



## Superbug reveals challenges with high-level disinfection

### Issue:

Recent outbreaks related to a highly resistant superbug, carbapenem-resistant Enterobacteriaceae (CRE), are claiming national attention. These outbreaks involve a specialized endoscope called a duodenoscope, a type of device that is challenging to high-level disinfect. The problems related to the CRE superbug are compounded by variation in staff competency, training, adhering to evidence-based guidelines and/or manufacturer's instructions-for-use – all of which are vital components in the prevention of infection transmission to patients. The Joint Commission continues to uncover serious noncompliance issues at accredited hospitals, ambulatory surgery centers, office-based surgery centers and other ambulatory settings. Infection Prevention and Control standard IC.02.02.01 addresses minimizing the risk of transmission of infection with medical equipment, devices and supplies.

Challenges specific to the high-level disinfection (HLD) of semi-critical devices (such as endoscopes and ultrasound probes) include:

- Endoscope reprocessing has a narrow margin of safety; any slight deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection.<sup>1</sup>
- The tendency to omit steps in the reprocessing process. HLD is a cognitively demanding process with a number of tasks that can easily be omitted.
- Not adhering to evidence-based guidelines or manufacturer instructions-for-use.<sup>2</sup> There may be a number of similar instruments that have different instructions-for-use; the lack of standardization increases cognitive load and burden on memory.
- Endoscope design itself poses a challenge to achieve minimal HLD.<sup>3</sup>
- Even with full adherence to reprocessing protocols, endoscopes may remain contaminated with pathogenic microorganisms that may result in patient exposure.

More health care-associated outbreaks of infection have been linked to contaminated endoscopes than to any other medical device.<sup>4</sup> While the incidence of infections associated with endoscopes has been reported to be very low (about 1 case per 1.8 million people) for years,<sup>5</sup> the true incidence of infections related to endoscopic procedures remains unknown due to the current lack of surveillance and underreporting.<sup>6</sup> Likewise, contemporary data to understand the enormity of HLD breaches in the U.S. and the risk they pose to patient health and safety is lacking, also due to underreporting and the lack of routine surveillance. It is only when these breaches result in an outbreak investigation, media attention, or regulatory scrutiny and penalty that attention is directed towards reprocessing lapses.

### Safety Actions to Consider:

Health care organizations can use the following safety actions to address the challenges associated with HLD of semi-critical devices, including duodenoscopes.

- Use of hand hygiene and appropriate personal protective equipment (PPE).
- Ensure that cleaning detergents, appropriate brushes, and other supplies or equipment for HLD processing are available and easily accessible.
- Follow evidence-based guidelines for HLD reprocessing.
- Follow manufacturer instructions-for-use for medical equipment, devices and supplies. Ensure that the instructions-for-use are updated, available, and user-friendly (e.g., follow FDA guidelines for instructions).
- Follow organizational/departmental policy and procedures for HLD.
- Assure staff are competent and trained specific to HLD processes (this includes managers/supervisors with HLD oversight responsibilities).

(Cont.)



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The information in this publication is derived from actual events that occur in health care.

- Perform quality control monitoring of HLD processes that includes complete documentation. Understand where process breakdowns may be occurring and why (e.g., time pressures, staff availability, or lack of instructions-for-use).
- Follow [FDA Safety Communication recommendations](#).
- Ensure sufficient space to separate dirty from clean equipment, and to perform the various steps in HLD (to include consideration for PPE).
- Reduce visual and auditory noise that can affect concentration, and minimize interruptions.
- Review caseload volume and instrument availability and usage with the goals to anticipate peak reprocessing times and mitigate time pressures. Ensure proper number of staff and time allocation to allow for the effective reprocessing of equipment.
- Provide cognitive aids to help reduce the omission of steps in the reprocessing process. Ensure cognitive aids support a user's mental model, follow sequence in task, and incorporate human factors and FDA recommendations.
- Follow processes for reevaluating and updating training when equipment design changes.
- As part of quality control management, follow a verification process to ensure the scopes are free of infectious materials (i.e., actually swabbing scopes to confirm no growth in cultures).<sup>7</sup>
- Incorporate human factors thinking into the HLD process by supporting worker's physical and cognitive capabilities while compensating for limitations (e.g., ensure cleaning items are easily available and accessible; reduce burden on memory; evaluate workload volume, schedules and equipment availability).

### Resources:

1. Alfa M: Automated washing with the Reliance Endoscope Processing System and its equivalence to optimal manual cleaning, *American Journal of Infection Control*, 2006;34(9):561-570
2. Dirlam Langlay A, et al: Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg, *American Journal of Infection Control*, 2013;41(12):188-1194
3. A 21st century nosocomial issue with endoscopes [Feature], *The British Medical Journal*, 2014;348:g2047 doi: 10.1136/bmj.g2047
4. Spach D, et al: Transmission of infection by gastrointestinal endoscopy and bronchoscopy, *Annals of Internal Medicine*, 1993;(118):117-128
5. Schembre D: Infectious complications associated with gastrointestinal endoscopy, *Gastrointestinal Endoscopy Clinics of North America*, 2000;(10):215-232
6. Kovaleva J, et al: Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy, *Clinical Microbiology Reviews*, 2013;26(2):231-254
7. Association for the Advancement of Medical Instrumentation: AAMI ST58, Annex L "User Verification of Cleaning Processes"
8. AAMI TIR55:2014 Human factors engineering for processing medical devices, January 2015
9. Anderson JD: [Using human factors engineering to improve the effectiveness of infection prevention and control](#), *Critical Care Medicine*, August 2010;38(8 Suppl):S269-S281

### High-level disinfection (HLD) Resources

- 2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities
- American National Standards Institute and Association for the Advancement of Medical Instrumentation: ANSI/AAMI ST58:2013 Chemical Sterilization and high-level disinfection in healthcare facilities
- Association of periOperative Registered Nurses: 2013 AORN Recommended Practices for Perioperative Nursing; Sterilization and Disinfection, Disinfection – High-level, Flexible Endoscopes – Cleaning and Processing
- Association for Professionals in Infection Control and Epidemiology: 2014 APIC Text of Infection Control and Epidemiology, 4th edition
- Society of Gastroenterology Nurses and Associates:
  - 2013 SGNA Guidelines for the Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes
  - Society of Gastroenterology Nurses and Associates: 2012 SGNA Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes

Note: This is not an all-inclusive list.



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