CIS SELF-STUDY LESSON PLAN

Lesson No. CIS 273 (Instrument Continuing Education - ICE)

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Transitioning from High-Level Disinfection to Sterilization for Semi-Critical Devices

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LEARNING OBJECTIVES

1. Discuss the reason behind transitioning from high-level disinfection to sterilization
2. Describe how to successfully transition from high-level disinfection to sterilization
3. Identify key steps involved in product verification testing and product reviews

Implementing the transition from high-level disinfection (HLD) to sterilization for semi-critical devices is a movement that is intended to improve patient care because sterilization kills all bacteria, including spores; provides a higher reduction in microbial contamination; and has a sterility assurance level (SAL). Being proactive by implementing a process that will improve the quality of patient care will also demonstrate the expertise, knowledge and commitment of the Central Service/Sterile Processing (CS/SP) department.

As experts in sterilization, CS/SP professionals can introduce this quality improvement process and then successfully guide the transition. During this process, it is important to involve all key stakeholders, along with upper administration. Administration must be informed of the benefits and be prepared to support this change in the event of any pushback. Keeping upper administration informed will enable them to respond to questions and concerns regarding this major change. Their support and approval will also be beneficial if additional equipment is needed.

Objective 1: Discuss the reasons to transition from high-level disinfection to sterilization

Transiting from HLD to sterilization for semi-critical items is being encouraged by industry leaders. On September 11, 2017, the Association for the Advancement of Medical Instrumentation (AAMI) held an endoscope stakeholders meeting with more than 40 experts from healthcare professional organizations [such as the International Association of Healthcare Central Service Materiel Management (IAHCSMM), manufacturers, testing labs, independent research groups, academia, patient and clinical end user interests, the US Food and Drug Administration (FDA), the Center for Devices and Center for Devices and Radiological Health (CDRH) and the Centers for Disease Control and Prevention (CDC)] to discuss outbreaks and other issues associated with flexible endoscopes. After reviewing the research

Transitioning from HLD to sterilization takes planning, research, communication and record keeping. Before implementing this transition, it is important to have all stakeholders actively involved; this is best accomplished by forming an interdisciplinary team with leadership from the Operating Room (OR) and CS/SP, a surgeon, and a representative from infection prevention.

and engaging in all-day discussions, the experts agreed that cleaning is the most important part of the process. Processing personnel must have training and demonstrated competencies, all instructions for use (IFU) must be followed, and the industry should move from HLD to sterilization of endoscopes. This is a process that will need to occur gradually, however.

The primary reason for the transition from HLD to sterilization is the fact that there are now pathogens that are resistant to HLD; this has been reported in evidence-based healthcare journals, which have shown that small, non-enveloped viruses (e.g., parvoviruses, coxsackieviruses, other enteroviruses, hepatitis A, norovirus) and resistant bacteria (e.g., the mycobacteria *M tuberculosis, M avium and M abscessus, M fortuitum, M chimaera*) are showing a resistance to HLD.

While pathogen resistance to HLD is a primary driver for transitioning to sterilization, there are other very important reasons to do so that some CS/SP professionals may be unaware. Sterilization can improve outcomes; it is a validated process used to render a device free from viable microorganisms and it provides an SAL, whereas HLD does not. HLD does provide a 6-log reduction in microbial contamination; however, sterilization can typically offer twice that amount at a 12-log reduction.

This movement from HLD to sterilization is also being recommended in the the Association of periOperative Registered Nurses' (AORN's) 2019 evidence-based *Guidelines for Perioperative Practice*. In all three guidelines that involve medical device processing, sterilization is recommended over HLD for semi-critical medical devices; these guidelines include the *Guideline for Manual Chemical High-Level Disinfection*; the *Guideline for Processing Flexible Endoscopes*; and the Guideline for Sterilization, which states there are pathogens resistant to HLD, including, but not limited to, small, non-enveloped viruses and resistant bacteria. This guideline coincides with the findings from the stakeholder experts that a lack of compliance with sterilization and disinfection guidelines has led to numerous infectious outbreaks and that many have been related to semi-critical items.

Objective 2: Describe how to successfully transition from high-level disinfection to sterilization

Transitioning from HLD to sterilization takes planning, research, communication and record keeping. Before implementing this transition, it is important to have all stakeholders actively involved; this is best accomplished by forming an interdisciplinary team with leadership from the Operating Room (OR) and CS/SP, a surgeon, and a representative from infection prevention.

Before the meeting, it is important that an agenda be prepared. Suggested agenda items include reasons for the transition; developing a team objective for transitioning semi-critical items from HLD to sterilization; identifying membership names; establishing a method for communicating progress and delivering any updates to those who use the medical devices, as well as dates and meeting locations for future meetings. At the initial meeting, it will be prudent to provide reference material that demonstrates why the healthcare industry is moving toward sterilization for semi-critical items. Meeting records should be kept and distributed to attendees.

