

Infection Prevention and Control

Ongoing Discovery of High-Level Disinfection of Endoscope Practices and the Use of Performance Improvement Methodologies to Improve Processes

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Preventing health care–associated infections, regardless of the setting (hospital, ambulatory, office-based), has become a priority. This focused attention can be attributed to leaders motivated to improve the quality of care with highly reliable, repetitive, evidence-based process practices; patient expectations of an uncomplicated health care experience; increased awareness of reported infections; and financial implications (positive and negative) to the organization. A topic that has recently become a main concern is high-level disinfection (HLD) and endoscopes used for endoscopic retrograde cholangiopancreatography (ERCP) procedures, as represented in the Food and Drug Administration (FDA) Safety Communication in February 2015.¹ Increased infection risk may reflect the complexity of the endoscope device, which contains many small working parts with hidden, often difficult to reach, crevices, and/or reprocessing errors, which can occur during any of the steps for precleaning, manual cleaning, HLD process, and endoscope storage.

An endoscope can be rendered free of harmful pathogens when the endoscope's manufacturer guidelines are adhered to, HLD instructions for use are followed, and the endoscope is managed in ways to minimize contamination following HLD.^{2,3} HLD challenges that impede achieving a pathogen-free endoscope can include competency of those who perform HLD, as well as their adherence to the manufacturer's multistep manual-cleaning guidelines for each scope and/or the HLD's instructions for use (for example, temperature parameters and minimal effective concentration), plus the environment in which HLD is performed and endoscopes are stored.^{4,5} The use of performance improvement methodologies and expert guidance from the literature and other organizations can facilitate the identification of HLD practice gaps that contribute to failures that lead to endoscope-associated infections and subsequent movement toward optimal practices to minimize the risk of cross contamination.

In their article, "Assessment of Endoscope Reprocessing Using Peer-to-Peer Assessment Through a Clinical Community," in this issue of *The Joint Commission Journal on Quality and Patient Safety*, Teter and colleagues report on an assessment of

HLD practices of endoscopes to guide improvement.⁶ Tapping into existing resources and following a peer-to-peer nonpunitive collaborative approach, the authors used a survey and tracer tool at 15 ambulatory practices to collect data on the current state of HLD and endoscope use. They aggregated the data to identify practice gaps and fed back the data to the practices, which were ranked by deficiency, and then conducted group discussions to develop improvement strategies. Lack of education/training and standardized processes ranked as the two predominant issues. These issues can contribute to inadequate HLD, possibly resulting in a contaminated endoscope and pathogen transmission, because transmission of infections can occur if inadequate cleaning is performed and recommended guidelines are not followed.^{4,5} The fact that this process was implemented before the FDA Safety Communication¹ (and the ERCP infections that prompted the FDA action) is impressive.

For physicians, nurses, technicians, and administrators responsible for conducting or overseeing HLD, the article identifies possible issues that could contribute to an undesirable outcome—a contaminated endoscope linked to a patient infection. The approach taken by the authors can assist others in conducting an evaluation to prioritize an improvement approach, and their assessment findings can be used as the starting point to standardize processes as per endoscope manufacturer guidelines, HLD instructions for use, and external guidelines.² After an HLD standard is developed, education and training can be conducted, followed by ongoing assessment in terms of standard measurements that are aggregated to provide data on progress, feedback of the data to those conducting and overseeing the process, and the implementation of ongoing data-based changes to comply with practice standards and sustain performance. The peer-to-peer assessment reported by Teter et al. is similar to the approach taken at Northwell Health early in 2015 following the release of the FDA's Safety Communication of infections following ERCP procedures.¹

At Northwell Health (formally known as the North Shore-LIJ Health System), a health system with 21 hospitals, long

term care facilities, and more than 450 ambulatory practices, we conducted an assessment, which in each case was completed by the site-specific infection preventionist and HLD area-specific management, and then implemented changes on the basis of the evaluation of practices in HLD locations in which reprocessed endoscopes were identified. Our own intervention also predated the alarm accompanying news of the ERCP infections, which allowed us to react proactively when it was announced. In summary, the following actions were taken:

