IAHCSMM Position Paper on the Management of Loaner Instrumentation

Healthcare facilities often have a need to borrow instrumentation and surgical implants for a surgical or invasive procedure from a specific vendor or neighboring healthcare facility. The management of loaner instrumentation and implants in healthcare facilities is recognized as a problem by many healthcare professionals today.

Loaner instrumentation often consists of multiple trays and many types of instruments and/or implants. Some of these items are very complicated or sophisticated devices that are new to the facility. It is a particular concern for Central Sterile Supply Department (CSSD) personnel who are responsible for processing, storing, and issuing reusable medical/surgical devices and equipment for those who provide direct patient care.

A formalized program, specific policies and established controls must be in place to effectively manage borrowed instruments and implants to ensure safe patient care. The Joint Commission (TJC) emphasizes the need to implement evidence-based practices for preventing surgical site infections in their National Patient Safety Goal (NPSG) 07.05.01. The *element of performance #3* stipulates that facilities implement policies and practices aimed at reducing the risk of surgical site infections. The policies and practices must meet regulatory requirements and be aligned with evidence-based guidelines for example the Centers for Disease Control and Prevention (CDC), the Association of periOperative Registered Nurses (AORN) and the Association for the Advancement of Medical Instrumentation (AAMI).[1]

In recognition of the need to systematically manage loaner instrumentation and implants, the International Association of Healthcare Central Service Materiel Management (IAHCSMM) has adopted the following position:

Healthcare facilities that borrow surgical instruments should have a well-developed loaner program and written policy that establishes standardized receipt and use of all loaner instrumentation. This policy should be established with input from CSSD, OR and various departments such as, Infection Prevention and Control (IPC), Administration, Materials Management, Risk Management (RM), and surgeons. The loaner instrumentation program should include:

- Requesting loaner instrumentation or implant(s);
- Time requirements for pre-procedure and post-procedure processing and inservicing, as needed;
- Acquisition of loaner items, including a detailed inventory list (preferably with pictures);
- Obtaining FDA-cleared manufacturers' written instructions for instrument care, cleaning, assembly, and sterilization;
- Cleaning, decontaminating and sterilizing borrowed instrumentation by the receiving facility;
- Transporting processed loaner instrumentation to the point of use;
- Post-procedure decontamination, processing, inventory;
- Returning to the industry representative; and
- Maintaining records of the transactions.

Note: IAHCSMM is not a standards-making group; therefore, this position paper is not a standard, but rather a tool to provide guidance and help facilities develop their own loaner instrument-related policies and procedures.

A well-established policy can be used as a guideline to help thoroughly manage loaner instrumentation and surgical implants. The designated staff responsible for the management of loaner instruments and implants must be trained and knowledgeable of all aspects of this process.

A partnership must be developed between the vendor, CSSD and the Operating Room. This partnership must be built on mutual trust and collaboration. Healthcare facilities should provide vendors with information regarding time requirements for pre-procedure and post-procedure processing, and these time requirements should be adhered to by the vendors.[2] Per the U.S. FDA labeling regulations (21 CFR 801), vendors must provide current, complete and comprehensive written instructions for handling, cleaning, disinfection, testing, packaging, and sterilization. [3] Vendors should also provide comprehensive inventory lists, preferably with pictures. CSSD should keep a record of each set that is used, including time in and out, and other processing specifics. The loaner program should be monitored, assessed and periodically reviewed for compliance.

The IAHCSMM sample policy on Processing Loaner Instrumentation provides a standard format of essential information that should be included in the facility's policy on management of loaner instrumentation.

Below is a simple tool that can be helpful in ensuring all the necessary steps are followed when a facility receives loaner instrumentation and implants.

Loaner instrumentation checklist

□ CSSD notified of loaners prior to receiving them
□ Received in facility (decontamination) at least two working days (48 hours) for existing loaner sets and three working days (72 hours) for new sets before scheduled case
□ Inventory list provided/available
□ FDA-cleared manufacturer written instructions for cleaning, packaging, and sterilization available
□ Inventory and quality checks completed
□ Multiple trays numbered and labeled (patient name, surgeon)
□ Trays do not exceed 25 pounds
□ All instruments in good condition, with no rusting or pitting
□ Container in good condition, with no rusting, tape, residue, etc.

Other Considerations

Items received as single-use devices (SUDs) in original packaging from the vendor should be inspected for damage and cleanliness. The integrity of the package must be confirmed. If opened but not used, return to vendor. Do not reprocess unless FDA-cleared manufacturer's instructions for reprocessing are provided, and all FDA requirements regarding reprocessing of SUDs are met. (*See FDA Medical Devices Frequently Asked Questions*, at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121093.htm).[4]

Instrument tracking software is becoming increasingly common in modern reprocessing departments and can play a major role in managing loaner instrumentation. Efficiencies may be gained from the ease of documentation of specific medical devices and/or trays, including implants and the need for biological testing; usage history, inventory control of implants, and proper cleaning and sterilization parameters built into the system to prevent non-conformance with quality production.

Asset management may be one in the same when considering tracking software, but given that many healthcare facilities continue operating with manual methods, it is important to focus on management of assets; in this case, loaner instruments and/or consignment trays. Asset controls will provide our customers with a history of usage and help them gather valuable information for fiscal budget planning and capital forecasts.

This is a process that should involve the original equipment manufacturer (OEM) representative. Asset management will also allow us to remain on contract with select vendors. When trays outside the negotiated contacts arrive, it should send up a red flag that we are operating outside the scope set forth by the product/cost committees. Should this occur, contact the key business or purchasing managers.

References

1. The Joint Commission. 2011 Hospital Accreditation Standards (HAS). 2011.
2. ANSI/AAMI ST79:2010. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities. Arlington, VA. Association for the Advancement of Medical Instrumentation. 2010.
3. Association of periOperative Registered Nurses. Recommended Practices for Sterilization in the Perioperative Practice Settings. Perioperative Standards and Recommended Practices. Denver, CO. AORN. 2011.
4. IAHCSMM Sample Policy & Procedure, July 2011.
5. FDA Medical Devices Frequently Asked Questions. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121093.htm.
6. Canadian Standards Association. Z314.3-09. Effective Sterilization in Healthcare Facilities by the Steam Process.
7. ANSI/AAMI ST77:2006(R) 2010. Containment Devices for Reusable Medical Device Sterilization. Arlington, VA. Association for the Advancement of Medical Instrumentation.