Quality Approach to Training and Competency Verification in Flexible Endoscope Processing

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LEARNING OBJECTIVES

1. Discuss the need for standardization in practices and policies when starting or revamping an endoscope education program
2. Review the need for a well-organized, rigorous training and competency verification program for endoscope processing and the equipment involved
3. Discuss why good documentation practices are essential to the overall quality of a training and competency program

Flexible endoscopes are potentially the most challenging devices to process on the market today. These devices' fragile nature and complex design require a robust staff training and competency verification program to deliver quality cleaning and disinfection outcomes. For a facility's training and competency program to be successful, we must dedicate sufficient time to all staff involved. Spending time on initial planning and training, verifying the knowledge required to process flexible endoscopes effectively and documenting activities will pay dividends in the quality endoscope of processing.

Objective 1: Discuss the need for standardization in practices and policies when starting or revamping an endoscope education program

Whether performing flexible endoscope processing duties in an Endoscopy (Endo) department, urology clinic or a Sterile Processing department (SPD), survey organizations will expect all areas that process endoscopes to adhere to the same policies. For example, if internal inspection with a borescope is required for specific endoscope models processed in Endo, it is expected that the same will be done in all departments processing that endoscope type. This presents a particular challenge if the facility has a decentralized policy creation and training/competency verification program.

Consider this scenario: The SPD covers processing duties for Endo in the case of after-hours emergency procedures. Do both departments have the same steps in their policies for processing each endoscope? Was the competency verification process conducted in the same way in both departments? If not, the endoscope (and by extension, the patient on whom the endoscope is used) may receive a different level of care depending on who

processes the endoscope. Solving these issues will take time and planning but will inevitably make for a better overall program.

It does not matter whether a facility is creating a new program or making improvements to an existing flexible endoscope processing training and competency program. For both, the process begins where all device processing activities should start—gathering resources and defining processes through policy. Suppose processing endoscopes is new to a department or the department recently inherited processing duties for specific endoscopes (e.g., gastroscopes or bronchoscopes) that require certain tools. One may start by gathering materials, such as brushes and leak testing equipment, and requesting an automated endoscope reprocessor (AER); however, this is only half the equation. Creating policies based on manufacturers' instructions for use (IFU) and nationally recognized standards and guidelines that outline all aspects of the process (including how and by whom initial training will be performed and when ongoing competency verification will be accomplished) is essential before moving forward. Considering the need for these documents early in the process means training can start before the first endoscope arrives in the department.

Objective 2: Review the need for a well-organized, rigorous training and competency verification program for endoscope processing, and the equipment involved

As with any new device to process, staff members must understand their role in handling the endoscope. To familiarize staff with the new device, the department can start with a departmental conducted inservice by either a vendor representative or a department educator/manager. This level of education, however, is only an initial step when it comes to processing endoscopes. Devices this complex require hands-on instruction between a trainer and each staff member. Also, demonstrating on just one model of an endoscope is not sufficient. Each staff member should receive training for every model of endoscope they have responsibility for processing.

Why is this necessary? Flexible endoscopes vary in size, complexity and design from manufacturer to manufacturer. As such, the steps for processing each endoscope can differ just as significantly. With many flexible endoscopes receiving only high-level disinfection instead of sterilization (whether because of the Spaulding classification or lack of compatible sterilization technologies), these devices do not have the safety margin that instrument sterilization provides. With that margin reduced, emphasizing effective point-of-use treatment is a must and will require in-depth staff training.

Support for rigorous training can be found in guidance documents from 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), to name a few. ANSI/AAMI ST91:2015, *Flexible and semi-rigid endoscope processing in health care facilities,* Section 5, outlines personnel considerations, including training and competence recommendations. In addressing the frequency of training, ST91 states, "Processing activities should be closely supervised until competency is verified and documented for each processing task, from point of use through storage of the endoscope and transport to the next point of use." Even when some processing steps are the same from one endoscope to another (e.g., transport), many others will be model specific. That specificity requires a trainer who understands the steps for each endoscope model to observe each staff member as they perform them.

There is no better example of this than the Olympus TJF-Q190V duodenoscope. From pre-cleaning to the drying required before disinfection, 256 manual cleaning steps are outlined in this endoscope's IFU. This endoscope model is remarkably complex; however, other large endoscopes often require more than 100 steps to clean manually. Regardless of the model, each step should be verified before a staff member is allowed to process the endoscope unsupervised. When processing moves outside of decontamination, rigorous training and competency programs must follow.

Inspection of endoscopes, especially internal inspection, as recommended by multiple professional societies, will require a borescope and training around its proper use. This training should include more than just how to use the borescope. It must convey to the processing staff what they should and should not see within an endoscope. When we consider that some staff members have never seen the internal channels of an endoscope, the importance of a well-planned training program on inspection becomes clear. In this case, a trainer must take the time to ensure all staff members are comfortable with using the inspection tool and with what they are seeing. The training should also include what to do when staff find something irregular. Investing in a borescope without investing in staff training will lead to misuse or underuse of the borescope.

