LOANED INSTRUMENTATION

WHO, WHAT, WHERE AND WHEN

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Objectives

- Discuss the issues and concerns related to the loaning of surgical instrumentation
- Explain process controls necessary for the management of loaner instrumentation
- Create a checklist addressing the steps necessary in the management of loaner instrumentation
- Develop a policy and procedure that enforces compliance
Loaned Instrumentation Is On The Rise

- Becoming common practice in most facilities
- Increasing need for use of loaned instrumentation, implants and other devices
The Real Issue

Inadequate time and information
(No instructions, inventory lists or pictures)

- Implants (requiring a Biological Indicator “BI”)
- Complex Instruments (unfamiliar specialty instruments)
- Lack of Instructions for use “IFU’s”, inventory pictures
- Heavy Instruments
- Frequently requires extended cycle or dry times
A formalized program between health care organizations and health care industry representatives should be established for the receipt and use of loaner instrumentation.

Implementation of tracking and quality controls and procedures are necessary to manage instrumentation and implants brought in from outside organization and companies.
Managing Loaners - A Team Effort

- Emphasis placed on developing a standardized, concrete system
- Effective policy
  - All involved parties must be familiar with the policy
  - OR, CSSD, IP, RM, MM etc.
  - Vendors
  - Neighboring facilities
- Communication
- Enforcement
  - Controls must be in place
  - Consequences spelled out
- Monitoring
Policy Development

Ordering

Transportation out

Check out

Post-procedure processing

Charging (if applicable)

Transportation

Pre-procedure processing

Check in
IAHCSMM Position Paper on Loaner Instrumentation

- Created and adopted by IAHCSMM
- Addresses the issues health care professionals face in effectively managing loaners
- Specific information on developing a policy & procedure
IAHCSMM Orthopedic Council Committee for Management of Loaners

- To partner with IAHCSMM, AAMI, AORN, APIC, Ortho Surgeons, Orthopedic Specialty Manufacturer’s Association (OSMA) and container manufacturers.
- To develop policies, procedures and products that enhance patient care and are safe and efficient
IAHCSMM Orthopedic Council Goals

- To develop sample policies & procedures
- To be a resource for IAHCSMM members for answering any questions pertaining to Orthopedic trays (loaners)
- To be the liaison between Central Service and the Orthopedic Specialty Manufacturers Association
- To provide the Manufacturers Cleaning and Sterilization recommendations by reaching out to the Orthopedic Manufacturers
- To stay abreast of any new processes/instruments pertaining to Orthopedic items
Designated Staff

- Must be trained and knowledgeable in all aspects of the policy and procedure
- Responsible for interacting directly with designated vendor staff
- Be informed about specifics of each loaner agreement
Acquisition of Loaner Instrumentation

- Surgeon or designee contacts vendor to confirm availability of loaners and IFUs.
- Communication from surgeon’s office to OR for scheduling of the case.
- Communication to Materials Management for a PO if required by hospital policy.
Operating Room Responsibilities

- Send request for instruments when the surgery is scheduled
- Specify quantities, estimated time of use and return, and restocking requirements
- Communicate with the vendor IFU requirements
- Communicate with the CSSD manager the above information, along with the date of the surgery, doctor & procedure at least one day in advance of arrival
Vendor Responsibilities Pre Surgery

- Supply the OR & CSSD with names and quantity of the trays, surgeon/case and method & time of delivery
- Provide written inventory sheet (with pictures preferably) and note any missing items with CSSD
- Ensure delivery in sufficient time for CSSD to properly prepare instruments for the case
- Ensure the weight of the trays does not exceed maximum weight allowance per current ANSI/AAMI ST79 (25 lbs) and CSA Z314.3-09 (22 lbs)
- Work with CSSD staff to ensure all information is on file for loaner instrumentation
Manufacturer’s Obligations for Reusable Medical Devices

U.S. FDA labeling regulations (21 CFR 801)

- Manufacturer’s responsibility is to provide complete and comprehensive written instructions:
  - Handling
  - Cleaning
  - Disinfection
  - Testing
  - Packaging
  - Sterilization

- Detailed FDA recommendations are provided in the FDA guidance document - Labeling reusable medical devices for reprocessing in health care facilities: FDA reviewer guidance (FDA, 1996).
Delivery of Loaner Instrumentation

- Loaner instrumentation and/or implants can be sent via
  - Courier
  - Public transport (bus, train, plane)
  - Mail (USPS, UPS, FedEx etc.)
  - Manufacturer’s representative
- Mostly “uncontrolled” environment
Loaners Delivered to Decontam

- Designated receiving area – DECONTAM
- Under all circumstances, the instrumentation must be considered contaminated
- Yes, even “pre-sterilized” and “pre-wrapped” items from another facility need to be reprocessed
- Wearing proper PPE – check in items
It was sterilized at another hospital...so why can’t we use it?

- Record of the sterilization process and quality assurance measures
- Your patient deserves to know you have monitored the process
- Was the integrity of the package protected during handling and transportation?
- Do not just trust the other facility protocol
  - Open, clean, inventory, inspect and re-sterilize
Accountability and Record Keeping

Check-in Area (Decontam)

- Wearing proper PPE, check for accuracy of order
  - Log receipt of loaner instruments
    - Date, time, person receiving, Dr. name, number of trays
  - Perform inventory control
    - Verify types and quantities of instruments and implants
  - Perform QA check (visually inspect for damage)
  - Follow manufacturers written instructions for reprocessing steps
  - Document problems (damage, etc.)
Loaner Checklist

- SPD notified of loaners prior to receiving them
- Received in facility (decontam) at least 24 hours before scheduled case
- Inventory list available
- Written IFUs, packaging, and sterilization available
- Inventory and quality check completed
- Multiple trays numbered and labeled (patient name, surgeon)
- Trays do not exceed 25lbs
- All instruments in good condition, no rusting or pitting
- Container in good condition, no rusting, tape, residue, etc.
CSSD Responsibilities

- Review manufacturer’s IFUs
  - Standard cycles may not always be sufficient for heavy instrument trays and or complex devices
- Review loaner inventory sheet for accuracy
- Examine all instruments for defects and proper working order
- Process according to manufacturers written instructions (IFUs)
Implants

ANSI/AAMI ST79 (10.6.3)

- Specific recommendations on the release criteria for implants
- According to the FDA: “device that is placed into a surgically or naturally formed cavity of the human body and it is intended to remain there for a period of 30 days or more”
Implants

- All implant loads should be monitored with a Biological Indicator PCD containing a Class 5 integrating indicator
- “The load should be quarantined until the results of the BI testing are available.” (CDC, 2003a)
- Emergency situations - Class 5 integrating indicator should be used to release implant
- Critical that all implants are traceable to the patient
Emergency Situations

ANSI/AAMI ST79 (10.6.3)

“Emergency situations should be defined in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management”
Sterilizing Implants

- Immediate use sterilization should not be used for implantable devices except in cases of an emergency when no other option is available.

- In an emergency when immediate use sterilization of an implant is unavoidable, run a
  - Rapid-action BI
  - and
  - Class 5 CI
Implants Needed for Emergency

1. Document the medical necessity
2. Review all monitors (sterilizer chart, chemical indicator/integrator)
3. Document the item was released without BI results (Exception form)
4. Notify Physician
Early Release of Implants

If documented medical exceptions dictate release of implant before BI result, use:

- Implant Log and
- Exception Form for premature release of Implant:
  - Name of implant
  - Name of patient
  - Name of surgeon
  - Reason for premature release
  - What could have prevented the premature release
Improving Processes

- Steps should be taken to reduce the frequency of emergency release of implantable items
- For example:
  - Ongoing periodic reviews of the exception forms and implant logs
  - Look for consistent patterns of events that are causing emergency release and that could be corrected
After Surgical Procedure is Completed

- Return to decontam
  - Disassemble, clean and decontaminate
- Verify all loaners are accounted for
- Report discrepancies to OR for correction
- Return to designated area for return to vendor
  - Record
    - Date,
    - Item, and
    - Signature
  - Maintain records
Post Procedure

- After use, loaner instrumentation are to be complete, decontaminated and returned to loaner shelf for pickup
- Inventory loaner sheets in CSSD must be maintained for verification that all components were returned
- Recordkeeping maintained per hospital policy
- An inspection for content and cleanliness to be done by the vendor and CSSD staff
- If loaner tray is to be held for another case, vendor is to reassemble and inventory the set prior to re-sterilization
What Does Success Look Like

- A solid policy and procedure that is created and supported by all parties involved
- Enforced compliance “teeth”
- Detailed documentation and paperwork
  - Pre-delivery
  - Check in
  - Check out
  - Implant
    - Early release form
    - BI recording
  - Post surgery
Questions
Contact Information

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References Used

- IAHCSMM position paper on Loaner Instrumentation, located on the web site:
- IAHCSMM Sample Policy & Procedure for Loaner Instrumentation, located on the web site: