

CRCST SELF-STUDY LESSON PLAN

Lesson No. CRCST 168 (Technical Continuing Education - TCE)

Sponsored by: **3M Health Care**

Tray Accuracy and Chemical Indicators

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LEARNING OBJECTIVES

- 1. Understand the importance of tray accuracy and how tray errors impact patient care
- 2. Learn the key components of a continuous quality improvement process to reduce tray errors
- 3. Understand how internal chemical indicators should be used and why they are essential for tray accuracy

ray accuracy is a very important aspect of the assembly process in all Central Service/Sterile Processing (CS/ SP) departments, and trays cannot be accurate without the presence of the chemical indicator (CI) in the tray; this is considered an important aspect of patient safety. When patients enter surgical suites for procedures, they expect that the trays processed for their cases will be complete and accurate. Incomplete trays and those missing the CI extend the length of time for the procedure, which can have significant negative impacts on surgical outcomes.

Objective 1: Understand the importance of tray accuracy and how tray errors impact patient care

Those in the CS/SP profession are taught how to assemble and reassemble a tray, and they are also taught that tray layout is important. The tray should be neat and orderly, have all instruments working correctly, and be complete with the CI located in the proper place. In most hospitals, the order of the tray is directed by team members in the Operating Room (OR) because these team members must use the tray to perform surgery; therefore, the tray is assembled according to the count sheet recipe or pick list CS/ SP professionals are given. Even so, it is not uncommon for OR professionals to open a tray for a surgical case and find instruments missing, instruments of the wrong size, extra instruments that were not on the list, contaminated items in the tray, or a tray that is jumbled, with no order.

An inaccurate tray affects the patient's overall surgical experience because the tray must be replaced or instruments must be located – and in some instances, the entire set-up on the back table must be replaced – all of which adds extra time to the case. Continuous quality improvement (CQI) programs can help prevent tray errors through the use of audits, inservices and competencies. Sending an inaccurate, incorrectly assembled or contaminated tray or instrument is unacceptable for the patient and the surgical team. CS/SP professionals have CRCST SELF-STUDY LESSON PLAN



the fiduciary responsibility to do no harm to the patient because their job is to provide surgical instrumentation that is clean, assembled correctly and sterilized according to the manufacturer's instructions.

Surgical tray errors are considered an incident because they may put the organization at legal risk.¹ Typically, a tray error originates from an event that was not consistent with the routine operation of the department; therefore, each CS/SP department should incorporate a specific tray quality process to check (on an ongoing basis) the quality of trays processed. ANSI/ AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities, recommends CQI programs as an effective means of improving performance of any process in the CS/SP department. A CQI process for CS/SP could also include review of aspects of design, decontamination processes, personnel, handling of contaminated items, packaging, sterilizer loading and unloading, immediate use steam sterilization, sterility maintenance, and problem investigation.

Objective 2: Identify the key components of a continuous quality improvement process to reduce tray errors

There should be a planned, systematic and ongoing process for verifying compliance with procedures. Quality procedures can be enhanced by audits that are conducted on a regular basis. Information attained from these activities should be summarized and made available to appropriate individuals or groups/teams.² The surgical tray CQI process will allow the CS/SP department to:

- Improve the quality of trays by reducing errors;
- Determine if the count sheet is

accurate;

- Schedule inservices, as needed, to correct oversights; and
- Reduce cost.

To gather the information needed for the quality improvement program, an audit form is needed so all components of the tray can be checked. Audits should be completed on an ongoing basis to determine if the quality of tray assembly is improving. To improve the quality of tray assembly, the following are needed³:

- Processing tables, which should be made of nonporous materials;
- Proper lighting for each assembly table or area;
- Magnifying lights;
- Lubrication station;
- Instrument storage and repair boxes;
- Heat sealers;
- · Testing equipment; and
- Handwashing stations.

