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Learning Objectives

1. Describe some basic AAMI performance areas of knowledge required for optimal sterile processing functions
2. Discuss key elements required for optimal sterile storage and materials management
3. Explain the importance of an OR/SPD taskforce, how to establish one, and how to develop some practical tools for successful communication

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Loaner instrument tray management: A shared responsibility

by Cory Nestman, BS, CRCST, ACE, and Michele McKinley, LVN, CRCST

One of the biggest challenges facing operating rooms and sterile processing departments today is the efficient management of loaner instrumentation. As surgical procedures become more technologically advanced and the cost of instruments keeps rising, the use of loaner instruments is becoming more common in hospitals. There can be one tray or as many as sixty trays for each surgery, depending on the procedure and surgeon preference, and within each tray are numerous instruments, some quite complex in nature.

There are several factors that impact the successful preparation of these loaners for patient use. First, the inherent complexity of the instruments themselves creates cleaning and sterilization challenges. Secondly, a previous user may not adequately clean and decontaminate loaner trays before the vendor retrieves them. In addition, bioburden can dry or in some cases bake on from a subsequent flash sterilization cycle.

In order to adequately manage loaner instruments, it is important to identify and understand the complete process and all potential constraints of a loaner tray management program. It is also important for the surgical and sterile processing departments to recognize that loaner tray management cannot succeed in departmental isolation. An optimal loaner tray management program requires idea sharing and collaboration from multiple experts and areas.

What's your loaner tray nightmare?

Let's look at some typical real-world scenarios that hospitals face on a routine basis; are any of these familiar?

1. 50 loaner trays are delivered at 10:30 p.m. the night before, for a 7:30 a.m. case.
2. The vendor representative delivers "sterile" wrapped trays from another facility the morning of surgery directly to the OR.
3. The vendor representative retrieves a set of loaner instruments from the trunk of

his/her car and delivers them directly to the OR. He/she informs the OR staff that the tray has been processed and is ready for a flash cycle.

4. When the vendor representative is asked how to clean and sterilize the set he states, "whatever you do with your other sets."
5. The surgical case is finished, so the vendor representative takes the dirty loaner trays to the hospital's SPD and explains the urgency of getting trays to another hospital that is waiting. He/she expects the SPD staff to stop processing their own hospital sets and prioritize the loaner trays to accommodate the vendor representative's schedule.
6. The vendor representative explains to a surgeon and the OR staff that their case is delayed because the SPD doesn't have the loaner trays ready (the root cause was actually a late delivery of the trays).

These are just a few examples of situations that can place patients at risk by bypassing optimal cleaning and sterilization procedures. These challenges also appear to place the burden of blame for incomplete processing directly on the SPD staff, sometimes resulting in the SPD being seen as the sole cause of surgical delays.

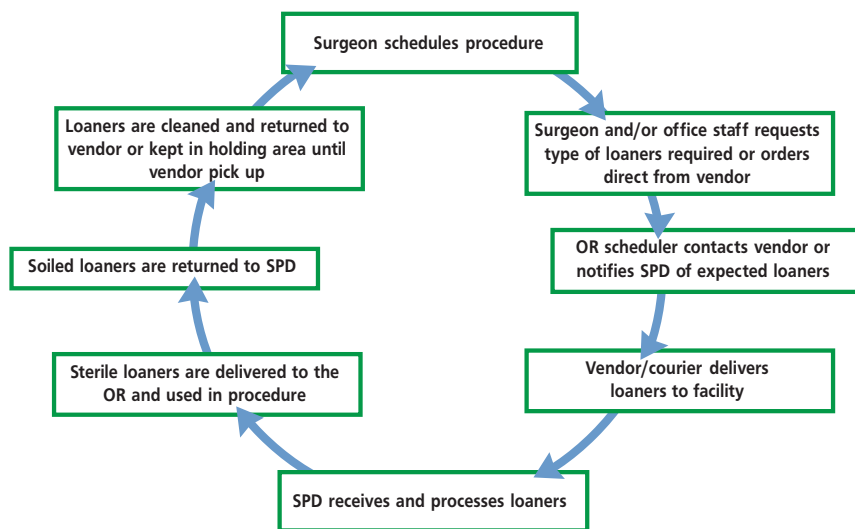
Identify the stakeholders and cross-functional contributors

Figure 1 shows a typical loaner tray process. This diagram illustrates the multiple participants who are directly involved in loaner tray management programs. These are subject matter experts with the most direct experience who can best determine the optimal loaner tray process and identify its risks and potential constraints.

To develop an effective, efficient and successful loaner tray management program, one must first bring together the stakeholders, who typically include the following groups:

1. Surgeons (or staff representatives)
2. Surgery Department
3. Sterile Processing Department

Figure 1: Loaner Tray Cycle



4. Infection Control Department
5. Administration/Purchasing

In addition, vendor representatives should be invited to participate in the group as thought partners after the initial plan has been developed and is ready to be deployed. Vendors should not be allowed to drive a hospital process, but their input pertaining to the process can be valuable, and their participation and understanding of the facility's needs is critical.

