Real-World Findings from Recent Practice Reviews Performed in Endoscope Processing Areas

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LEARNING OBJECTIVES

1. Review findings from recent Consultative Practice Reviews
2. Discuss why some practices keep occurring, even when clear guidance recommends against them
3. Discuss strategies for fixing lapses in best practice

Why are some practices so slow to change? As members of the Clinical Affairs team at Healthmark Industries, our educators are privileged to be invited to review current practices in processing departments across the country. Unfortunately, time and again, our team finds the same practice deviations repeated in endoscope processing suits, regardless of size or location. Why do these practices persist even when clear guidance against them is provided by standards and best-practice organizations? This lesson explores a few repeated issues regarding cleaning verification (CV), endoscope transport and endoscope storage that our team encounters regularly.

Objective 1: Review Findings from recent Consultative Practice Reviews

Cleaning verification: The practice of CV is recommended by many organizations, including the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN) and the Society of Gastroenterology Nurses and Associates (SGNA). It is also recommended by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). With clear support for CV, one might assume it occurs everywhere. Sadly, recent experience demonstrates the contrary. Many facilities are not performing regular CV on their endoscopes, and if they are, many are doing it at the wrong time—often after high-level disinfection (HLD).

CV is one of the simplest quality assurance (QA) measures a processing unit can take. Available products are quick, reliable and allow for detection of one or multiple residual soils. On the most basic level, endoscope processing professionals can think of it this way: would anyone knowingly send a soiled endoscope to the next patient without thorough processing? One would hope the answer is no.

Visually determining whether a flexible endoscope is completely clean with the naked eye is virtually impossible. Due to the color (dark and opaque) and complex design of flexible endoscopes, a CV tool is necessary to accurately determine if an endoscope is clean. ANSI/AAMI ST91:2015, *Flexible and semi-rigid endoscope processing in health care facilities* states, "The use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning." Enhancing inspection with CV tools adds quality to processing practices and should provide cleaner endoscopes for patients.

One might ask: Why not perform CV after HLD? Simply put, verifying an endoscope is clean should come before any further processing. CV tests for the adequacy of cleaning. The tests are not intended (and do not test) for microbial contamination. Remaining soil in endoscopes impedes the disinfection process, which means that using CV following HLD is simply too late. ANSI/AAMI ST91 stresses this by stating, "Meticulous manual cleaning is essential for the removal of organic contamination that can interfere with high-level disinfection." A secondary issue with checking for soils at this point is that the high-level disinfectants themselves may interfere with the sampling process, thereby providing inaccurate results.

Endoscope transport: A second issue of concern lies with endoscope transport, specifically in regard to the clean transport of disinfected endoscopes and the soiled transport of used endoscopes. Concerning practices in both areas are still observed.

When transporting high-level disinfected endoscopes, avoiding contamination is the primary priority. Unfortunately, handling these endoscopes with bare hands, placing them in visibly soiled transport bins, and engaging in inconsistent transport procedures have all been witnessed. While these are not the only ways to contaminate a patient-ready endoscope, they are frequently encountered examples.

Once an endoscope has been used, it is a potential source of contamination for staff and the environment until it can be decontaminated. Why then are contaminated endoscopes frequently hand-carried across hallways to processing areas? Why are endoscopes often wrapped in drapes or placed in bags intended for patients' belongings? Not only can these scenarios lead to accidental exposure of staff and/or the surrounding area, but they are all against the law. The Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogen standard states, "Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be puncture resistant; labeled or color-coded in accordance with this standard; and leakproof on the sides and bottom, in accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps." Even though this regulation has been a legal requirement for decades, instances of noncompliance are all too common.

Endoscope storage: Third, let us discuss endoscope drying and storage cabinets. Once again, minimizing the potential for contamination of high-level disinfected endoscopes is of utmost importance, and ensuring appropriate drying and storage practices helps make that happen. Regrettably, it is still a regular occurrence to open an endoscope storage cabinet and find an absorbent pad in the bottom; this is typically a sign that wet endoscopes are being placed into storage. Why is this a problem? The long-held belief that flexible endoscopes dry themselves if they are hung vertically is false. Research has proven that gravity does not influence small water droplets within endoscopes, and moisture can remain inside endoscope channels for days, if not longer. Because wet environments are breeding grounds for microorganisms and biofilm formation, not removing all of the water from the endoscope's channels presents a safety risk to patients.

Wet endoscopes are not the only storage-related problem. Improper use of storage cabinets is often observed as well. Purchasing the best storage cabinet available makes little difference if it is not used properly. Finding cabinet doors ajar or fully opened is a common occurrence. Witnessing endoscopes touching each other or the sides or bottom of the cabinet also happens all too often.

