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Learning Objectives

1. Explain why loaner instrumentation is a growing concern for the OR and Sterile Processing.
2. Define ethical and moral responsibilities and patient safety issues associated with loaner instrumentation.
3. Develop a policy for managing loaner instrumentation.

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SELF-STUDY SERIES

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SPD and OR working together to manage loaner instrumentation

by Rose Seavey, RN, BS, MBA, CNOR, ACSP

Healthcare facilities often need to borrow surgical instruments or implants for specialty operative procedures for an assortment of reasons. Across the country the use of loaner instrumentation is on the rise. To our dismay it is becoming common practice in most hospitals and ambulatory surgical centers.

Surgical technology is changing constantly and it is impractical for each healthcare organization to own every instrument and implant that may be needed for every surgical procedure. Surgeons are often introduced to new technology, or a procedure is done so infrequently that a facility cannot afford to purchase all of the instruments.

This article will offer guidelines for creating a policy on loaner instrumentation and implants.

Why the big concern?

A major responsibility of healthcare providers is to minimize patient risks while increasing patient safety. In the operating room, this is particularly important in regards to surgical wound infections. An essential way to help avoid surgical wound infections is to present surgical items that are free of contamination at the time of use.¹ If you borrow instruments from another institution or a vendor, you have the responsibility to ensure these items are free of contamination when used on your patients.

The management of loaner instrumentation and implants is recognized as a growing concern by many healthcare professionals. If you borrow instruments from a vendor or another facility, it is the ethical responsibility of the facility who is using the instruments to make sure the items are safe to use on their patients and that the process is properly documented and fully traceable to the patient.

Loaner instrumentation is a huge worry for Sterile Processing employees who reprocess instruments and implants because they are responsible for decontaminating, packaging, sterilizing and tracking these items.

When loaner instrumentation comes in the day of the case, as a stat, the Sterile Processing technicians have to stop what they are doing to take care of them. This pressing situation causes an interruption to the routine, takes technicians away from their other customers, and may result in errors or elimination of critical tasks. As a result, it may negatively affect the patients on whom the stat items will be used, and could negatively affect other patients in some way as well.

Monitoring is a must

Hands down, the biggest concern with borrowed items is the lack of time available to properly process the borrowed items. The user facility must have sufficient time to reprocess the items according to the device manufacturer's instructions for cleaning, assembling, packaging and sterilizing. If there are implants, a biological indicator (BI) must be run in the load and the results read out as negative before they can be released for use. According to the Association for the Advancement of Medical Instrumentation (AAMI) standard, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, ANSI/AAMI S179:2006, section 10.6.3, "The sterilization of implantables should be closely monitored and each load containing implants should be quarantined until it is verified that BI testing has yielded negative results."²

Product testing should also be performed on all loaner instrumentation "as a part of a complete quality assurance program to ensure the effectiveness of the sterilization process and to avoid wet packs."² This testing starts by placing multiple BIs and chemical indicators (CIs) in areas of the loaner instrumentation packaging considered to be the coldest or greatest challenge to sterilant penetration. The wrapped or containerized instrumentation should then be labeled as a product test, placed in a typical load, processed according to the medical device manufacturer's instructions, and the results of the test documented. Loaner instruments should only be routinely pro-

cessed after these tests show negative BIs and acceptable CIs.

Controls should be in place for successful management of these instruments and implants. Any policies written to guide staff in the appropriate handling of these borrowed items should be enforced.

Flashing is not the answer!

In some facilities it seems it is "normal procedure" to flash large amounts of instruments and implants. AORN does not recommend flash sterilization of implants.

"Flash sterilization should not be used for implantable devices. Implants are foreign bodies, and they increase the risk of surgical site infection. Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices. When an implantable device is sterilized at a healthcare facility, a biological indicator should be run with the load and the implant should be quarantined until the results of the biological indicator are known. If an emergency situation makes flash sterilization unavoidable, a rapid-action biological monitoring device should be used along with a class V chemical integrator. The implant should not be released until the rapid-action indicator provides a negative result. After the rapid-action negative result is obtained, the implant can be released for use in the immediate situation."¹

Making a difference

Given insufficient time to reprocess instrumentation, technicians may take shortcuts, and these shortcuts (i.e. flashing of instruments and implants) may become part of the routine or structure. This is never a good idea. What can we do about it? It starts with somebody that has the passion, moral standards, and willingness to make a difference for the patients. You need to continue to push the button until the process is improved. There are others that can help you in this quest, such as Infection Control, Quality, and Risk Management. After all, their main concerns are the safety of the patients. If you see a practice that is obviously wrong it is your moral and ethical responsibility, as healthcare providers and professionals, to do something about it. Your patient's safety depends on it!

Obtainable resources

In April of 2004, the American Society for Healthcare Central Service Professionals (ASHCSP) and the International Association of Healthcare Central Service Materiel

Management (IAHCSMM) published an updated joint position paper on effectively managing loaner instruments and implants.³ In the fall of 2007 it was announced that these two professional organizations have agreed to unify.