During the meeting, it will be important to describe how the transition from HLD to sterilization will also improve daily operations. Some members of the interdisciplinary team, especially those unfamiliar with sterilization processes, may not be aware of some of the key operational benefits that will be attained by transitioning from HLD to sterilization. Some at the meeting may not know that low-temperature sterilization can be achieved in a short period of time, which is one of the reasons HLD has been used in the past; however, it will be important to bring to the multidisciplinary team's attention that a sterilized item will be packaged and in

a "ready to use" state, with no need for reprocessing prior to use.

A risk assessment should be performed to determine if sterilization is feasible and if transitioning to sterilization will improve the quality of the medical devices. Some suggested factors to review include:

- The level of disease transmission risk of the items processed by HLD verses those that have undergone sterilization;
- Documented validation testing for a specific HLD or sterilization modality;
- Storage time and requirements of items processed by HLD, as opposed to items sterilized in sterilization packages
  - » Process that provides rapid availability
  - » Process that results in additional processing, which causes wear on endoscopes;
- Chemical safety for both HLD and low-temperature sterilization. The safety data sheet (SDS) from these chemicals provides employee and patient safety considerations;
- The complexity of the process. HLD is a complex process and the more complex the process, the more prone to errors the process becomes;
- The level of assurance that the quality monitors provide for the process to assure patient safety [e.g., minimum effective concentration (MEC) test strips for HLD, as opposed to chemical and biological monitors used for sterilization];
- Processing/turnaround time of each process. Long turnaround times can be a deterrent;
- The process for evaluating possible damage to the item;
- When switching from an HLD chemical to another chemical process, there should be a review to determine if residue is present. If so, is it possible to remove the residue?
- Acquisition time to obtain an HLD processed item opposed to a packaged sterilized item. HLD items are unpackaged and may require a process to undergo HLD before use.

This risk assessment should be documented and records of the assessment should be retained.

After the risk assessment and after receiving support and approval to move semi-critical items from HLD to sterilization, it is time to begin the actual transition process. The transition should be implemented on a "one item at a time" basis because of all the ground work that must be laid for a successful transition to occur. During this transition, having a designated information location for any transition updates (for the CS/SP and all impacted departments) will keep staff members informed of all changes.

Every item considered for transition requires that the medical device's instructions for use (IFU) be reviewed to determine if the medical device has been validated for sterilization. Should the medical device not include a method of sterilization, the facility's low-temperature sterilizer manufacturer may have conducted a validation study for the device. Many medical devices have been in use prior to low-temperature sterilizers entering the marketplace; therefore, the device manufacturer would not have had the ability to have a sterilization validation performed. Most of the low-temperature sterilizer manufactures have had sterilization validation performed on highly-used medical devices. If a sterilizer manufacturer has conducted a sterilization validation of a medical device, it can provide documentation on the type of sterilization the device is validated for, along with the type of cycle to use. When requesting this information, the product name, manufacturer and catalog number will be used to correctly identify the validation information. Many of these medical devices also have accessory parts, such as the containment device or tray and attachments, that should be included in this process. All sterilization information should be available in a manner that can be recorded, maintained and made accessible for reference.

If one's facility does not have a low-temperature sterilizer that is validated to sterilize a medical device or most semi-critical medical devices, there are two choices: either discontinue the transition because of the lack of a sterilizer or develop a proposal to purchase a new sterilizer that can sterilize most of the items.

If a new sterilization modality is being implemented, the packaging and quality monitors need to be reviewed to ensure that they, too, are validated for that type of sterilization. CS/SP professionals require training on the sterilization system, new packaging and quality monitors. Personnel using the medical device also require training on the packaging system, so they can open it aseptically and correctly identify and read the quality monitors.

When transitioning from HLD to a sterilization method, there should be a review of HLD residue on the device. The medical device manufacturer and sterilizer manufacturer can be consulted if this is a possibility. If there is a possibility of residue, it is critical to have the documented information on how prevent or eliminate it.

As the validations are confirmed and recorded for reference, the interdisciplinary team and infection prevention professional should be informed of the progress.

