How Clean Is Clean?

Chemistry Can Damage Medical Equipment In the Quest to Meet Stringent Guidelines

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What happened at Advocate Lutheran General Hospital in Park Ridge, IL, is a nightmare for any hospital. In 2013, the country's largest outbreak ever of a highly dangerous bacteria—carbapenem-resistant enterobacteriaceae (CRE)—was linked to endoscopic procedures performed at the hospital.[1] According to the Centers for Disease Control and Prevention, even manual cleaning and "high-level disinfection" failed to kill *E. coli* and other bacteria in the device. There were, however, no flaws in the hospital's cleaning protocol (which has since been changed to include gas sterilization for these devices, which exceeds the manufacturer's recommended cleaning and disinfectant guidelines).

This kind of incident is why hospitals are going into overdrive with infection-prevention tactics to reduce the rates of healthcare-acquired infections. A growing number of "superbugs" are related to some of the worst infections and are increasingly difficult to treat. There is also economic pressure—the Affordable Care Act is moving toward pay for performance (positive outcomes) rather than pay for service, with Medicare and Medicaid reducing reimbursements for certain hospital-acquired infections.

As a result, "the infection prevention and control community has adopted a zero-tolerance approach to healthcare-acquired infections, making the rates of infections a key quality indicator for healthcare facilities," said Gerald McDonnell, vice president of clinical and scientific affairs for STERIS Corporation, a Mentor, OH–based provider of infection-prevention solutions.

This means there is a greater focus on cleaning and sterilizing medical devices and equipment. A critical step is following the cleaning procedures recommended by the medical device manufacturers—but is that enough?

"New and/or stronger bugs keep pushing the contamination (and decontamination) worries," said Paul Kelley, director of biomedical engineering at Washington Hospital in Fremont, CA. "A device purchased before a new microbe is identified may not have been tested against the disinfectants that will kill that microbe. In some respects it is like an arms war—as the bugs get stronger, we need better defenses."

The method and time to clean and sterilize also should be taken into account.

Being certain that equipment is safe to be used on the next patient is a high-stakes,

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stressful decision. Has enough been done to ensure this is the case?

"Hospitals often have a great deal of difficulty with trying to (ensure) that equipment is cleaned and patient-ready," noted Shannon Thibault, director of operations for Mainspring Healthcare Solutions in Waltham, MA. "A top concern I hear repeatedly from healthcare professionals is that they never really know if the equipment they use on their patients is truly (sterile)."

Next-Generation Chemistry

Healthcare facilities have thousands of devices, constructed from hundreds of different materials. Making sure they are all cleaned and disinfected properly, with the recommended chemistry, can be a very complicated, time-consuming process. The market for cleaners is also evolving rapidly, bringing out new products that work faster and better across a wider range of devices. After cleaning infusion pumps, for example, rack-drying for at least seven to eight minutes may be standard practice before releasing the pumps into the patient population. New cleaning products today, however, only require two to three minutes of contact time and do not harm the device surfaces. Some newer cleaning products are not recommended on all types of products, so, again, following the instructions for use (IFUs) are key.

More hospitals are trying out new-generation cleaners and detergents—not just to save money, but to improve overall efficiency by having fewer cleaners that work on a greater variety of products. This does require, however, careful due diligence and mindful testing. For example, Woodland Healthcare, a 120-bed facility in Woodland, CA, is using a wider array of disinfectants, which have different requirements for "wet time." "Wet time is not necessarily the same as wait time," says biomedical services coordinator Bill Snyder. "It's confusing and time consuming for staff and requires more education."

Detergents or disinfectants sometimes are adopted by institutions so quickly that they are not fully tested. Damage to devices and equipment from cleaning (or worse, negative patient outcomes or harm to the staff using them to clean) can result. As new products arrive, facilities may not have the resources to thoroughly vet the compatibility of the chemicals with every device.

The proper cleaning and sterilization of medical equipment, such as this endoscope, is a crucial component of keeping patients safe.

It's expensive to repair or replace devices—costs can range from $50 for a pair of scissors to $30,000 or more for an endoscope. "Let's say the wrong (detergent or disinfectant), which is not manufacturer recommended, is used on an infusion pump simply because it is cheaper and has a similar result," said Thibault. "If this damages parts within the device, or the plastic screen, we are talking $300 to $1,500 to replace either part. This happens more frequently than we think it does."

High-pH chemistry can damage surfaces and colored anodize finishes. Bleach products cause crazing on some plastics, which can degrade and break more easily. Some products leave a film on touch screens and displays, making them hard to read or nonresponsive to touch commands. Some are wetter than others and can seep into devices and cause internal problems with circuitry and seals.

