Disinfection and Sterilization: Emerging Trends and Technologies

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Disinfection and sterilization practices in health care settings have rapidly moved to the forefront of the ongoing battle against health care–associated infections. Heightened media coverage of lapses in basic cleaning, disinfection, and sterilization of medical devices has placed tremendous focus on strict adherence to manufacturers’ instructions for reprocessing. Government entities such as the Centers for Medicare & Medicaid Services and state departments of public health and accrediting agencies including The Joint Commission have all substantially increased the emphasis on ensuring patient safety related to disinfection and sterilization processes.

Adverse events reported in 2015, such as those caused by carbapenem-resistant Enterobacteriaceae in patients undergoing endoscopic retrograde cholangiopancreatography with duodenoscopes, increased the focus on multidrug-resistant bacterial infections in 2016. A widely publicized carbapenem-resistant Enterobacteriaceae outbreak and the subsequent US Food and Drug Administration (FDA) safety communication notice alarmed health care providers and motivated them to methodically inspect internal cleaning, disinfection, and sterilization methods.1 These events also prompted the Centers for Medicare & Medicaid Services to release a memo to state survey agencies notifying all Centers for Medicare & Medicaid Services survey and certification staff members about the expectation that hospitals, critical access hospitals, and ambulatory surgical centers will meticulously follow manufacturer’s instructions for reprocessing duodenoscopes and adhere to the nationally recognized guidelines developed by multiple expert organizations.2 Soon after this memo was released, the Centers for Disease Control and Prevention issued an alert to health care providers and facilities regarding “the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices.”3

In an effort to ensure that disinfection and sterilization practices meet the expectations of regulatory and accrediting bodies, surveyors are persistently and rigorously assessing both inpatient and outpatient procedures in all areas where medical and surgical instrumentation or equipment is used or reprocessed. Regular blogs hosted by professional organizations such as the Association for Professionals in Infection Control and Epidemiology and AORN feature accounts of surveyor attention to any processes associated with disinfection and sterilization.4,5 Certainly, 2016 has signaled a new paradigm in the way in which both inpatient and outpatient facilities are surveyed.

Some outbreaks have occurred despite appropriate disinfection and sterilization practices, and many have occurred because of the complexities of equipment design, as is the case with duodenoscopes. One study has yielded disconcerting results demonstrating that residual simethicone, an antiflatulent medication that is commonly administered (orally or through endoscope channels) to patients undergoing endoscopic procedures to reduce foam and bubbles to improve visibility and diagnostic accuracy, may remain inside endoscopes despite reprocessing.6 The remaining simethicone may be the result of intricate ports and channels inherent in endoscope design that can affect the ability to achieve effective reprocessing (Figure 1).

Effective precleaning, disinfection, and sterilization notwithstanding, public awareness of general hospital cleaning standards and gaps in patient safety efforts linked to disinfection and sterilization practices has further fueled an increasing sense...
of urgency, and manufacturers are responding. The pressure to
meet minimum standards for disinfection and sterilization has
set the stage for new and emerging trends in innovative
products and technologies targeted at decreasing the risks
associated with disinfection and sterilization.

EMERGING PATHOGENS
The inactivation of antibiotic-resistant bacteria is a compli-
cated phenomenon and one that deserves the persistent
attention of health care providers. Although resistant
bacteria such as methicillin-resistant Staphylococcus aureus,
vancocycin-resistant enterococci, Acinetobacter species, and
Clostridium difficile are commonplace in many health care
facilities today, other significant pathogens present unique
challenges. For example, Burkholderia cepacia has become
problematic. In 2016, the Centers for Disease Control and
Prevention and FDA collaborated to investigate a multistate
outbreak of B cepacia infections in which contaminated liquid
docusate (a stool softener) was implicated and subsequently
recalled.7 Burkholderia cepacia has also been identified in
liquid hand soaps and contaminated antiseptics containing
chlorhexidine, which are used for skin antisepsis before
blood collection.8,9 England et al10 reported an investigation
at a medical center that revealed a previously reprocessed
gastroscope that cultured positive for B cepacia.