A containment device or instrument tray may be needed to securely hold the item to prevent damage and to completely expose all surfaces of the

…as new medical devices are purchased, the product review should include CS/SP in the review process to check the sterilization modality in the IFU. If the product does not list sterilization in the IFU, the low-temperature sterilizer manufacturer may have performed this validation and can provide this information. This documentation is required as the device is evaluated prior to being placed into service.

item to the sterilant. If a new type of containment device or instrument tray is used to package the item, it must be validated for that type of sterilization. *Note: The cleaning instructions also must be reviewed and communicated to the CS/SP staff.*

Objective 3: Identify key steps involved in product verification testing and product reviews

Manufacturers perform validation. In healthcare facilities, product testing can be performed to verify that an item can achieve sterilization in a low-temperature sterilizer by following these steps:

1. Biological indicators (BI) and chemical indicators (CI) should be placed within an item or set in areas most resistant to the sterilization process. The number of BIs and CIs used within each product test sample will depend upon the size and configuration of the package being tested. The medical device manufacturers can assist in identifying where to place BIs and CIs.
2. Document the placement of the BIs and CIs. A digital camera is the best method to document placement.
3. Label each BI and CI with its location. This will assist in an investigation, if needed, to determine where the positive BIs and/or unresponsive CIs were located.
4. The product test samples should be placed strategically throughout the load in areas that present the greatest sterilization challenge.
5. The test pack should be labeled as a "test pack."
6. After the sterilizer cycle is initiated and successfully completed, the physical parameters should be reviewed.
7. After sterilization, the package should be removed, opened and inspected.
8. The BIs and CIs should be removed from the test pack and checked for acceptance.
9. The test pack contents will be either reprocessed or discarded, as appropriate.
10. If positive BIs and/or unresponsive CIs indicate the product testing samples were not properly sterilized, a thorough investigation must be performed to determine the reasons for the failure.

If a positive BI or unacceptable CI result occurs, it may be necessary to change the configuration of the load or the items within the package. Be sure to check the sterilizer IFU to ensure the loading pattern is acceptable. The sterilizer performance may also need to be assessed.

The item being processed should not be placed into service until the problem is resolved. The test protocol, test results and any corrective actions taken should be documented and maintained as part of the sterilization log, quality assurance program and transition record. Documentation of product testing activities should be maintained. This documentation should include the date the testing was performed; the name of the master product; product family name; identification of the locations of BIs and CIs within the master product; and test results.

The preparation instructions in CS/SP will need to be changed. If an instrument tracking system is used, each medical device should be changed to reflect the change to sterilization as it occurs. The use of pictures to show placement of a cap or adaptor will be helpful.

CS/SP professionals should undergo training for each of the medical devices. In addition, the direct users, such as surgical staff, need to be kept informed of these changes and may also require instruction. The changes that most impact the user functions are:

- Packaging: The user needs to be aware of the packaging, so they can be prepared to aseptically open the package and understand that the items may not be visible through the packaging material.
- Turnaround time (to enable the using staff to schedule cases).
- Labeling: The user needs to know what description is being used on the package for when it is needed.

- Storage location: Packaged sterilized items are often stored in different locations than those that undergo HLD.
- Quality monitors: The direct user needs to know how to identify an item that has successfully undergone sterilization.

Going forward, as new medical devices are purchased, the product review should include CS/SP in the review process to check the sterilization modality in the IFU. If the product does not list sterilization in the IFU, the low-temperature sterilizer manufacturer may have performed this validation and can provide this information. This documentation is required as the device is evaluated prior to being placed into service. This process may exempt some semi-critical items that do not have an available sterilization modality listed in their IFU from the purchasing consideration; however, it is important to note that, at this time, there may be some essential semi-critical medical devices that lack the sterilization validation claim.

A policy and procedure should be developed with the interdisciplinary team that clearly states sterilization is the preferred method of treatment for semi-critical items, when sterilization is available. This policy will support the requirement of a sterilization claim for further purchases of semi-critical items. The policy should be supported and approved by the infection prevention committee and administration.

Conclusion

This lesson has addressed some of the benefits of transitioning from HLD to sterilization. During this transition period, it may not be possible to completely transition all semi-critical items to sterilization; however, as new items are purchased, the implementation will expand. The transition should occur in an organized manner that keeps all stakeholders – especially the transition committee, infection prevention committee and user departments – informed of the progress.

While sterilization does provide a higher patient care standard, it is important to point out that cleaning is a critically important part of the sterilization process. Neither HLD nor sterilization can be achieved if the medical device is not thoroughly cleaned. Research and best practices have emphasized the significance of diligently following all IFU. AAMI standards and AORN guidelines emphasize the importance of thorough cleaning, sterilization, proper handling and storage conditions, training, and adequate time to process. Transitioning to sterilization will take time and careful attention to detail.

As this transition proceeds, facilities' administration will see the benefits of improved quality, which benefits patient care. Medical staff will see this proactive action as a true commitment to a higher level of quality patient care. A commitment to improving the quality of patient care motivates CS/SP and other healthcare professionals every day, and the transition from HLD to sterilization is another step that can be taken toward reaching that essential goal. C

RESOURCES

Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST58: 2013, *Chemical sterilization and high-level disinfection in a health care facilities.*

Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST91: 2015, *Flexible and semi-rigid endoscope processing in health care facilities.*

Association of periOperative Registered Nurses. Guideline for cleaning and processing flexible endoscopes and endoscope accessories. *Guidelines for Perioperative Practice*. 2019.

