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A Proactive, Systematic Approach to Endoscopy Management

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Between 2010 and 2015, more than 41 hospitals worldwide, most of them in the U.S., reported bacterial infections linked to endoscopes, affecting 300 to 350 patients.[1] Additionally, 35 deaths in the U.S. from 2012 through 2015 were linked to inadequate cleaning of endoscopes.[2] ECRI Institute (formerly the Emergency Care Research Institute) ranked inadequate cleaning of instruments such as endoscopes as its number one health technology hazard in 2016 and number two hazard in 2017.[3]

Proactive performance improvement activities partnered with infection prevention measures effectively reduce the incidence of contamination as well as the patient impact and cost of serious safety events from unclean endoscopes. These additional trends support investigation into endoscope cleanliness:

- Conflicting industry guidance. Industry recommendations as outlined by the Association of periOperative Registered Nurses (AORN), the Association for the Advancement of Medical Instrumentation (AAMI), the American National Standards Institute (ANSI), and the Society of Gastroenterology Nurses and Associates are shifting.
- Poor controls over cleaning practices. Inappropriate practices for endoscope processing and disinfection include inadequate monitoring of water temperature and quality, lack of visual inspection during and after cleaning for scope defects and bioburden left on an endoscope, and repeated use of single-use sponges.
- Antiquated equipment and environments. The inability to follow current endoscope manufacturers' instructions due to changes in equipment design (for example, inappropriate workflow, environment, lighting, and airflow) leads to increased risk of contamination.
- Costs associated with processing scopes. The International Association of Healthcare Central Service Materiel Management estimates that the cost for reprocessing one endoscope approaches $114 to $280 per use.[4] This investment is small when compared to the lives put at risk when contaminated scopes are used, the impact of malpractice lawsuits is realized, and the potential regulatory fines for serious safety events is introduced.

What Clinical Audit Can Identify

Healthcare organizations can avoid patient infections. An ECRI Institute program manager stated, “Hospitals should be diligent in addressing risks related to endoscope reprocessing before a contamination – or even worse, a patient infection – occurs.”[5] Proactive detection of gaps and failures in endoscope management allows a hospital to avoid the reputational and personal disaster that might befall institutions and mass numbers of patients who have been infected by contaminated endoscopes.

A clinical internal audit function can identify process failures in endoscopy management before catastrophe strikes. Clinical auditors should test facilities’ internal controls in three important areas:

1. Policies and procedures for endoscope management,
2. Quality monitoring and surveillance
3. Procedural staff competency

Examining these areas is critical to identifying deficiencies in endoscope management that lead to cross contamination and patient infection.

Policies and Procedures

Are policies and procedures aligned with current industry standards?

Audits should test whether or not policies are in place to provide specific guidance for processing areas at the hospitals. If guidance is available, the auditors should assess whether hospital procedures align with current industry standards, as set forth by ANSI, AAMI, and the manufacturers’ instructions for use (IFUs). These are common deficiencies found in this area:

- Policies are in place but not current.
- Manufacturers’ IFUs are not incorporated and cannot be carried out due to lack of required technology (for example, temperature and humidity monitoring while not in use).
- Policy changes are not always communicated to the staff working in the area.

Policies and procedures are effective only if they are accurate (relevant to the equipment being used), current, and communicated to staff – especially in the fast-paced environment of endoscopy procedural areas. Because most endoscopy areas require staff to be flexible and work with different types of equipment in multiple settings, regularly updating, standardizing, and communicating policies and procedures reduces the risk of infection from use of contaminated scopes.

Monitoring and Surveillance

Are processes monitored for policy compliance and effectiveness?

To determine if controls are operational and effective, auditors should test whether facilities' infection prevention teams are involved in the decisions governing the endoscopy processing areas and whether compliance is being monitored. A common issue is that infection prevention professionals are not actively involved in endoscope management oversight. Monitoring to identify infection clusters and pseudo-clusters is not being performed.

Contamination occurs or remains between endoscope uses because staff does not thoroughly understand how to maintain clean areas and equipment in the processing room, how often unused endoscopes require reprocessing, and what documentation needs to be maintained. Quality surveillance by infection prevention professionals protects patients and staff from contamination and reduces the risk to the organization of regulatory penalties and malpractice lawsuits. Deficiencies in controls can be addressed simultaneously with identification during real-time monitoring of cleaning procedures and documentation at repeated intervals.

Staff Competency

Are the staff who work in the endoscopy procedural areas competent with the endoscopy equipment being used?

Auditors should assess the levels of staff competence with equipment used in their facilities. In many health systems, staff members use different equipment in different settings within the organization. These are common deficiencies identified during clinical internal audits:

- Training is not always completed for the equipment used by procedural staff.
- Training does not always reflect current standards.

