendations, which William Rutala, PhD, MPH, the lead author said HICPAC regrets.

Prions, the misfolded proteins that cause Creutzfeldt-Jakob disease (CJD) and related diseases, are unusually resistant to conventional disinfection and sterilization.

The prion recommendations would have contradicted the CDC's current recommendations, which follow 1999 guidance from the World Health Organization (WHO). The WHO protocol combines chemical treatment with an agent such as sodium hydroxide followed by sterilization using extended time and temperature.

But Rutala notes that the WHO recommendations are not referenced and do not include research performed in the past 10 years. He says more than 25 peer-reviewed articles have evaluated the ability of disinfectants, sterilants, and detergents to inactivate prions.

"Many of these studies were done using methodology that more closely mimics reprocessing of instruments in health care," he said in an e-mail to *OR Manager.* The new prion guideline, now under review, will be endorsed by the Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA).