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Auditing Endoscope Reprocessing

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LEARNING OBJECTIVES

1. Describe preparation and initial steps for successful auditing
2. Define the basis for auditing flexible endoscope processing
3. Outline considerations for the implementation of auditing processes

Over 40 years ago, one of my first healthcare roles was working as a hospital orderly. It was easily one of the lowest-ranking positions, yet it afforded such a world of experience—and a strong foundation for understanding the culture of healthcare delivery. In those years, when it came time for our external accreditation survey, we very aggressively cleaned up and organized to make spaces, processes and staff look "just right." A good example was ensuring that stretchers and wheelchairs were no longer lining hallways. We found unused classrooms, offices and hidden hallways or stairways to hide them. This was a norm: to make things look good while surveyors were present.

Fast forward 20 years and we were essentially doing the same thing, except I was now serving as a Clinical Manager at a large health system. In the interim, however, external surveying was maturing and, thankfully, we were coincidentally realizing the importance of establishing the expectation of continued readiness. We also recognized the value in promoting a "culture of safety" that included being more proactive than reactive.[1] One of the related changes in my health system was our recognizing the need for oversight and ongoing auditing for high-level disinfection (HLD) and flexible endoscope processing. We pointedly wanted to limit preventable errors and near misses in reusable device processing. A consensus goal: it was time for us to internally assess and audit—in a very focused way, and on an ongoing basis—and not wait for an external surveyor or agency to point out deficiencies or weaknesses.

Objective 1: Describe preparation and initial steps for successful auditing

A first and very significant step in the auditing process is to establish a multidisciplinary team; these people become the key stakeholders for auditing. Any one individual by themselves [e.g., endoscopy manager, Sterile Processing (SP) manager, infection preventionist] has a limited experience base and focus. Combining the varied academic preparations, clinical experiences and system roles adds strength in developing valid content, collaborating with processing sites and creating more sustainable

processes.[2] Additionally, frontline staff and local management will more likely recognize, respect and respond to a unified team approach. *Author's note: In our early months of doing this, it was not uncommon to hear frustration and confusion from customer sites regarding the historical disconnect between what Infection Prevention (IP) said versus what accreditation said when it came to directing the processing of flexible endoscopes. In working together, we mitigated varying interpretations and directions to the frontline.*

Multidisciplinary team make-up and the number of participants will vary from one institution to the next; however, partner members should minimally represent processing professionals, infection prevention, accreditation, and safety.[3] It is key that team membership includes an experienced content expert for endoscope processing; this enhances the validity of the team and related processes. To be successful, an integral assumption is that this team has the ongoing support of higher-level administration. That becomes especially significant when resources and/or reinforcement are needed for eventual system or policy changes, and/or when resistance from individual departments is encountered. Ultimately, the leadership of the organization will be held accountable for any deficiencies within the institution.[4]

Initial work for the team involves establishing the current state for endoscope processing within the health system. This can take the form of surveying (e.g., by email); however, it is important to realize the inherent bias (or "blindness") a manager/delegate may have when providing an accurate self-assessment of potential gaps. Even when a survey is used, it is critical to round and assess firsthand. Such initial evaluations provide for gap analyses that help inform where risks exist, as well as provide necessary content for ongoing auditing.[5] This also helps to prioritize team efforts (e.g., which clinical sites require formal auditing first, which policy content requires editing sooner versus later, and where those misses and near misses are currently occurring). Even during these initial visits, it is necessary to address any egregious processing gaps on the spot, prioritizing to patient and staff safety considerations.[2,6]

These initial surveys and/or site visits allow four important functions: 1) discovery of current practices; 2) establishing that system-wide expectations and standardization are the new norm; 3) introduction of the multidisciplinary team approach; and 4) launching a working relationship with management and staff at clinical sites.[3]

The introductory surveys and site visits additionally direct the timing and priorities for necessary education or re-education. Often, the work of assessment visits, policy discussions, educational development, and audit development are occurring simultaneously, with focus shifts dependent on the highest-risk discoveries. Not surprisingly, "lack of education/training and standardized processes" are common findings early on.[2,7]

Objective 2: Define the basis for auditing flexible endoscope processing

The next step is to formally identify the content for institutional endoscope processing policies and practices. This is essential because the policies form the reference point for all clinical sites to be audited against. Endoscopy, Infection Prevention, Sterile Processing, Operating Room, and ambulatory care all need to have meaningful discussions and come to common ground. There may be one or more existing written policies related to endoscope processing within the health system. The goal is to establish one over-arching policy that applies across the entire system.

Any practice conflicts need to be discussed and resolved. It is critical (and expected) that processing practices are consistent across the health system. External accreditation agencies survey for standardization across the organization.[4] Processing-specific policies and practices should be based on manufacturers' instructions for use (IFU), national standards and guidelines, and an organization's own related written policies. To clarify further, the endoscope processing policy needs to complement and not contradict the cleaning and disinfection policy and the sterilization policy from Infection Prevention.

In a healthcare setting, there is a distinct obligation to not only have and keep IFU, but to know the content and to follow the prescribed IFU steps in actual practice. Not knowing or not following the IFU is where a lot of problems arise (as well as citations on surveys). *Note: Remember also that this is not just the device IFU (e.g., the endoscope being processed) but also the IFU for any processes, including brushes, automated equipment, and chemistries (e.g., detergents, high-level disinfectants, and sterilants). Surveyors will be looking to ensure IFU are current, available and easily accessible. Written policies should always reference the expectation of following manufacturers' IFU.*

It will be important to have discussions that compare standards and guidelines related to processing of flexible endoscopes—and from that to have consensus decisions on which organization(s) will be referenced in one's institutional policy.

In the U.S., organizations are legally obligated to follow regulations from the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA). Healthcare professionals, including reprocessing professionals, should also follow guidance from the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), as well as standards and guidelines from professional societies and standards organizations such as the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of Gastroenterology Nurses and Associates (SGNA), among others. Accreditation and surveying agencies such as the Joint Commission and the Accreditation Association for Ambulatory Health Care (AAAHC) use regulations, guidelines and standards as reference points; however, one of the first questions they often ask upon arrival is "Show me your policy for endoscope processing." There should be a cohesive endoscope processing policy that applies, regardless of the clinical department, and actual practices must match the policy.

More than one reference organization can provide foundational content for policies. It is acceptable, for example, for a master endoscope processing policy to reference AAMI, AORN and SGNA guidelines; however, where those guidelines differ needs to be clarified for that facility. An example would be endoscope hang time. It is not acceptable for the endoscopy department to subscribe to a seven-day hang time while the organization's offsite urology center follows a 21-day hang time. This is an example where the multidisciplinary team needs to incorporate risk assessments to guide decision-making, policies, and expected practices.[8]

Objective 3: Outline considerations for the implementation of auditing processes

With a multidisciplinary team in place to do the work of auditing, the team having evaluated the current state of processing practices and performed initial gap analyses across the system, and the team having reviewed (and revised, if necessary) the existing policy that directs endoscope processing—based on current standards, guidelines, regulations and IFU—the next steps involve ensuring that system-wide education occurs,[7] along with the development of an audit tool and performing the actual ongoing audits.

The tool should be standardized to follow the steps of processing—from point-of-use treatment through processing, to storage, and back to clinical use. *Remember: Within each step, it is essential to follow both the IFU and the institutional policy. Any gap would be identified and reported. Surveyors often will ask team members to "show the IFU for that." Internal audits should ask the very same questions and ensure accessibility to and understanding of IFU.*

Auditing content related to each step can be incorporated from existing standards/guidelines (e.g., from AAMI, SGNA or AORN). Additionally, the good news is reprocessing professionals and the multidisciplinary team do not need to start from scratch with an audit tool. Various endoscope processing example audits are available from the CDC[8], TJC[4] and AORN[9], to name a few.

The audit should include descriptive information for each customer department. This allows tracking and trending by department, as well as across the institution. Example content would include identifying supervisory personnel and their designated leads, current endoscope inventory, automated processing equipment, and chemistries. Each successive survey for an individual department should mention significant changes since the last survey (e.g., management and staffing turnover, new HLD/sterilization processes, new devices requiring processing, increased procedure volumes, and new procedures added). *Author's note: More than once, I ran into scenarios where because there had been staff or management turnover quality control was compromised—and risks existed that were not there previously. An important caution is when the designated lead (e.g., lead technician) is no longer in that role.*[10]

Audits should include who performs each step of processing (including how many of which job families). This helps inform follow-up questions related to documentation of training and competencies. It is important to pointedly ask whether any temporary personnel are involved in processing. That can alert to a red flag if their level of training and competency may not match threshold expectations. Again, auditing the documentation of training and competencies for all endoscope processing staff must include ensuring the frequency intervals match the expectations written into policy. There should be evidence of device-specific training and competency for each responsible staff member.

Review of documentation is critical. This is "low-hanging fruit" for external survey citations. Examples include documentation of HLD cycle completion, minimum effective concentration (MEC) testing, expiration dating for HLD supplies, endoscope tracking to individual patients, as well as quality control and maintenance for automated equipment. If not monitored,

electronic documentation may have gaps, just like manual logs. The audit follow-up should reinforce responsibility at the local level to incorporate routine screening for completeness.

Personal protective equipment (PPE) is an indispensable component of auditing. Very simply, audits look to see that PPE is available and that it is being used correctly, according to the task being performed. A risk assessment may be needed at an institutional level to guide standard practice across the system. PPE should ideally be referenced for each of the various processing steps (in policies that direct endoscope processing).

Auditing the physical spaces for each step of processing can seem laborious. The process is essentially helping identify visual red flags and compromises for containing contaminants, preventing cross-contamination and minimizing staff exposures.[11] This is where the IP and Safety partners can provide expert oversight. Among the most common challenges (especially for smaller endoscope processing areas) is maintaining unidirectional soiled to clean workflow. Physical space evaluation also includes validating appropriate locations for eye wash and hand washing stations (separated from processing sinks). Additionally, adequate ventilation and room pressurization is a common survey citation that requires involvement of facilities and possible escalation to administration.

Visual cues and signage should be evaluated throughout the survey process. Are areas appropriately labeled "dirty" and "clean"? Do endoscopes post-HLD processing have standard visual cues to indicate "patient-ready" status? Do the entrances to the processing area indicate restricted access and PPE is required?

Conclusion

It is important to audit "in real-time… side-by-side with staff as they complete the processing."[6] When it comes to endoscope processing, research and clinical investigations have highlighted the very real gaps that occur in both manual and automated processes. Sufficient auditing cannot occur by having a staff member simply "talk you through the steps." For example, organizations will not want to rely on a well-meaning staff member to assure they "always visually inspect the endoscope after cleaning" (and then later discover that they rarely do). It is crucial to observe and audit process steps as they happen. It can be valuable to take photos (of both good practices and deficiencies) as auditing occurs. It is difficult for a local manager to contest a finding if a photo proves the finding. Additionally, photos often help in making a case to upper-level administrators.[6]

Good will with customers can be established early on by asking about the local management's current concerns regarding endoscope processing (e.g., what keeps them up at night?). This can also help inform what to pointedly review during the auditing of their site. If they are worried about something, there is probably a reason. It is not uncommon to hear worries related to adequate staffing and maintaining training and competencies. It may also be that system-level advocacy is needed to support desired changes, especially when it comes to budgeting for additional resources.

When audits occur, departments are part of a "positive safety culture (where safety is a shared priority).[1] The driving principles behind this are patient safety and minimizing preventable errors and near misses. Sites that successfully integrate periodic auditing of endoscope processing have seen sustainable improvements in processing practices.[6]

When delivering audit results to customer sites, potential solutions should accompany any deficiencies or opportunities for improvement. The act of auditing should be inclusive and positive. *Author's note: I always started my audit reports with positive words of appreciation. There is always something good to find and it often starts with the frontline worker who truly cares about what they are doing. That mindset needs to be reinforced. Engaging staff with open-ended, positive queries and "teachable moments" helps establish good working relationships, which serves very well when problems do arise.*[3]

Auditing is also an opportunity for staff to understand the rationale behind the task. They may never have heard the rationale before. A safe culture is proactive, not waiting for problems to arise. Routine auditing can elevate safety expectations for a system. Similarly, endoscope processing staff can integrate the general concepts of auditing and safe culture into their daily routines.

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