Count sheets are an important part of the tray assembly task in the CS/SP department. The count sheet should be designed by both the CS/SP team and members of the OR, Catheterization Lab, Labor and Delivery, Endoscopy and all other departments serviced by the CS/ SP department. Count sheets aid in tray assembly, while ensuring greater accuracy by the technician. In the assembly process, ring-handled instruments are placed on a stringer and arranged in the order they will be used in surgery. Retractors, knife handles and all non-ring handled items should be neatly placed in the bottom of the tray. Count sheets should include the following columns to allow these components to be listed:

- Instrument, with description;
- Alternate names (nicknames) for instruments, when needed;
- Catalog number;

- Required quantity of instrument;
- Subtotal of instruments in each section;
- Total number of instruments in tray;
- Name of technician who assembled tray; and
- Date tray was reassembled.

When the instrument tray is first received in the decontamination area, it is checked for completeness and prepared for the washer-decontaminator or hand washing. Once the cleaning process is completed, the instruments are then sent to the assembly area where a technician uses the count sheet to begin reconstructing the tray. At this point, the following steps are required to aid in tray reassembly:

- Inspection;
- Drying; and
- Lubrication, if needed.

The count sheet is then accessed on the computer or manually (on paper) and used to check off each instrument as it is placed on the stringer in the tray. Any missing instrument must be accounted for on the sheet, with that tray not going into use without first consulting with the OR specialty team to ensure the missing item will not compromise a surgical case. The instrument set is then checked for neatness, with the count sheet placed with the tray for use by the OR team to count the instruments before the case, during as instruments are added, and before closing the surgical site.

Objective 3: Understand how internal chemical indicators should be used and why they are essential for tray accuracy

The use of internal CIs in the reassembly process is a standard part of tray setup. The CI is a visual tool that shows whether the sterilant has penetrated inside the tray and has reached the

indicator inside, and that the sterilization parameters have been met. There are multiple types of CIs (3, 4, 5 or 6). Type 3 indicators react to a single critical process variable and type 4 indicators react to multiple critical process variables. ANSI/ AAMI ST79:2017 recommends the use of a type 5 or 6 indicator because these types of CIs react to all critical process variables. A type 5 indicator is often called an integrating indicator because it integrates all the process variables into a single result; a type 6 indicator is referred to as an emulating indicator as they are cycle specific. Type 5 indicators can be used in cycles with different parameters, but a type 6 indicator can only be used in cycles where the process parameters match the indicator's instructions for use (IFU). All indicators should be used for the cycle(s) in which they are labeled and used in accordance with the manufacturer's written IFU.3

The CI in a trav provides visual assurance to OR team members that the tray is safe for patient use. A tray that is assembled without the CI is not usable and can cause a delay in the surgical case while a replacement is located. The absence of the CI is considered an error in the reassembly process and the tray is then listed as not being processed correctly. To combat this failure, it is usually taught that the CI should be placed in the most challenging area for steam to reach in the tray – and it should be placed before instruments are added to the tray. ANSI/AAMI ST79:2017 notes the following for the placement of internal CIs:

- One CI should be visible to the person opening the package;
- CIs should be placed in the area or areas considered least accessible to steam penetration; and
- CIs should be placed in accordance with all applicable written IFU.

The CI should be retrieved from the tray and interpreted by a knowledgeable user to determine whether the criteria and characteristics were met (pass or fail). If there is any question as to a pass or fail result, an appropriate supervisor should ensure the entire tray is returned for reprocessing. As part of the process, whenever the CI is found to be missing from the tray or has an inappropriate result the supervisor must perform research on the load to determine whether a recall is needed.

Note: The pass reading of a CI does not mean that the item or items in the sterilizer load are sterile; it means the parameters for sterilization that the CI was designed to measure have been met.⁵

Conclusion

The goal of any CS/SP department is to provide trays that are clean, inspected, dry, lubricated (if needed) and assembled with one or two indicators. The tray should be assembled in an orderly and complete fashion, with any missing items noted. Trays with missing instruments should not be placed into service without prior clearance from the OR team members. CS/SP professionals should always assemble and reassemble trays using some type of a template for that tray.