Visual inspection is only one aspect of the processing activities flexible

endoscopes require once they are cleaned. Cleaning verification (CV), another quality process, is also a recommended practice that should be considered. This activity is a multi-step procedure that can give false results when performed incorrectly. Taking time to train each staff member and observe a return demonstration to verify their understanding of the process is the only way to reduce the risk of error in a CV process. At this point, an endoscope is ready for disinfection, and the training/competency verification needs to continue.

The disinfection process for endoscopes presents not only procedural challenges but regulatory ones as well. These challenges are greater when performing manual high-level disinfection (HLD), but they apply even when an AER is used. Due to the chemicals involved, not only is training of the processing steps required, but also safety training on handling the chemicals themselves. Any regulations from the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) around the use, accidental spill and disposal of HLD chemistries must be conveyed to staff members. Locations of personal protective equipment (PPE), eyewash stations and spill kits are all things staff members should be able to point out and know how to use without hesitation. As previously stated, using an AER does not negate the importance of this training. In fact, it adds a layer of complexity to the process.

AERs are excellent aids for endoscope processing staff, but they require thorough training to operate safely and correctly. AERs come in different sizes and have various capabilities. Some manufacturers claim certain units can allow staff to skip many of the steps for manual cleaning from the IFU. This increases the importance of proper processor usage. The complexity of the machines and the multiple chemicals utilized within many systems make staff training on the unit itself as important as if the endoscope were being processed manually. Preventive maintenance duties (i.e., replenishing chemistries, changing connector sets and cleaning/disinfecting the unit) will also require training and competency verification.

In addition to these maintenance processes, AERs also require training/competency to the unit's higher functions. For example, many processors have the option to select distinct levels of processing (meaning that an endoscope can be cleaned or disinfected—or cleaned and then disinfected consecutively). Ensuring that staff members understand all the AER's functions, including record-keeping capabilities, is paramount. Cycle selection can mean the difference between a patient-ready endoscope and one that is not ready/safe for patient use.

Objective 3: Discuss why good documentation practices are essential to the overall quality of a training and competency program

Competency verification is the next phase in ensuring quality endoscope processing. A good rule of thumb is if initial training was provided for a process, then that process needs competency verification to ensure continued adherence to it. The current recommendations for competency verification include an annual observation of each staff member processing each endoscope model. As previously noted, this should also apply to any equipment used to process endoscopes. Depending on the number of staff members and the variety of endoscopes in inventory, this process can take weeks, if not months, for larger departments. Again, time is often a significant factor for compliance with recommendations.

When considering requirements for competency verification, it is important to ensure adequate time is allocated—and this involves more than just observing each staff member process each endoscope. It will also take time to coordinate the acquisition of each endoscope model (if they are not stored within the department), schedule staff to demonstrate their adherence to facility policy and manufacturer's IFU, and make a processing sink available. All of these steps require planning and allocation of resources. It is beneficial to consult with any unit that brings an endoscope to the department for processing to ensure the activities do not disrupt their schedules. To save time, it may be possible to verify competence of some staff on some endoscope models as part of the department's everyday activities. Still, some endoscope models and staff members will inevitably need to have their competency verification done at a pre-planned time (it is also essential to accommodate and include staff members from the night shift).

Documentation of all competency training and activities is the final step that requires a significant amount of the trainer's/manager's time. The common phrase "If it wasn't documented, it wasn't done" is an accurate one and survey organizations will look to ensure documentation is thorough and well organized. The risks to the patient associated with poor endoscope processing practices are well known. Having a documentation system that is organized and easily accessible will demonstrate a commitment to quality and safety.

Record retention methods will depend heavily on the department size

and whether the facility already has a system in place. Keeping paper records is acceptable, and departments with small staffing levels may prefer paper-based documentation as it can be kept close for easy access. Still, digital record keeping offers many benefits. The ability to access files from anywhere within the facility, generate reports that track staff and department progress, and gain peace of mind from knowing the records are ready when questions arise during surveys are all great reasons to adopt digital documentation. It is important, however, to not let this strength become a weakness. Not knowing the system well, forgetting the password, or fumbling when looking for records will all appear as potential problems in the eyes of surveyors.

Conclusion

Anyone involved in processing flexible endoscopes understands the instruments' importance in diagnosing patient illness. Unfortunately, endoscope processors are also aware of time pressures, complex IFU, variations between standards and recommendations, and uncertainty around their role, all of which can prevent these staff members from processing endoscopes correctly. Ensuring staff members are thoroughly trained—and with current competencies kept on file—will demonstrate that these devices can provide all the benefits they are capable of while also mitigating as many of the risks as possible.

RESOURCE

American National Standards Institute/ Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST91: 2015, *Flexible and semi-rigid endoscope processing in health care facilities*, p. 22. Available for purchase at https://www.aami.org.