Association of periOperative Registered Nurses. Guideline for Manual Chemical High-Level Disinfection: *Guidelines for Perioperative Practice*. 2019.

Association of periOperative Registered Nurses. Guideline for Sterilization. *Guidelines for Perioperative Practice*. 2019.

Association for the Advancement of Medical Instrumentation. Strong Evidence for Sterilization of Endoscopes Presented at Stakeholder Meeting. Website accessed/posted September 13, 2017.

CIS Self-Study Lesson Plan Quiz - Transitioning from High-Level Disinfection to Sterilization for Semi-Critical Devices

Lesson No. CER 273 (Instrument Continuing Education - ICE) • Lesson expires May 2022

1. During the Association for the Advancement of Medical Instrumentation Endoscope Stakeholders meeting, experts agreed that research has demonstrated that:
- a. Sterilization can kill everything on medical devices
- b. Cleaning is the most important part of the process
- c. Mandatory sterilization can be achieved by 2020
- d. The sterility assurance level of sterilization is double that of high-level disinfection

2. The primary reason for transitioning from high-level disinfection to sterilization is:
- a. Sterilization is less expensive than high-level disinfection
- b. Sterilization is now faster than high-level disinfection
- c. There are pathogens that are resistant to high-level disinfection
- d. If an item is not cleaned, sterilization will kill the microbes

3. Which of the following organizations recommends sterilization for semi-critical items, when possible?
- a. US Food and Drug Administration
- b. The Society of Gastroenterology Nurses and Associates
- c. Environmental Protection Agency
- d. The Association of periOperative Registered Nurses

4. If a facility does not have a low-temperature sterilizer that is validated to sterilize a medical device or most semi-critical medical devices:
- a. Either the transition should be discontinued because of the lack of a sterilizer or a proposal should be developed to purchase a new sterilizer that can sterilize most of the items
- b. The facility can still sterilize certain instruments if reprocessing professionals are experienced and competent
- c. The surgeon should be consulted to determine the best processing method
- d. None of the above

5. Which of the following provides the necessary information for a Central Service/Sterile Processing professional to sterilize a medical device?
- a. Medical device instructions for use
- b. Surgeon order
- c. Centers for Disease Control and Prevention
- d. Association for the Advancement of Medical Instrumentation

6. A main consideration of a complex process like high-level disinfection is:
- a. It takes too long to process a medical device
- b. There are too many steps for today's busy Central Service/Sterile Processing departments
- c. Complex processes are more prone to errors
- d. None of the above

7. If a new sterilization modality is being implemented, which of the following should be reviewed to ensure it is validated for that type of sterilization?
- a. Packaging and quality monitors
- b. Instrument tracking system
- c. Employee competency
- d. Purchasing contact

8. Which of the following performs validation?
- a. US Food and Drug Administration
- b. Healthcare facility
- c. Product manufacturer
- d. Association for the Advancement of Medical Instrumentation

9. Which of the following performs verification testing?
- a. US Food and Drug Administration
- b. Healthcare facility
- c. Product manufacturer
- d. Association for the Advancement of Medical Instrumentation

10. When performing verification testing, where should the chemical indicator and biological indicator be placed?
- a. Opposite one another
- b. On the bottom of the tray
- c. On the top of the tray
- d. In areas most resistant to the sterilization process

11. If the product test has positive biological indicators and/or unresponsive chemical indicators, which action should be taken?
- a. Inform the surgeon of the problem
- b. Avoid using the item until the problem is resolved
- c. Perform a recall
- d. Try another type of sterilization

12. During the transition from high-level disinfection to sterilization, who should be included in the approval process as new products are purchased?
- a. Central Service/Sterile Processing
- b. Clinical Engineering
- c. Fiscal Services
- d. The Association for the Advancement of Medical Instrumentation

13. Transitioning from high-level disinfection to sterilization can result in:
- a. Improved quality and a higher standard of care being provided
- b. Reduced processing costs
- c. Faster device turnaround time
- d. Compliance with US Food and Drug Administration standards

14. Documentation of product testing activities should be maintained and include:
- a. The name of the individual(s) who performed the testing and the date the testing was performed
- b. The date the testing was performed, the name of the master product and product family, the identification of the locations of biological indicators and chemical indicators, and test results
- c. The length of time required to complete the product testing activities
- d. All the above

15. A policy and procedure should be developed that states sterilization is the preferred method of treatment for semi-critical items, when sterilization is available. This policy should be supported and approved by which of the following:
- a. The infection prevention committee and administration
- b. All surgeons employed by the facility
- c. Central Service/Sterile Processing directors
- d. Biomedical engineering professionals

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