"The anti-glare coatings on more than 50 of our surgical touch-screen monitors were damaged and needed replacement after less than three years of use," said Ted Cohen,

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manager of clinical engineering at UC Davis Medical Center in Davis, CA. "Almost all of this damage was the result of cleaning (or disinfecting)."

Many surfaces routinely are treated with disinfectants based on alcohols, quaternary ammonium compounds, and phenolics. Most of these products are effective against important microorganisms like HIV, hepatitis B, and *Methicillin-resistant Staphylococcus aureus* (MRSA), but may not work well against other resistant forms of microorganisms, like the norovirus. Therefore, to be safe, personnel may use harsher chemicals, such as high concentrations of chlorine.

"This has led to reduced life of many furniture and fittings, as well as devices that have been inappropriately disinfected with bleach and other chlorine-based products, such as chlorine-containing wipes," said McDonnell.

The intense pressure on healthcare facilities to reduce the rate of hospital-acquired infections will continue, most likely at the expense of damaged equipment. "The cost of equipment maintenance is insignificant compared to a septic patient in ICU for a couple of weeks, which will not be reimbursed," said Snyder.

More than Just Chemistry

It would be a relief if the solution to this vexing problem were as simple as a better understanding of chemistry—instead, it is more about managing human behavior and the work environment.

The first step is following the IFUs for devices and instruments, as well as for cleaners and detergents, which are provided by the manufacturers. "As with any detergent, it is imperative that the manufacturer's instructions are followed," said Mary Ellen Fortenberry, senior director of IM solutions for PREZIO Health in Madison Heights, MI. "Not following the IFUs can cause damage to instruments and equipment. More importantly, it could lead to unclean instruments. Changing detergents also requires staff re-education and environmental monitoring to ensure the IFUs are followed."

According to Peggy Spitzer, a clinical technical support specialist at Certol International, a Denver, CO–based provider of infection prevention and cleaning products, both medical equipment manufacturers and clinical end users may have limited knowledge of cleaning chemistry. "Sometimes, manufacturers even produce IFUs that may be incomplete and conflicting, or recommend chemistry that actually interferes with removal of blood protein soil," she said. "End users are then stuck with poor instructions unless they have the knowledge to challenge the information from the manufacturer."

There are also plenty of handling issues that contribute to damaged or contaminated equipment.

Damage can be caused by surgeon abuse, failure to wipe items during surgery, items piled up on carts by the surgical team, corrosion caused by dried soil when items are left too long before cleaning, mishandling during transport and cleaning, and failure to open jointed items, resulting in corrosion and cracking. The washer also must be well-maintained and function correctly. "Correct dosing is important," added Spitzer. "Too much detergent can actually interfere with washer function. Water quality is also a big factor, and of course personnel must be trained to load and operate the washer correctly. Rinsing is an underappreciated aspect of working with chemicals during cleaning. Detergent residue is a potential contaminate that can damage instruments and cause surgical problems."

Defining a Strategy

Each healthcare facility must take ownership of this problem by developing a detailed cleaning and sterilization protocol and providing the resources to maintain it, including any required training. Infection

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"A big problem is that hospitals want to limit the number of cleaners they use, and the vendors want to protect their equipment," said Cohen. "In general, vendors do a poor job in specifying cleaners. We had one company specify a cleaner for the screen portion of a monitor that was different from the cleaner for the plastic shell. Does this vendor really think the housekeeper will switch cleaners and keep one cleaner on only one part of a product, and the other cleaner on the other parts of the product?"

Overall, Thibault said she thinks that most healthcare organizations with centralized cleaning departments have a good grasp on what needs to be done to minimize damage to equipment while protecting patients. "These departments are checked and monitored by the infection control department on a weekly basis," she said.

Clinical engineering departments and healthcare technology managers must be involved in developing thorough systems for evaluating new detergents and cleaners. Enough time must be taken to thoroughly test all cleaners on as many devices as needed.

"Clinical Engineering is represented on our Product Standards Committee," said Cohen. "Both Clinical Engineering and the Infection Control Committee evaluate cleaning products. We recently tested one cleaner that was advertised as 'universal'—it actually removed the antireflective coating on a monitor, so we didn't purchase it." Sterile processing departments also may have a hand in this process.

New cleaning or disinfecting products continue to arrive in the medical marketplace that may or may not meet the evolving needs of hospital cleaning departments. Depending on their chemistry, these products also may have been developed with a smaller body of testing data to consider.

"We will continue to see new types of disinfection and sterilization technologies, but care should be taken to understand how and if they can be of benefit to healthcare facilities,"

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said McDonnell. "If safety and efficacy can be assured, these should be adopted. There will be new guidelines and standards that will continue to encourage facilities to adopt best practices. It is also clear that, over time, staff—including technicians and managers—will need to demonstrate competency and even certification in performing these important duties in hospitals." ■

References

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