It is extremely important to engage the surgeons and administrative staff in loaner tray process development because high-level support may be needed when working with vendors. Since surgeons and instrument vendors typically develop a relationship outside the hospital setting, there can be a perception of vendor authority and immunity to process rules established by the hospital. For this reason, a program can only be successful if a surgeon is involved in helping to establish loaner protocol, and if hospital administration takes a strong stance on enforcing the rules of the loaner program.

An infection control professional should also be involved in process development to provide support and ensure that there is compliance to accepted standards and best practices. His or her perspective on reducing patient risks related to infection will help to discourage such practices as improper or incomplete cleaning and sterilization practices carried out to accommodate loaner instruments that are delivered late.

Once a multidisciplinary team has been formed, a routine series of meetings should be scheduled to initially develop and approve the plan, and then to monitor and maintain compliance.

Overarching goal and specifics

The multidisciplinary team must identify the goal of their loaner tray management program. For example, the ultimate goal could be to provide the OR "customer" with loaner trays that are 100% clean, complete, and sterile, delivered 100% on time.

Once the goal has been approved, key operational steps must be established to achieve that goal. As part of the development plan, the team should also identify possible constraints at each point in the process. Once identified, a step-by-step plan should be developed to provide solutions to the possible constraints and compliance measures. For example, one potential concern might be the timely delivery of instruments by the vendor to the Sterile Processing Department (SPD). A rule could be established that, to allow a full processing cycle before the trays are delivered to the OR, a reasonable drop-off time should be determined as part of the tray management process (i.e., 5:00 p.m. the day before a surgical case). Vendors can then be notified of the hospital's expectations, and compliance to the set delivery time can be tracked by the SPD staff.

The following steps should be considered during planning. These have already been

applied by numerous facilities as best practices for a successful loaner management program.

1. Commit to following regulatory guidelines for cleaning and sterilization of instruments outlined in AAMI ST79:2006 Sections 7 and 8.
2. Establish a designated time frame for vendor delivery of loaner trays to the facility. SPD instrument tray turnaround times must be examined to determine the appropriate time necessary to process the loaner trays along with the hospital-owned instrument trays. The following are points to consider when examining instrument throughput in the SPD:
 - a. Total tray processing time (including cool-down of processed trays)
 - b. Appropriate staffing to process the extra workload
 - c. Time of scheduled procedure
 - d. Number of sets
 - e. Processing and chamber capacities of all washers and sterilizers
 - f. Manufacturers' recommendations for cleaning and sterilization
3. Determine what steps will be taken to address loaner trays that are delivered outside of the established timeframe and without manufacturers' instructions. (i.e., vendors could receive a notice from hospital administration documenting the dates of non-compliance to the hospital policy).
4. Decide on the protocol for late loaner trays in advance, and hold the team accountable for it. Document whether or not procedures will be delayed until loaner sets are properly and fully processed, in order to be in compliance with AAMI ST79:2006.
5. Determine how trays will be processed to adhere to manufacturer's instructions if they fall outside of routine processing practices.
6. Develop consequences for lack of vendor accountability (i.e., hospital will charge vendor or deduct from invoice payments for implants, for example).
7. Put the policy in writing, and include all steps and responsible parties for management of loaner instrumentation.
8. Prepare a letter to vendors outlining the facility requirements and the vendors' responsibilities, including the consequences for non-compliance. Distribute the letter and a copy of the policy and procedure to

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- each vendor and have each sign a confirmation of receipt document to file at the facility.
9. Track and monitor vendor compliance through a loaner tray sign-in document or computer tracking system scanned into the facility's instrument tracking program.
 10. Establish a document (i.e., inventory control sheet) to capture valuable information about the loaner trays being received. This receiving document should include:
 - a. Date and time of the surgery
 - b. Signature of the individual delivering the loaner trays
 - c. Signature of the individual receiving the loaner trays in the SPD or the OR
 - d. Physician's name
 - e. Patient's last name or medical record number (hospital HIPPA restrictions should be consulted)
 - f. Number of trays and implants (SPD should perform an inventory control check to verify the types and numbers of instruments)
 - g. Names of each of the trays
 - h. Verification that instrument quality check was performed (inspecting for cleanliness and damage).

Communication is another key element of a successful loaner tray management program. Once the entire program and related documentation are in place, all members of the team should share this information, including the vendor letter, policy and procedures, and any other documents, with each of their respective teams. This will ensure that all departments are aware of the new program and the accountability that's involved.

