The headlines seem ripped from horror-movie posters: A “deadly bacteria” sweeps Florida. A “nightmare bacteria” outbreak emerges in Chicago. California hospitals battle a “superbug.” Even more alarming, these illnesses aren’t being spread in crowded malls or airplanes—they’re happening in healthcare settings.

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—Ann Blouin, PhD, RN, FACHE, executive vice president, The Joint Commission

The “nightmare” behind many of the headlines is the highly resistant superbug carbapenem antibiotic-resistant Enterobacteriaceae. Yet while CRE grabs the bold font, the real problem lies in its unsuspecting carrier—endoscopes, particularly endoscopic retrograde cholangiopancreatography duodenoscopes and other specialized endoscopes.

Duodenoscopes and Disinfection
More than 500,000 patients undergo procedures using duodenoscopes in the United States every year, according to the U.S. Food and Drug Administration. Unfortunately, the instrument’s design is a mixture of tiny, complex parts that make it extremely difficult to completely disinfect, even when following manufacturers’ cleaning instructions.

For example, one step of the manual cleaning instructions is to brush the elevator area. However, the moving parts of the elevator mechanism contain microscopic crevices that may not be reached with a brush. Residual body fluids and organic debris may remain in these crevices after cleaning and disinfection. If these fluids contain microbial contamination, subsequent patients may be exposed to serious infections, according to the FDA. It is worth noting that although this infection risk is problematic, for many patients in need of surgery requiring a duodoscope, the benefits outweigh the risk of infection when proper guidelines are followed.

As these cases continue to unfold and undergo scrutiny, I am reminded again of the need for the Joint Commission’s Infection Prevention and Control Standard, which addresses the minimization of risk of transmitting infection via medical equipment, devices and supplies. Lack of compliance with this standard has long ranked in the top 10 among the four settings in which The Joint Commission conducts accreditation: hospitals, critical access hospitals, ambulatory surgery centers and office-based surgery practices. And in recent years, its ranking has moved higher.

Identifying the Problem
“Senior leaders have a critical role in raising awareness of the importance of proper management of infection prevention, including effective disinfection and sterilization,” says Ann Blouin, PhD, RN, FACHE, executive vice president, The Joint Commission. “Assuming ‘all is well’ because nothing has come to the senior leader’s attention is not sufficient to protect patients from harm.”

In 2014, 52 percent of hospital surveys uncovered serious noncompliance issues with this standard. That made it the third-highest standard for noncompliance among Joint Commission-accredited hospitals. The numbers were...
not much better for the other three settings:

- Critical access hospitals—51 percent noncompliance (fourth highest among standards)
- Ambulatory surgery centers—41 percent (second highest)
- Office-based surgery practices—39 percent (second highest)

Breaches in high-level disinfection as they pertain to scope and ultrasound probe reprocessing and the instrument sterilization process are increasing. Common breaches include the following:

- A lack of adherence to or knowledge of evidence-based guidelines
- Not following manufacturers’ instructions for use
- A lack of or incomplete documentation of competency, training and oversight
- Failure to adhere to and document physical/mechanical, chemical and biological monitoring of instruments
- Failure to maintain equipment to ensure high-level disinfection and sterilization efficacy
- Lapses in room pressure, temperature and humidity monitoring lapses

It is important to note that the majority of organizations are compliant with this standard. That is why these numbers and breaches require some context to understand why they are trending in the wrong direction.

First, The Joint Commission continually heightens its surveyors’ education in regard to high-level disinfection and sterilization. In addition, survey-process activities related to high-level disinfection and sterilization are designed to increase awareness on potential breaches. This increased education and focus on high-level disinfection and sterilization makes it less likely for a surveyor to miss any breaches than in the past, thus increasing the number of identified noncompliance issues.

Second, organizational design may be seen as a high-level disinfection
We’ve often seen high-level disinfection and sterilization processes fail to be followed because so much focus from key stakeholders was placed on competing priorities such as hand-hygiene adherence or monitoring for central line-associated infections.

One of the main issues uncovered during surveys is staff who lack competency and training on this standard. We’ve often seen high-level disinfection and sterilization processes fail to be followed because so much focus from key stakeholders was placed on competing priorities such as hand-hygiene adherence or monitoring for central line-associated infections. The result: untrained staff members who are not aware of their responsibilities under this standard. This is where an organization’s healthcare leaders can make a difference.

Developing Proactive Solutions
This past spring, the FDA released an alert to healthcare professionals, including those working in reprocessing units in healthcare facilities, to explain the particular challenge of effectively cleaning ERCP duodenoscopes.

The day following publication of this alert, the Centers for Disease Control and Prevention reported a rise in lethal CRE infections, citing a “seven-fold increase in the spread of the most common type of CRE during the past 10 years” ("Patients Face More Lethal Infections from CRE,” www.cdc.gov/features/vitalsigns/hai/cre).

Nearly a month later, the FDA released final guidance on reprocessing of reusable medical devices aimed at helping device manufacturers develop safer reusable devices, especially those devices that pose a greater risk of infection.

These reactions were in response to yet another of the increasingly prevalent CRE outbreaks, and they were important steps to take. That said, they were also just that—reactions. To prevent further outbreaks, healthcare organizations need to be proactive.

“Senior leaders must ask key questions of the leadership team in clinical and support operations,” Blouin says. “They must observe departmental core processes and request patient outcomes and statistics regarding infection prevention and control. These are essential efforts to providing a safe environment of care, regardless of whether the setting is ambulatory or acute care.”

With that understanding and background knowledge, stakeholders can then begin to formulate a real-world plan for addressing high-level disinfection and sterilization. Simple questions such as “How high is high-level disinfection and sterilization on our list of priorities?” and “Who owns our high-level disinfection and sterilization processes?” can provide meaningful triggers to improvement. Then, proactive measures are a matter of impressing on staff the key practices for compliance:

- Following evidence-based guidelines
- Training staff
- Following manufacturer instructions for use

Taking these steps allows an organization to proactively identify and prevent breaches instead of reactively trying to do so after a survey.

In the end, healthcare leaders have to determine what their goals are. Even if their organizations cut high-level disinfection and sterilization breaches in half, is that where they want their organizations to be? The goal is, and always should be, zero. ▲

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