Other findings related to endoscope cabinets have to do with the storage of buttons or valves and the inappropriate use of automated endoscope reprocessor (AER) recording tapes. The need to keep buttons together with an endoscope (as a unique set) has produced many creative but inappropriate solutions, such as putting buttons in cups within

the cabinet, resting buttons directly on a small lip within the cabinet, and placing buttons into non-breathable plastic bags. As simple or useful as these solutions may seem, the cups become soiled, the buttons fall off the lip, and condensation can be observed in the plastic bags. While all of these approaches were an attempt to comply with standards, the way in which they are done creates another set of challenges.

Finally, it may seem logical to use AER recording tapes to identify endoscopes as patient-ready in the cabinet. Since it is recommended to both identify the endoscope and retain the AER printout, some may question why they should not be placed together. First, placing paper products within the cabinet can contribute to lint and dust, which can end up on the endoscope. Second, keeping the printout with the endoscope in the cabinet for traceability, identification or both has led many to tape the printout directly to the endoscope handle. Not only does this contaminate the endoscope, but it also adheres sticky residues to the handle that will attract and trap contaminants.

Objective 2: Discuss why some practices keep occurring, even when clear guidance recommends against them

With guidance documents advising against the aforementioned practices for years, if not longer, the question becomes, *why do these sub-standard practices keep occurring?*

Cleaning verification: CV is one of the very few ways to know what may still lurk inside an endoscope after cleaning. The practice has wide support in industry standards and guidance documents. Even with the clear importance of CV, some processing professionals rationalize not performing the task due to a lack of time or space. While these are legitimate obstacles to overcome, there are no excuses for not following best-practice guidelines. Flexible endoscopes are complex medical devices that are difficult to clean, even when all steps of the instructions for use (IFU) are meticulously followed. CV is a much-needed quality check that is well worth the time it takes to perform.

Transport issues: Proper transport practices for endoscopes are often dismissed because of the short distances they travel. Extremely poor practices are often allowed because employees claim they are "only going across the hall." OSHA regulations do not change with proximity, and a surveyor will not accept this excuse when observing improper transport of endoscopes. A well-thought-out facility policy is required for the practice to be safe and effective.

Storage issues: Storage of semi-critical medical devices deserves greater attention. Because these devices are seen as less of an infection risk, noncompliance with proper storage conditions is also seen as less important. Statements such as "I only left the cabinet open while I ran to the other room," and "Our cabinet is in a restricted hallway, so the public isn't in there" have been used to excuse poor practices. Storage cabinets are designed to protect flexible endoscopes from environmental contamination, but for the cabinets to be effective, proper use is critical.

Objective 3: Discuss strategies for fixing lapses in best practices

Cleaning verification: Before initiating or redesigning the CV process, it is important to conduct some research. Selecting a tool that tests for one or multiple clinically relevant soils—and one that is sensitive enough to detect even low levels of those soils—is important. A list of clinically relevant soils can be found in ANSI/AAMI ST91. Remember: If processing staff does not feel that they have the time or space to perform CV, they often will not. Discussing the need for this QA process with providers and processing staff is key to prioritizing the time needed to perform CV.

Safe transport: Solutions to transport issues are two-fold. First, everyone involved must understand their role and why it is important to follow the facility's policy on transport, regardless of the distance the endoscope is traveling. Additionally, a standardized transport process will ensure that all departments (receiving and returning endoscopes) follow the same steps, a key to achieving compliance. The second solution involves transport bins. For the process to be successful, the bins must be the appropriate size to avoid endoscope damage. Each must also have an IFU that states its material compatibility, disinfection process and (for soiled transport) OSHA compliance.

Proper storage: Products specifically created to address storage needs are available. Endoscope processing professionals must evaluate label usage for viable solutions (e.g., identifying endoscopes without contaminating them, tracking days until unused endoscopes must undergo reprocessing, and using mesh pouches for organizing buttons). Products purposefully designed for these processes remove the temptation to create an inappropriate solution, and such products should come with IFU. Referencing IFU when creating policies and training/competency documents provides readily available answers to surveyors' questions. Again, training

and competency verification are necessary to correct and standardize human factors that plague storage.

Conclusion

Seeking standard product solutions will help a facility improve practice gaps, but none are a silver bullet. Investments in resources, time and education are just as important as investing in endoscopes. A well-planned training program, comprehensive competency program and periodic internal practice audits are necessary to ensure effective, long-lasting solutions.

RESOURCES

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST91:2015, *Flexible and semi-rigid endoscope processing in health care facilities*. Available for purchase at https://www.aami.org.

2. U.S. Department of Labor, Occupational Safety and Health Administration. "Code of Federal Regulations: Occupational Exposure to Bloodborne Pathogens. Title 29 [Bloodborne pathogens], Standard No. 1910.1030." https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030.