Thinking about the department's CQI processes should help CS/SP technicians quantify their team's accuracy in surgical tray processing. This information is important to overall patient care and in understanding how incomplete, disorganized or contaminated instruments can lead to procedure delays. The CQI process will help CS/SP professionals find the root cause of tray errors, including those not assembled with the correct number of instruments and/or indicators. Using due diligence and an audit form to note all inaccurate tray information will allow the CS/SP department to improve accuracy and ensure that the surgical team has all the instruments needed at the time of the procedure. Θ

REFERENCES

- 1. Healthmark Industries Inc. http://www. healthmark.info/Cleaning Verification/ Hemocheck/Improving Quality of Surgical Trays.pdf
- 2. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2017, *Quality process improvement*, pp. 106-107, Sections 14.2.1 and 14.2.3.1.
- 3. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*
- Infection Control Today. http://www. infectioncontroltoday.com/environmentalhygiene/chemical-indicators-101-applicationsuse.

CRCST Self-Study Lesson Plan Quiz -Tray Accuracy and Chemical Indicators

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- 1. The instrument order of a surgical tray is usually determined by:
 - a. The Association for the Advancement of Medical Instrumentation
 - b. The lead Central Service/Sterile Processing technician
 - c. The Central Service/Sterile Processing director
 - d. The Operating Room
- A continuous quality improvement program designed to prevent errors includes:
 - a. Audits
 - b. Inservices
 - c. Competencies
 - d. All the above
- **3.** A continuous quality improvement process allows Central Service/Sterile Processing professionals to:
 - a. Improve performance
 - b. Assemble trays more quickly
 - c. Adjust the tray contents based on instrument usage
 - d. Reduce the need for tray turnovers
- Part of a continuous quality improvement program for tray assembly includes auditing the process for:
 - a. Magnifying lights, handwashing stations and proper lighting
 - b. Tape dispensers and alcohol wipes
 - c. Computerized instrument tracking and tray inventory levels
 - d. None of the above

5. Instrument count sheets should include:

- a. Alternate instrument names
- b. Instructions for instrument cleaning
- c. The date the tray was last refurbished
- d. All the above

- **6.** Instrument trays should be assembled: a. By arranging the instruments
 - according to size
 - b. By memory
 - c. In the order the instruments would be used
 - d. None of the above
- 7. Internal chemical indicators:
 - a. Demonstrate that a tray is sterile
 b. Replace the need for a biological indicator
 - c. Should be placed in-between the folds of the wrapper
 - d. Show the tray was exposed to a sterilization process
- **8.** This type of chemical indicator reacts to all critical parameters of a sterilization cvcle.
 - a. Class 3
 - b. Class 5
 - c. Class 4
 - d. Class 1
- 9. The type of chemical indicator that is
 - cycle specific is:
 - a. Class 6
 - b. Class 4
 - c. Class 3
 - d. Class 5
- **10.** Trays received in the Operating Room without a chemical indicator:
 - a. May be used as long as the external indicator has changed properly
 - b. Should undergo immediate use steam sterilization prior to use
 - c. Should not be used
 - d. Should not be considered a tray assembly error

- **11.** Chemical indicators should be placed:
 - a. In accordance with the indicator's instructions for use
 - b. On the bottom of the tray
 - c. In the corner of the tray
 - d. None of the above
- 12. A continuous quality improvement process can help Central Service/Sterile Processing professionals determine the root cause of tray errors.a. True
 - b. False

13. Inaccurate trays can:

- a. Lengthen a surgical procedure
- b. Require the back table to be replaced
- c. Can cause the Operating Room team to open another tray
- d. All the above
- **14.** Tray errors are considered an incident because they can place the facility at risk for legal liability.
 - a. True
 - b. False
- **15.** A continuous quality improvement
 - program should be:
 - a. Planned
 - b. Systematic
 - c. Ongoing
 - d. All the above

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