HEADS UP…

The Joint Commission

TOPIC: Reducing risk associated with high-level disinfection and sterilization of medical equipment
***SETTING:* Hospital (HAP) and Critical Access Hospital (CAH) Programs**

Why is this important?

A major risk for patients undergoing surgery and other procedures is infection from pathogens through contact with medical equipment, devices, or supplies. Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Failure to properly clean, disinfect, or sterilize and use or store medical equipment, devices and supplies not only carries risk associated with breach of host barriers but also poses risk for person-to-person transmission of pathogens. There are numerous steps involved in the cleaning, disinfecting, and sterilization of medical equipment, and it is crucial that health care staff follow standardized practices to minimize infection risks. (source: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/introduction.html).

Scope of the Problem:

Time period: **January 1, 2021 to July 31, 2021**
Number of surveys performed: **HAP = 1235; CAH = 99**
Number of high and moderate risk findings: **HAP = 245 (20%); CAH = 21 (21%)**
Relevant standard/EP: IC.02.02.01 The hospital [critical access hospital] reduces the risk of infections associated with medical equipment, devices, and supplies. **EP 2** The hospital [critical access hospital] implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. (See also EC.02.04.03, EP 4) Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes. (see also Hospital Conditions of Participation (COP) §482.51, §482.51(b), §482.42(a) or Critical Access Hospital (CAH) Conditions of Participation §485.639, §485.640, and §485.640(a)(2)).

Sample survey observations [from surveyor notes] and contributing factors

Sample observations

- The organization was not performing daily tubing and machine decontamination of the automated endoscope flushing equipment as required in the manufacturer's instructions for use. Detergent rather than a disinfectant was being used to perform the decontamination. In addition, daily flow verification testing was not done.
- Daily washer checks were not completed on the days that they were in used as directed by the organizations chosen evidence-based guideline and the manufacturer instructions.
- The time required to achieve high level disinfection in accordance with the manufacturer's IFU was not met.
- High level disinfection cycles were performed and recorded at temperatures below 68˚F which was not consistent with manufacturer's IFU.
- Unable to verify that the endoscope on the "difficult airway cart" had been high level disinfected between uses.
- Organization failed to follow manufacturer instructions for use as evidenced by the Foot Clinic instruments were high level disinfected instead of being sterilized as required by the manufacturer and intended use.
- Instrument tape was not applied or maintained in accordance with the tape manufacturer instructions. A variety of issues were identified: tape did not wrap all the way around the instrument, on some instruments it was wrapped around multiple times, it was peeling or chipping off.
- Staff using sterilized instruments could not identify when a sterilized instrument should not be used including when there was not an internal indicator, evidence of moisture damage of the package, writing on the paper side of peel pouches, improperly disassembled or packaged items.

Potential contributing factors to non-compliance of standards

- Reprocessing staff were not aware of how instruments or equipment was used and therefore did not reprocess based on how the item was used.
- Staff performing reprocessing did not have access to manufacturer's instructions.
- The organization knew that services were being provided but did not identify the equipment necessary to provide the service.
- Policies and procedures for reprocessing that staff were to instructed follow did not incorporate manufacturer's instructions.
- Products and accessories necessary to follow instructions were not available.
- Staff had received general training and education on sterilization processes but had not been trained or educated on the specific sterilization issues identified by the surveyor.
- Competency oversight and assessment was done by a person who was not qualified or competent to provide oversight of the cleaning, disinfection, and sterilization process
- Forms used to document procedures did not provide the specific requirements to follow if parameters (e.g., time or temperature) were not met.

How to identify potential problems in your organization

Review your processes, procedures, and policies

☐ Are they consistent with intended use of instruments and equipment (e.g., Spaulding Classification)?

☐ Do they include review by someone who can determine that the level of reprocessing meets the intended use of the instrument or equipment being reprocessed?

☐ Once it is verified that the manufacturer instructions for use meet the required level of reprocessing based on intended use, has a person who is competent verified that manufacturer instructions can be implemented and identified any additional equipment, supplies, training, etc. do so?

☐ Does the hospital / CAH define what staff competencies are necessary to perform critical aspects of cleaning, sterilization, and high-level disinfection?

OBSERVE staff (e.g., reprocessing staff and users)

Initially focus on high-risk devices and equipment (e.g., robotic equipment, cardiovascular, orthopedic) or equipment that is brought from one department for use in another (e.g., endoscopes, brachytherapy equipment) and decentralized areas performing reprocessing where oversight may not be provided by a knowledgeable individual.

☐ Using the manufacturer instructions for reprocessing the device or instrument, observe the process from point-of-use in the procedure room through cleaning, decontamination, high-level disinfection or sterilization and storage? Is every step followed? Are all the required products and accessories available and used? Are the products and accessories used for reprocessing also used in accordance with their manufacturer instructions? If alternative products or accessories are in use has compatibility been verified?

☐ Do staff have access to the manufacturer's instructions or "cheat sheets" that provide information that varies from the most common process that is followed (e.g., rinse 3 times versus once for most items)?

☐ Have any conflicts or deviations been identified and as the manufacturer (s) been contacted to resolve any issues?

☐ Have staff received training on each step of their job duties relevant to cleaning, disinfection, high-level disinfection, and sterilization?

☐ Review the process for ensuring staff competency, does it involve using IFUs and having staff demonstrate application of the reprocessing instructions to ensure that they are follow?

Assess the reprocessing and storage environment

☐ Does the reprocessing location support the cleaning, disinfection, and sterilization process? Does it support flow from dirty to clean? Does the physical layout and equipment allow compliance with the required reprocessing procedures (e.g., number and depth of sinks, automated equipment, magnified lights, etc.)? Is preventative maintenance of equipment performed as required by the manufacturer's instructions?

What are some resources can assist me in mitigating risks in these areas?

Manufacturer Instructions for use for all medical devices (e.g., instruments, equipment) that require reprocessing between uses, as well as those for products (e.g., detergents, brushes, wraps) and accessories (e.g., washers, sterilizers, reusable containers, etc.) used for reprocessing

The Joint Commission. Dispelling the Myths Video https://www.jointcommission.org/resources/patient-safety-topics/infection-prevention-and-control/disinfection-and-sterilization/dispelling-the-myths/

Joint Commission, Frequently Asked Questions: Manufacturers' Instructions for Use – expectations regarding access to manufacturers IFU for cleaning, disinfection, and/or sterilization of instruments, devices and products used in the delivery of patient care. https://www.jointcommission.org/standards/standard-faqs/hospital-and-hospital-clinics/infection-prevention-and-control-ic/000002250/

CMS Survey and Certification Letter 14-44-Hospital/CAH/ASC. August 29, 2014. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-44.pdf

Centers for Disease Control and Prevention (CDC), Sterilization and Disinfection in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

The Instrument Reprocessing Working Group (AKI) Instrument Reprocessing: Reprocessing of reusable instruments to retain value (aka Red Book). Available for free download at: https://8ad5d244-3245-4d36-bc7f-7e3589f4c29b.filesusr.com/ugd/e5e300_d8c2c54d2849453b89a265ae70443b19.pdf?index=true

Association for the Advancement of Medical Instrumentation (AAMI) available for purchase at https://store.aami.org/s/store#/store/browse/cat/a0s2E000008YVpaQAG/tiles

ANSI/AAMI ST79:2017: Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities

ANSI/AAMI ST58:2013/(R)2018: Chemical sterilization and high-level disinfection in healthcare facilities