Several countries have reported an increase in severe illness
caused by Candida auris. This yeast is often unaffected by
commonly used antifungal medications, making infections
difficult to treat. Further, C auris is challenging to identify
with standard laboratory testing methods, and special tech-
nology using molecular methods is needed to prevent
misidentification, which may lead to inappropriate treatment.
Surgical patients with wounds are especially vulnerable to
postoperative infections caused by C auris.11

No discussion of emerging pathogens would be complete
without mention of Mycobacterium chimaera, which is a type
of nontuberculous Mycobacterium (NTM) that may cause
serious illness or death, placing surgical patients at extraordi-
narily high risk. Heater-cooler units (HCUs) commonly used
in open-chest heart surgery to assist in extracorporeal circu-
lation have been identified as a source of M chimaera. The mode
of transmission was not well understood until a study
confirmed the airborne transmission of M chimaera aerosols

![Figure 1. Endoscopes can be difficult to process because of the complexity of the inner channels. Reprinted with permission from the “Guideline for processing flexible endoscopes.” In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2016.](image-url)
from a contaminated HCU to an open surgical field despite ultraclean air ventilation. In June 2016, the FDA announced a meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The FDA sanctioned this committee in an attempt to “seek expert scientific and clinical opinion related to contamination of heater-cooler devices, associated patient infections, and mitigation strategies based on available scientific information.” The primary goals of the meeting included making recommendations related to the effectiveness of HCU cleaning and disinfection methods and premarket data necessary for validation and label claims. The FDA has published an executive summary of this meeting; however, final recommendations are still pending.

The FDA has provided new recommendations related to <i>M. chimaera</i> infections connected to the use of the Stöckert 3T Heater-Cooler Systems in patients undergoing cardiothoracic surgery. The FDA has identified potential root causes of contamination from HCUs, including growth of NTM in the units’ water tanks, which become aerosolized. Exhaust fans inside the devices may disrupt laminar airflow above the patient, causing NTM to be carried onto the surgical field; in addition, poor HCU design, including inefficient air filters and internal fans, may facilitate aerosolization of NTM from inside the HCU into the surrounding OR.

**SURGICAL INSTRUMENTS**

Bioburden remaining on reprocessed instruments can be difficult to remove and can compromise the effectiveness of disinfection or sterilization. Even unused instruments have the potential to contaminate the entire surgical field if organic material is left behind during ineffective processing. Manual precleaning at the point of use is essential and should be completed as soon as possible after the instrument is used because organic material dries quickly. This crucial step renders instruments safe for handling and additional processing in preparation for reuse.

Scrub personnel should keep instruments free from gross soil during procedures. Throughout a procedure, scrub personnel should wipe instruments with a surgical sponge or lint-free cloth wet with sterile water and periodically flush lumina with sterile water. After the procedure, scrub personnel should use a spray or gel instrument precleaner according to the manufacturer’s recommendations. These vital steps are intended to be completed as close to the point of care as possible because they are critical in safeguarding against drying. Precleaning instruments as an initial step loosens and softens gross soil to make the decontamination process easier and augments the effectiveness of decontamination. Although the concept of precleaning is certainly not new, this facet of disinfection and sterilization has received a significant amount of attention this year.

The proper removal of visible debris, including blood, protein substances, body fluids, and tissue fragments, from surgical instruments at the point of use and before decontamination has been intensely inspected during The Joint Commission’s recent triennial surveys. The primary standard addressing high-level disinfection or sterilization processes for all settings is IC.02.02.01: Reducing the risk of infections associated with medical equipment, devices, and supplies. If an organization does not demonstrate consistent precleaning practices that include removing bioburden at the point of use and maintaining moisture of instruments until decontamination can be completed, the organization may be cited for violation of this standard. Many health care organizations accredited by The Joint Commission have been found to be noncompliant with high-level disinfection of semicritical devices and sterilization of critical devices. The percentage of noncompliance with this standard has been steadily increasing for several years. Because these breaches may result in an immediate threat to life, an adverse accreditation decision may be awarded.

Several organizations offer standards and guidance related to instrument cleaning, high-level disinfection, and sterilization, including AORN’s <i>Guidelines for Perioperative Practice</i> and the Association for the Advancement of Medical Instrumentation’s standards and education resources. In 2016, The Joint Commission published the High-Level Disinfection and Sterilization BoosterPak. The comprehensive BoosterPak is a quality improvement tool that can assist facilities in achieving and maintaining compliance. This informative document includes checklists that can be used during rounding; useful tables related to types and applications for use of sterilization monitoring devices and sterilization monitoring recommendations; and a thorough review of other applicable standards specific to leadership, human resources, and the environment of care.