Additional issues to consider

Flash sterilization and loaner trays: the Association of periOperative Registered Nurses (AORN) cautions facilities that flashing should only be used when there is insufficient time to process by the preferred wrap or container method. Flash sterilization should not be used with implants, and is not a substitute for insufficient instrument inventory. Flash sterilization should only be used in selected clinical situations and in a controlled manner. Flashing should be considered only if all the following conditions are met:

- a. The device manufacturer's written instructions are available and followed.
- b. Items are disassembled and thoroughly cleaned with detergent and water to remove soil, body fats and other substances.

- c. Lumens are flushed with the cleaning solution and rinsed thoroughly.
- d. Items are placed in a sterilization container or tray in a manner that allows steam to contact all instrument parts.
- e. Measures are taken to prevent contamination during transfer to the sterile field.
- f. Documentation of cycle information and monitoring results is maintained to provide tracking to the individual patient.

Physicians bringing in their own instruments and not sending them to SPD for full reprocessing: Often surgeons bring their own instruments directly to the surgical department and insist that OR staff members flash-sterilize the instruments right before a case. In addition, if the surgeon has back-to-back cases and prefers to use personal instruments, these trays may be flashed without going through the proper reprocessing steps as they are performed in SPD. These situations should also be reviewed by the team in advance, and procedures set to ensure that reprocessing practices are standardized.

Ensuring best practices for the patients' benefit

Healthcare professionals are inherently committed to the best interests of their patients, so the design and execution of an optimal loaner tray program is a natural extension of this commitment. The very best programs start with a multidisciplinary team agreeing on the process and holding all parties accountable for their roles. The team establishes the hospital's loaner policy, procedures and work instructions, and educates all parties and departments involved. They also set realistic timeframes for loaner tray delivery and have a plan for dealing with trays that arrive outside that timeframe. Most importantly, the team assures that appropriate cleaning and sterilization practices are consistently carried out, to ensure the best possible outcome for patients.

Once they are armed with best practices and a consistent protocol, the team can be confident that they are providing optimal surgical instrument management, whether the instruments belong to the hospital, the surgeon or a vendor. **HPN**

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Loaner instrument tray management: A shared responsibility

Circle the one correct answer:

1. Which of the following factors impact the successful preparation of loaner instruments for patient use?
 - a. The inherent complexity of the instruments themselves
 - b. The timing of delivery by the vendor
 - c. Lack of adequate cleaning and decontamination of loaner trays by a previous user before the vendor retrieves them
 - d. Bioburden that dries or in some cases bakes on from a subsequent flash sterilization cycle
 - e. A, B and C only.
 - f. All of the above
2. Which of the following is NOT true about procedures for management of loaner instruments?
 - a. Items in loaner trays should be inspected for cleanliness upon delivery to the hospital.
 - b. Number of items in loaner trays should be confirmed upon delivery to the hospital
 - c. Loaner trays can be taken directly to OR for sterilization if the vendor representative states they are clean.
 - d. The manufacturer's specifications for reprocessing should be followed.
3. Which of the following are steps to consider for late tray delivery?
 - a. Decide on the protocol for late loaner trays in advance, and hold the team accountable for it.
 - b. Document whether or not procedures will be delayed until loaner sets are properly and fully processed.
 - c. Determine how trays will be processed to adhere to manufacturer's instructions if they fall outside of routine processing practices.
 - d. Develop consequences for lack of vendor accountability.
 - e. All of the above.
 - f. B and D.
4. Information regarding cleaning process for loaner instrumentation should be provided by:
 - a. the operating room staff
 - b. the instrument manufacturer
 - c. APIC
 - d. the hospital engineering department
5. Which of the following is NOT necessary when completing the inventory receipt sheet for incoming loaner instruments.
 - a. Date and time of surgery
 - b. Patient and physician information
 - c. Signature of the individuals delivering and receiving the loaner trays
 - d. The date the instruments and containers were manufactured
6. It is not necessary to record the number and individual tray names when receiving a set of loaner instruments as long as they are received as a system such as "Total Knee Revision System."
 - a. True
 - b. False
7. Which group is NOT a direct stakeholder in the management of loaner instrumentation?
 - a. Sterile Processing/CS department
 - b. Surgery department
 - c. Facilities management
 - d. Administration
 - e. Infection Control department
8. AORN cautions facilities that they should not flash loaner trays with implants, and that flash sterilization is not a substitute for insufficient instrument inventory.
 - a. True
 - b. False
9. The key factors for success in managing loaner instruments are:
 - a. The multidisciplinary team agreeing on the process and holding all parties accountable for their role.
 - b. Establishing a hospital policy, procedure and work instructions and educate all parties involved in the process for management of loaner instruments.
 - c. Setting realistic timeframes for loaner tray delivery and having a plan for dealing with trays that do not arrive within the designated timeframe.
 - d. Maintaining appropriate and consistent cleaning and sterilization practices to ensure the best possible outcome for the patient.
 - e. All of the above.
 - f. B and C only.
10. Once the entire program and related documentation are in place, all members of the team should share the vendor letter, policy and procedures, and any other documents with each of their respective teams.
 - a. True
 - b. False

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