The position paper addresses issues that healthcare professionals face daily in effectively managing loaner instrumentation and implants. These up-to-date guidelines should be used when developing policies and procedures to improve management of these instruments and implants. The emphasis is on developing a standardized system that will allow all involved parties to access information easily.

The following is a summary of the suggestions formed and adopted by ASHCSP and IAHCSMM.

- A joint venture must be developed between the vendor, SPD, and the OR. This partnership must be built on cooperation and trust. Healthcare facilities should inform vendors about time requirements for pre-procedure and post-procedure processing. These time lines should be adhered to by the vendors. Vendors should supply precise directions for reprocessing requirements to include cleaning, disassembling, sterilization (including flash recommendations if necessary) and packaging. Sterile Processing should maintain a record of each tray that is used, including time in and out, and other processing specifics.
- Policies and procedures should be created in cooperation with vendors and/or other healthcare facilities, to address the efficient management of loaner instrumentation and implants from acquisition to disposition. These policies and procedures should include ordering, transport in, check in, pre-procedure processing, charging (if applicable), post procedure processing, check out and transport out.
- The designated staff responsible for the management of loaner instruments and implants must be trained and knowledgeable of all aspects of this process.
- Facilities should develop policies and procedures that can be used as instructions to systematically manage loaner instrumentation and surgical implants. This includes items loaned from other healthcare facilities and vendors for specific surgical procedures as well as items consigned by a vendor to a healthcare facility and stored in-house for their use.
- The procedure should discuss acquisition of loaner instrumentation, including the following: initial request, communi-

cation, transportation, and designated receiving area which should be the decontamination area.

- Accountability and record keeping to include:
 - Instruments delivered to healthcare facility with sufficient time to permit in-house disassembly, cleaning, packaging, and sterilization of the instruments before the scheduled surgery in accordance with policy and procedures;
 - Inventory list and manufacturer's reprocessing instructions;
 - Date and time of receiving the instrumentation as well as date and time of procedure and surgeon's name;
 - Quality checks;
 - Cleaning and decontamination after use;
 - Maintenance of complete records.
- Disposition of items to include:
 - Returning items to vendor or other healthcare facility;
 - Documentation;
 - Arrangement for replacement of any damaged or lost instruments and used implant software.
- Other considerations:
 - Items received as single-use devices should be in the original packaging from the vendor;
 - Instrument tracking software is helpful in managing loaner instrumentation.³

Policy should be in writing

In order to make changes and to ensure safe management of loaner instrumentation a policy must be written. The joint paper noted above can be very helpful in writing your policy. It is imperative that this policy be written and approved by SPD, OR, Infection Control, Risk Management, and surgeons. Two other resources that should be consulted when writing your loaner policy are:

- The Association of perioperative Registered Nurses (AORN) 2007 *Recommended Practices for Sterilization in the Perioperative Practice Setting*, and
- AAMI's *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST79:2006.

One of the most important recommendations that both organizations address is the need to quarantine surgical implants until the results of a biological indicator (BI) is read as negative.

It is also a good idea to spell out, as part of the policy, the consequences if the policy is not followed.

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SELF-STUDY from page 31

Dealing with implants

According to the Food and Drug Administration (FDA), an implant/implantable item is defined as "a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also 'implants.'" [21 CFR 812.3(d)]²

Implants are foreign bodies left behind that require additional attention to the sterilization and quality control process because the threat of surgical site infection is greater.²

There is a greater risk of infection to patients with an implant because:

- "First, they are left behind at surgery, so if there are microorganisms on them, these will remain in the body. Infections associated with implants may not be evident for up to a year after surgery.
- Second, the placement of an implant often means the removal of tissue, with interruption of blood supply and significant manipulation of the tissues immediately adjacent to the implant, creating an area of potential safety for microorganisms to multiply, further increasing the risk of infection.
- Third, because there is interrupted blood supply, antibiotics cannot easily get to the microorganisms if they do multiply enough to cause a clinical infection.
- Fourth, the implant itself may be vital to continuing function of a body system, such as would occur with a total joint replacement, vascular graft, or intraocular lens placement. An infection may not be curable with the implant in place, and removing it could cripple or kill the patient."⁵

AAMI's newest document on steam sterilization has specific recommendations on the release criteria for implants (ANSI/AAMI ST79:2006, section 10.6.3):

"As with all cycles, the sterilizer operator should review the sterilizer chart or printout and the results of other indicators that

have been used to monitor the sterilization process. The load should be quarantined until the results of the BI testing are available (CDC, 2003a)."²

AORN's updated policy agrees with the AAMI recommendation. AORN states,

"When an implantable device is sterilized at a healthcare facility, a biological indicator should be run with the load and the implant should be quarantined until the results of the biological indicator are known".¹

If there truly is not enough time to wait for the results of the BI due to an emergency situation, AAMI's position states: "When documented medical exceptions dictate (e.g., the need for trauma-related orthopedic screw-plate sets), it could be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented. It is critical that this documentation be fully traceable to the patient. Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule. Emergency situations should be defined in written guidance developed in con-

sultation with infection prevention and control, the surgeon, and risk management."²

