Unprocessed tray incident prompts investigation, leads to process improvements

The circulating nurse was cleaning up after surgery in an ambulatory surgery center (ASC) when she noticed the internal chemical indicator (a Class 5 integrating indicator) had not reached its appropriate endpoint response, which is a pass. That meant an unprocessed instrument tray had been used on the patient. Her discovery set off an investigation to determine why this occurred.

Could this happen in your facility? This article discusses the events that led to the use of the unprocessed tray and describes the process improvements implemented to reduce the chance for such an event in the future.

Patient notification
After the unprocessed tray was discovered, the surgeon promptly informed the patient in a manner that conveyed full disclosure, compassion, and accountability. The surgeon also prescribed antibiotics to decrease the risk of postoperative infection and closely monitored the patient for signs and symptoms of infection.

Although the risk of transmission of bloodborne pathogens was assessed as low, the facility followed its procedure for management of patient exposure to blood and body fluids. The patient underwent postexposure testing for bloodborne pathogens for 6 months after the surgical procedure, as recommended by the Centers for Disease Control and Prevention.

Root cause analysis
A team of the ASC’s stakeholders was called together to determine how an unprocessed instrument tray was used for a procedure and how to prevent this from happening again. The team consisted of the surgeon, OR staff who were in the room during the case, and nursing and physician leaders from the departments of surgery, sterile processing, infection prevention, and patient safety.

By the time the team met, ASC staff and leaders had conducted a preliminary investigation and made some discoveries about why the instrument tray was not processed. A few days prior to the incident, a sterilizer needing repair had been taken out of service, creating a backup of trays to be loaded into the remaining sterilizer, which was operating correctly. The physical space in the sterilizing area was small and immediately adjacent to the sterile storage area. The unsterilized instrument tray was inadvertently placed in the sterile storage area.

First event
The first event that led to use of the unprocessed instrument tray was that the tray was placed in the sterile storage area and released for use. Personnel did not read the external chemical indicator on the tray before it was released. Though a barcode scanning system was used in the department, the system did not have the capability to identify whether a package had not been processed.

Process improvements to consider
• Update or write a policy and procedures that state actions to take when a sterilizer
is removed from service so all personnel know where to place trays/packages to be sterilized once the sterilizer is placed back into use.

• Review the storage areas in the sterile processing area to determine if more space can be created for storage of unsterile items. A human factors approach would be to avoid having the sterile and unsterile storage areas next to each other to prevent medical devices from being stored in the wrong area.
• Upgrade the instrument-tracking system or purchase a new workflow management information system with the capability of scanning packages before and after the sterilization process, including when they are released for use, to determine if they were processed. The results of the physical monitors and chemical and biological indicators could also be accessed at this time. Such a system could alert you if the wrong sterilization cycle was used, if the physical monitoring results were not correct, or if a biological indicator was not run with an implant. This is just a short list of features of newer information systems.
• Train OR/sterile processing personnel to read and identify the acceptable endpoint results of the external chemical indicator to ensure the packages have been through the process before they are released for use. Verify and document competency.
• Ensure that an experienced, knowledgeable person makes decisions about load release based on the evaluation of all available data (physical monitors, chemical and biological indicators) for particular loads.

Second event
The second event that led to the use of the unprocessed tray was failure of the OR staff to read external and internal chemical indicators. Contributing factors to this event included:
• A new employee with previous OR experience was setting up the case. The handoff process for nurse preceptors did not provide clear communication about specific skills for which the new employee was expected to demonstrate competence, including chemical indicator reading.
• The day the chemical indicator was not read was a heavy case-load day, and there was pressure to turn over rooms as quickly as possible.
• During setup of the case, nurses reported frequent interruptions by anesthesia providers and other staff.

Process improvements to consider
• Use the AORN Comprehensive Surgical Checklist, which includes recommendations from the World Health Organization and the Joint Commission’s Universal Protocol and National Patient Safety Goals. This is a single, comprehensive, multidisciplinary checklist to use for preprocedure check-in, sign-in, time-out, and sign-out for every surgery to reduce surgical complications and mortality. During the time-out, the scrub person and circulating nurse should check the box, “Sterilization indicators have been confirmed.”
• Train OR personnel to read and identify the acceptable endpoint results of the external chemical indicator and internal chemical indicator to ensure the trays/packages have been through the sterilization process, and the sterilant reached the inside of the tray/packages before they are introduced to a sterile field. Verify and document competency. The preceptor also needs to check the chemical indicator results before placing the set on a sterile field. A second check by another staff member would add another safety factor.
• Follow the AORN recommended practice for sterile technique, which states, “Perioperative team members should inspect the sterilization chemical indicator in the
sterile package to verify the appropriate color change for the sterilization process selected.” This is done before the package is placed on the sterile field.

- If your facility uses rigid sterilization container systems, open the container on a separate clean, flat, and dry surface to inspect the integrity of the packaging (eg, security locks, latch filters, valves, and tamper-evident devices to ensure they are intact). Check the endpoint results of the external indicator before opening the container and the internal indicator before placing the tray on the sterile field. Place the tray on the sterile field only if the integrity of the container is not compromised and the chemical indicators have reached their acceptable endpoint.

- Minimize interruptions during the room setup, and establish a feasible time frame for turnover to reduce the chance for mistakes that could affect patient safety.

**Risk assessment**

Doing a root cause analysis after an event helps to identify possible sources for the event and action plans to prevent future occurrences.

Facilities should also perform a proactive risk assessment. This process includes identifying the likelihood that such an event could occur, the consequences if an event does occur, assessment of how to prepare the facility to manage the event, implementation of actions to take to ensure an event does not occur, and communication of the changes being implemented to prevent an event.

Consider performing a risk assessment of the sterilization process (eg, decontamination, preparation and packaging, sterilization, quality control, sterile storage, and product distribution) to identify events that could lead to failure. Eliminating risk points helps improve patient safety.

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**References**

AORN. AORN Comprehensive Surgical Checklist. www.aorn.org