Common Endoscope Sterilization Deficiencies

This exhibit illustrates additional findings identified by clinical audits of endoscopic sterilization[6]:

Endoscope Management	Infection Prevention Monitoring	Policies, Procedures and Competency
Decontamination workflow inconsistent with industry standards	Absent partnership between Infection Prevention team and endoscopy	Out-of-date policies for current industry standards
Interruptions resulting in delayed decontamination	Lack of monitoring for identification of infection clusters	Policy determinations inconsistent with AORN-specified approval pathways
Reuse of single-use cleaning sponges	Missing or inconsistent monitoring of required equipment checks	Lack of annual training for all appropriate staff
Failure to maintain chemical disinfectant procedures at appropriate temperatures		Lack of current industry standards in training
Lack of clear labeling of clean versus dirty on sinks		Lack of training for unique brands of equipment
Improper storage or labeling of disinfected scopes and expiry dates		Inconsistent documentation of annual training
Inconsistent use of barrier precautions while handling scopes		

Source: CHAN Healthcare

What Hospital Leaders Can Do to Resolve Deficiencies

Proactive use of clinical audits is an effective performance improvement measure. Pre-emptive identification of weak controls, misaligned processes, and ineffective maintenance practices can prevent many issues and reduce the risk of harming a patient. A hospital partnership with clinical auditors will strengthen process controls and improve patient and staff satisfaction in the high-volume world of endoscopy.

Maintain Consistent Policies, Protocols, and Education

It is paramount that hospital leaders make sure policies and procedures are correct and frequently updated.

Required actions for leaders:

- Review policies and procedures at least annually or when changes to equipment are implemented or industry standards change.
- Incorporate manufacturers' recommendations for care of the unique instrument brands used in the facility into organizational policies for sterilization

Conduct Monitoring and Surveillance

Monitoring of endoscope processing is critical to verify correct procedures are being followed.

Required actions for leaders:

- Integrate infection prevention into all organizational quality monitoring processes, including real-time observation of endoscope sterilization.
- Implement data verification of each cleaning cycle performed (for example, a log of each cycle should be made available).
- Establish a testing system for detecting clusters of infections or pseudo-infections associated with endoscopic procedures.

Verify Support Staff Competency

Written documentation of competency shows that staff members are performing at the highest level.

Required actions for leaders:

- Create a formal process for staff training on endoscopy equipment.
- Provide education and training for all personnel involved in endoscope processing.
- Require personnel to complete competency verification activities related to their endoscope processing duties upon initial hire, at the time of regulatory changes, and whenever new products are introduced to endoscopy.

Conclusion: The Benefits of Clinical Audit

Patients who undergo endoscopy procedures entrust their well-being to healthcare professionals and expect a safe experience, which can be achieved by testing and monitoring the controls that govern endoscopic processing. Clinical audit is a tried-and-true industry method for proactively detecting process weaknesses and enhancing the operational effectiveness and outcomes in the area of endoscopy. As healthcare providers continue on their patient safety journeys, clinical audit can help organizations provide the safest, best care possible to the patients and communities they serve.

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[1] Chad Terhune, "Number of Deadly Infections From Dirty Scopes Is Far Higher Than Previously Estimated," Los Angeles Times, April 15, 2016, http://www.latimes.com/business/la-fi-0415-olympus-scopes-20160414-story.html

[2] Dan Mangan, "35 Deaths Linked to Scope Infections After Olympus Told Execs Not to Warn Hospitals," CNBC, July 25, 2016, http://www.cnbc.com/2016/07/25/35-deaths-linked-to-scope-infections-after-olympus-told-execs-not-to-warn-hospitals.html

[3] ECRI Institute, "Executive Brief: Top 10 Health Technology Hazards for 2016," report from Health Devices, November 2015, www.ecri.org/2016hazards; ECRI Institute, "Executive Brief: Top 10 Health Technology Hazards for 2017," report from Health Devices, November 2016, www.ecri.org/2017hazards

[4] Cori L. Ofstead, Mariah R. Quick, John E. Eiland, and Steven J. Adams, "A Glimpse at the True Cost of Reprocessing Endoscopes: Results of a Pilot Project," Communiqué, May 2017, https://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/portfolio-group/LithoVue/pdfs/Sterilization-Resource-Handout.pdf

[5] "Endoscope Reprocessing: The Importance of Being Proactive," ECRI Institute news, Dec. 1, 2014, https://www.ecri.org/Resources/PSRQ/Superbug/Endoscope_Reprocessing_The_Importance_of_Being_Proactive.pdf

[6] The findings in this article are based on clinical audits performed by CHAN Healthcare staff between 2015 and 2017 at more than 20 hospitals and health systems nationwide.

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