Another ongoing quandary central to precleaning instruments is the frequent confusion around precleaning hinged instruments. Concerns about sharps injuries may result in reluctance among many surgical team members to open hinged instruments before decontamination. A basin full of open contaminated instruments, including scissors or other sharp objects, undoubtedly poses a risk of injury. This has been an issue that The Joint Commission has diligently...
followed during surveys. AORN guidelines do not specifically address the precleaning of hinged instruments at the point of use but rather refer to the preparation of instruments for manual cleaning before decontamination by opening joints or disassembling instruments that are composed of more than one piece (according to the manufacturer’s instructions) to ensure that cleaning solution contacts all surfaces. Neither the Association for the Advancement of Medical Instrumentation nor The Joint Commission standards include explicit recommendations related to the preparation of hinged instruments before transport to the decontamination area. Although the point-of-use checklist in The Joint Commission BoosterPak calls for precleaning and the use of foam, gel, spray solution, or moist towels (according to the manufacturer’s instructions), there is no overt statement directing personnel to maintain hinged instruments in the open position. Nevertheless, perioperative professionals have recently shared personal testimonies at national conferences pertaining to survey citations received for hinged instruments treated with a precleaning product but remaining in the closed position.

One area of technology that is evolving in response to demand is ultrasonics. Manufacturers are developing advanced equipment with cutting-edge capabilities such as improved cavitation, faster cycle times, and the elimination of “cold spots” that facilitates exposure to every instrument surface. Other companies are improving methods for evaluating the cleaning effectiveness of automated instrument washers with challenge devices that closely mimic a stainless steel instrument soiled with dried blood. Such challenge devices are identical to instrument parts that are usually hidden from view (eg, hinged box locks).

COMPLEX MEDICAL INSTRUMENTS
Surgical instrumentation is advancing at a steady pace to meet the needs of increasingly complicated surgical procedures, including minimally invasive surgeries. Innovations include items such as illuminated retractors for spinal procedures, cannulated reduction forceps with channels and ports, and exceedingly small diameter instruments that make laparoscopic surgery even less invasive than traditional laparoscopic surgery. Powered surgical instruments are often delicate; expensive; easily damaged; and difficult to clean, disinfect, and sterilize. Whether an instrument is powered by an electrical source or compressed gas, the power cord must be able to withstand sterilization. Fluid invasion may occur when cleaning solutions and rinse water are allowed to enter the hand piece of a powered instrument. Multiple attachments and tiny accessories present additional problems that may affect the efficacy of cleaning and disinfection. Such sophistication in manufacturing requires scrupulous attention to precleaning, manual or mechanical cleaning, and sterilization, in addition to careful observance of the manufacturer’s instructions for use specific to reprocessing practices.

Surveyors tend to seek out instruments with lumina and cannulas to determine the thoroughness of cleaning, disinfection, and sterilization. Fragile equipment such as cameras with lenses and fiber-optic pieces are particularly tricky to manage, and surveyors are keenly aware of this. It is also important to remember that significant heat can be generated by high-power lasers that are used with some fiber-optic instruments. If the heat source comes in contact with contaminants on the end face of the fiber-optic connection, the heat can spark a fire. The foundation in ensuring safe and effective processing is following the manufacturer’s instructions for use precisely. Surveyors may request a copy of these instructions, so it is advisable to have them readily available.

ENDOSCOPES
During the past year, endoscope reprocessing may have received more attention than other medical devices because of the outbreaks associated with these devices. The FDA notified Olympus in March 2014 that the manufacturer needed premarket clearance for their closed elevator channel TJF-Q180V model duodenoscope, which had not been previously cleared for marketing. The duodenoscope had a sealed elevator channel (Figure 2) to avoid the need to clean and disinfect this difficult-to-clean area. However, the seal was not secure, so fluids and other materials were able to penetrate the sealed elevator channel. Sterile processing personnel could not effectively reach this area of contamination. In January 2016, the FDA cleared the duodenoscope after the manufacturer modified the device’s design and labeling to help reduce the risk of bacterial infections. Olympus altered the original design of the elevator channel sealing mechanism to create a tighter seal and reduce the potential for leakage of patient fluids and tissue into the closed elevator channel. Accompanying FDA clearance, Olympus also released updated reprocessing instructions and notified customers of the duodenoscope’s design and labeling changes.

Another notable circumstance requiring widespread effort by health care facilities was the Custom Ultrasonics recall. In November 2015, the FDA issued a safety communication...
recommending that health care facilities using Custom Ultrasonics’ System 83 Plus Automated Endoscope Reprocessors (AERs) transition to alternate methods to reprocess flexible endoscopes, including duodenoscopes. The catalyst for this recommendation was FDA allegations that Custom Ultrasonics failed to demonstrate that its AERs could adequately wash and disinfect endoscopes to mitigate the risk of patient infection. By February 2016, the FDA notified personnel at health care facilities of this recommendation. In May 2016, Custom Ultrasonics issued an urgent recall for all System 83 Plus AERs, stating that these machines should not be used for cleaning or high-level disinfection of duodenoscopes until further notice. Finally, in August 2016, the FDA communicated that the System 83 Plus AER may remain in service for the reprocessing of endoscopes other than duodenoscopes.

