HEADS UP…

The Joint Commission

TOPIC: Reducing risk associated with reprocessing of medical equipment
***SETTING:* Ambulatory Health Care (AHC) and Office-Based Surgery (OBS) 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: **AHC = 417**; **OBS = 42**
Number of surveys with high and moderate risk findings for IC.02.02.01 EP 2: **AHC= 92 (22%)**; **OBS = 14 (33%)**
Relevant standard/EP: IC.02.02.01 The organization reduces the risk of infections associated with medical equipment, devices, and supplies.
EP 2 The organization 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.

Sample survey observations [from surveyor notes] and contributing factors

Sample observations:

- Manufacturer's instructions for use of cleaning products used prior to HLD or sterilization were not followed (e.g., expired product, not properly diluted, temperature requirements not met, not applied properly).
- Endocavity probes (e.g., vaginal, rectal, TEE), laryngoscope blades, and/or endoscopes were not processed in accordance with intended use (e.g., come in contact with mucous membrane but not high level disinfected) and/or manufacturer instructions for use (e.g., not high level disinfected, steps missed such as pre-cleaning and leak testing, not rinsed in accordance with instructions, solution not monitored, solution did not meet minimum temperature test strips not used correctly).
- Instruments that touched the eye were not reprocessed in accordance with intended use or the manufacturer instructions (e.g., high level disinfectant, or sterilization) NOTE: Bleach solution used in accordance with IFU is acceptable in lieu of high-level disinfection; Alcohol is not an acceptable alternative if high level disinfection is required.
- HCO was monitoring ambient room temperature rather than the temperature of the high-level disinfectant solution.
- The HCO did not have appropriate facilities for performing the endoscope cleaning process (e.g., did not follow one-way flow moving from dirty to clean, no designated sink(s)).
- Sterilization cycle used did not meet manufacturer's validated parameters (e.g., gravity cycle used when parameters required pre-vacuum cycle, sterilization temperature too low, duration of sterilization, dry time).
- Immediate-use steam sterilization (IUSS) used as sole means of reprocessing medical equipment devices and supplies.

- Biological indicators not used in accordance with manufacturer instructions for use (e.g., expired, controls not used, control lot number did not match test lot number.) or not performed at least weekly.
- Chemical indicators not included in every pack, container, or pouch sterilized.
- Dental devices (composite applicator guns, Xray sensors, intraoral cameras, impression gun) were not covered with an appropriate barrier as required by MIFU.

Potential contributing factors:

- 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.
- 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/practice

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 organization/practice 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., endoscopes, orthopedic 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 of 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, biologic and chemical indicators) and accessories (e.g., washers, ultrasonic, sterilizers, reusable containers, etc.) used for reprocessing

The Joint Commission. Video: 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.

The Joint Commission. Quick Safety, Issue 49 (May 2019). Disinfection of tonometers and other ophthalmology devices.

FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized

Potential Risks Associated With The Use of Ozone and Ultraviolet (UV) Light Products for Cleaning CPAP Machines and Accessories: FDA Safety Communication

Centers for Disease Control and Prevention (CDC), Sterilization and Disinfection in Healthcare Settings.

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/a0s2E00000 8YVpaQAG/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