If implants must be flashed

According to Ramona Conner, RN, MSN, CNOR, Perioperative Nursing Specialist for the AORN Center for Nursing Practice, "If there is not time to wait for the BI results due to an emergency situation, the sterilized implant can be placed on a corner of the back table and segregated from the rest of the sterile field until the rapid-readout BI is ready to read. When the BI result is negative, then the implant can be placed in the patient. If the BI result is positive, the implant hasn't been used and the rest of the sterile field hasn't been contaminated."⁴

Every effort should be made to avoid flashing of implants. For instance, can the surgical schedule be moved around if you have back-to-back cases to allow enough time to properly reprocess the necessary items between cases? Another idea is that if there is an anticipated need to use an instrument set with implants in it (e.g. plates and screws) for back-to-back cases, and you cannot obtain another set, you could wrap and sterilize additional plates and screws separately.

That way, you have the implants sterile with the BIs read out in advance.

If an implant must be released before the BI results are known, AAMI suggests use of an Exception Form for premature release of implants (see Figure 1). This form allows you to document the pertinent information about the incident, including the reason for premature release, and what could have prevented premature release of the item. This should be included into the policy and a copy of the Exception Form should be sent to infection control and risk management for additional monitoring. These forms can be monitored to identify ways to decrease the need to flash implants. Having hard data, rather than anecdotal information, will help our efforts to follow the AAMI guidelines and to achieve our ultimate goal, which is to provide safer patient care.

Exception Form for Premature Release of Implantable Device/Tray

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

PLEASE COMPLETE ALL INFORMATION:
 DATE: _____ SHIFT: _____ TIME: _____ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

OPERATING ROOM REPORT:
 PATIENT NAME: _____
 SURGEON NAME: _____
 TIME OF PROCEDURE: _____ AM PM DATE: _____
 REASON PREMATURE RELEASE WAS NEEDED: _____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE/TRAY? _____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON: _____

Figure 1: Exception Form for Premature Release of Implantable Device/Tray

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Summary

A written policy is extremely helpful in spelling out the accountability and consequences when dealing with loaner instrumentation. Having all related healthcare providers (including the vendors) involved and on the same page in this effort is a must if you hope to have a successful loaner program. Loaners must be considered contaminated and sent directly to decontamination for reprocessing and the manufacturers' representatives must provide reprocessing directions in writing. Responsibilities and the need for good documentation must be spelled out in the policy. Implants should have BI results before they are used and they should not be flashed.

We can no longer make excuses by saying we can't do that. Instead we need to say we **MUST** do it. The OR and SPD working together need to be the change agents to make this happen. Begin by involving Infection Control, Risk Management, and Quality in your efforts. Share the issues and "excuses" with them and ask for their help. We all have an enormously big part in infection prevention and we can make a difference in creating a successful loaner program, and improving patient safety. What if the patient was your loved one? Would you want their instruments "rushed"? **HPN**



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Seavey is an active member of the Association of periOperative Registered Nurses (AORN). She was honored with AORN's award for Outstanding Achievement in Clinical Nurse Education in 2001. She served as the President of the American Society of Healthcare Central Service Professionals (ASHCSP) in 2003 and is the 2002 recipient of ASHCSP National Educator of the Year award. Seavey is a member of several AAMI committees that are developing recommended practices and is currently a co-chair for the AAMI ST8, Hospital steam sterilizers.

1. Recommended Practices for Sterilization in the Perioperative Practice Settings. Association of periOperative Registered Nurses. AORN Standards, Recommended Practices, and Guidelines. 2007.

2. The Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. ANSI/AAMI ST79:2006.

3. ASHCSP/IAHCSPMM position paper on Loaner Instrumentation (April 2004), located on the web site: http://www.ashcsp.org/ashcsp/news/Joint_paper_on_loaner_instruments.pdf or http://www.iahcspmm.com/current_issues/joint_paper_loaner_instrumentation.htm.

4. Conner, Ramona, AORN Center for Nursing Practice, phone interview 10/7/2006.

5. Schultz, Janet. Monitoring and Load Release for Implants Sterilized by Steam Within Healthcare Facilities. Managing Infection Control. Jan 2004.

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SPD and OR working together to manage loaner instrumentation

Circle the one correct answer:

1. Loaner instrumentation is a not a concern in most healthcare facilities.
A. True
B. False
2. Surgical technology is changing constantly making it impractical for facilities to own every instrument and implant needed.
A. True
B. False
3. Healthcare providers have a major role in minimizing patient risks and increasing patient safety.
A. True
B. False
4. Controls should be in place for successful management of loaners.
A. True
B. False
5. Implants should not be released before the results of the biological indicators have been read.
A. True
B. False
6. AAMI and AORN published a joint position paper on effectively managing loaner instruments and implants.
A. True
B. False
7. Flash sterilization should not be used for implantable devices.
A. True
B. False
8. There is a lower degree of chance of infection with implantable devices.
A. True
B. False
9. All loaners must be considered contaminated and delivered directly to the decontamination area.
A. True
B. False
10. If an implant must be released before the BI results are known, AAMI suggests you use an Exception Form for premature release of implants.
A. True
B. False

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