Surveyors understand the inherent risks associated with sterilizing and disinfecting endoscopes and allocate adequate time in their schedules to ensure that systematic and exhaustive tracers take place in all areas where endoscopy procedures and associated activities occur. Typical topics for exploration during surveys include precleaning of all endoscopes at the point of use, transportation of used endoscopes between the point of use and decontamination (transport in a closed, rigid or leak-proof container with a “biohazard” label), and high-level disinfection or sterilization. Proper documentation of temperatures of high-level disinfection solutions; single-use or clean, processed reusable brushes for endoscope cleaning; and storage of endoscopes (in a drying cabinet or closed cabinet with a high-efficiency particulate air filter) is also important.

**ENDOCAVITARY PROBES**

Few health care facility surveys are completed without questions specific to the reprocessing of endocavitary probes such as vaginal and rectal probes. Disinfection strategies vary for these semicritical items, and the FDA requests that manufacturers include at least a single validated cleaning and disinfection/sterilization protocol in the labeling for these devices. Studies have shown that 3% to 7% of transvaginal ultrasound probes may be contaminated with human papillomavirus (HPV) DNA even after routine disinfection, which suggests that high-level disinfection may not always be effective. A study published in 2014 found that certain high-level disinfectants such as glutaraldehyde and orthophthalaldehyde were ineffective against HPV even after long exposure times. Endocavitary probes come in contact with mucous membranes and are therefore semicritical devices that require a minimum of high-level disinfection. Because probe covers may fail, this applies whether or not the probe is used with a protective sheath.

A new automated device that uses ultrafine hydrogen peroxide mist to high-level disinfect probes, including the handle, has greatly enhanced ultrasound probe processing technology. In 2016, Ryndock et al found that this technology was effective against HPV16 and HPV18 virions and Rutala et al found it to be effective in the complete inactivation of vancomycin-resistant enterococci and carbapenem-resistant *Klebsiella pneumoniae*. The system is closed, quick, and easy to use and can be installed in a procedure room, making disinfection easy for staff members. Precleaning at the point of use is a must, but inserting the probe into a machine in close proximity greatly simplifies the process. Personnel may consider storing disinfected probes in color-coded, rigid, covered containers marked “clean”; however, the manufacturer’s instructions for use must be followed for specific storage recommendations.
ENVIRONMENTAL CLEANING AND DISINFECTION

The cleanliness of the environment is as much a cornerstone of cleaning, disinfection, and sterilization as hand hygiene is to the overall decrease in health care–associated infections. The persistence of multidrug-resistant organisms in the environment has been well established, and contaminated ORs increase the risk of transmission because of the many bacterial reservoirs in this setting.39,40 Despite the best efforts of environmental services personnel, a high percentage of environmental surfaces may remain contaminated even after terminal cleaning.41

“No touch” technology is swiftly changing the health care landscape, with continual advances in ultraviolet and visible light disinfection.42 Visible light disinfection works by creating a continuous and automatic hostile environment for bacteria that kills or inactivates the organism.43 Ultraviolet environmental disinfection has been shown to reduce bacterial contamination in the health care environment and may be effective as an adjunct to manual cleaning, yet additional research is required in the perioperative setting.43,44 No technology can take the place of manual cleaning and disinfection, but this emerging technology may be an option for supplemental cleaning in the future.

CONCLUSION

This year has been both exciting and immensely challenging as health care providers attempt to keep up with a continuously growing set of disinfection and sterilization requirements. Disinfection and sterilization practices in health care are likely to evolve as standards become more stringent and are vigorously enforced by regulatory agencies. The medical technology industry is expected to work nonstop to keep up with increasing health care demands and new products will undoubtedly abound. Amid the increasing demands, new requirements, and changing technologies related to disinfection and sterilization processes, one thing is certain—there is no substitute for well-trained and competent health care teams committed to excellence toward preventing infections and ensuring patient safety.

Editor’s notes: Stöckert is a registered trademark of the Stöckert Instrumente GmbH Corporation, Munich, Germany. Standards BoosterPak is a registered trademark of The Joint Commission, Oakbrook Terrace, IL.

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