- All HLD locations and endoscopes reprocessed were identified.
- Compatibility letters for each endoscope and method of HLD or sterilization were validated.
- HLD policies and procedures were reviewed and standardized to create a set of HLD procedural reference documents for all HLD areas within the health system.
- Competencies, based on manufacturer instructions for cleaning and reprocessing, were written, and all health care personnel (HCP) performing HLD was deemed competent through direct observation.
- HLD procedures and products (for example, automated endoscope reprocessors [AERs], flushing devices, magnification mirrors) were standardized.
- Endoscope tracers from precleaning to storage were conducted to identify variances from approved policies and procedures by health system resources. Just-in-time training and practice modifications were introduced as issues were identified.
- An environmental assessment of the HLD reprocessing areas was conducted and work-flow modifications were made to support a one-way flow to minimize cross contamination.
- A point-of-use test for ERCP endoscopes was introduced to support a clean endoscope after manual cleaning and before receiving HLD.
- All ERCP endoscopes were cultured once, and negative microbiology results were reported.
- An RN was reallocated to perioperative corporate services to support endoscopic practices and lead continuous HLD process improvement.
- Monthly meetings with those who oversee HLD were coordinated by the RN from perioperative corporate services to discuss and implement meticulous cleaning of the elevator with an enzymatic cleaner and specific brush, proper-positioning angle (45°) of the ERCP elevator during reprocessing, flushing the scope with isopropyl alcohol after reprocessing, hanging the endoscope in a horizontal vented cabinet between use, reprocessing scopes every 14 days, and tagging clean scopes as “clean” following HLD. The group continues to meet to discuss and

implement best practices based on practice discoveries within their practice environment, published in the literature, and/or from expert guidance.

We also explored the use of remote video auditing (RVA) technology to assess the multistep manual cleaning of ERCP endoscopes, which is undertaken before HLD. In October 2015 a Northwell Health hospital committed to ensuring adherence to the ERCP endoscope manual-cleaning steps, as outlined by the endoscope manufacturer and external resources.^{2,3} Cameras were placed within the endoscope reprocessing area with a feed into a digital video recorder that was accessed by a third-party auditing company. The recorded activity provided the auditors with a high-resolution complete view of the sinks used to manually clean the endoscopes before they were placed into the AER. Trained auditors, located external to the facility, viewed video of the activity, including the ability to zoom into close-up video imagery of precise reprocessing processes, such as proper cleaning of the scope tip elevator. After the auditors observed an ERCP endoscope being placed in the reprocessing sink by the HCP, his or her compliance with each item on the checklist, as well as the total duration of cleaning, were recorded. The auditors assigned a *Pass* to each item on the checklist when the HCP completed each task and the amount of time spent to complete the entire checklist was recorded. Conversely, auditors indicated a *Fail* when an HCP missed tasks on the checklist. What we learned is that the 41-item manual-cleaning ERCP checklist can be viewed and scored with the use of RVA. Monitoring, feedback, and reeducation with the support of leadership have increased audit compliance results from less than 50% to greater than 90%, which is similar to findings reported in other studies using RVA.⁷⁻⁹ The success of RVA and ERCP endoscope cleaning has led to their expansion to other Northwell Health hospitals.

To continue the health system's improvement journey, the Joint Commission High-Level Disinfection (HLD) and Sterilization BoosterPak™ (BoosterPak), which is intended “to ensure practices are carried out following regulatory standards and evidence-based guidelines for HLD and sterilization in order to minimize the potential risk of infection transmission to patients,”* became the basis for the development of a health system tool, “High-Level Disinfection (HLD) of Semi-Critical Devices Assessment.”¹⁰ This tool has two components to the risk assessment. The first section identifies HLD areas, HCP training and competencies, reprocessing environment, HLD

* A Standards BoosterPak™ is a searchable document intended to provide detailed information about a single standard or topic area that has been associated with a high volume of inquiries or noncompliance scores in the health care field. Booster-Paks are available on the secure *Joint Commission Connect™* extranet to organizations accredited and certified by The Joint Commission.

practices based on endoscope manufacturer guidelines, HLD instructions for use, and health system HLD policies and procedures.* The second section is an HLD observation tool used to assess current practice and quantify near misses and/or practice variations. The observation tool guides observation of practices, and when observation does not align with outlined standards, immediate actions, which may include just-in-time training and practice modifications to avoid potential HLD failures, are taken. Examples of observations and changes based on standardized policies and procedures include precleaning at point of use prior to transporting the endoscope to the reprocessing area, endoscope manual cleaning within an hour of use, removal of tip protectors on stored endoscopes, wearing clean gloves when handling disinfected endoscopes, and keeping accessories with the endoscope or conversion to disposable accessories.

What we have learned is that the BoosterPak, coupled with improvement methodologies, can lead to improved practice advancements and quality. The ongoing cyclical evaluation of performance measurement data, which are analyzed to identify improvement or maintain optimal practice, supports reliability through subsequent elimination of error.¹¹ In this improvement process, near misses and practice variations (attributed to drift from the ideal state, shortcuts taken to complete the task, or deficits in knowledge due to lack of training or the relative infrequency of the task being performed) can be identified.¹¹ We, as leaders in the health care delivery system, are responsible for the care we deliver and have to always remember that associated with every infection is a patient (and family) who expected high-quality care and services, not harm. Patient safety improvements focused on HLD do not necessarily require large investments; reallocation of organizational resources, accountability, and ongoing assessment to ensure process reliability should continue to evolve HLD processes to optimize patient safety. ■

* The risk assessment can be requested from the author at darmelli@northwell.edu.

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