Taming the Loaner Instrumentation Beast

Objectives

1. Discuss the issues and concerns related to the borrowing of surgical instrumentation.
2. Describe process controls necessary for the management of loaner instrumentation.
3. Identify resources available to help develop policies and procedures and the management of loaned medical devices.

Objective 1

Discuss the issues and concerns related to the borrowing of surgical instrumentation.

Loaners Present Many Challenges and Risks

- Both for the sender and the receiver
  - Communication (SP, OR, surgeon, vendors)
  - Timeliness
  - Instructions for Use
  - Inventory
  - Set weights
  - Product Testing, etc.
- Consistent standardized approach
  - Define responsibilities
  - Address critical requirements for patient safety

Problems Inherent with Loaners

- Ever changing technology
- Multiple cases in the same day
  - Block scheduling
  - Specialty days –
    - Visiting surgeons
    - Training (Robotics)
- Procedures done infrequently
- Specialty procedures (i.e. pediatrics)
- Cannot afford to purchase everything
- Space/storage issues

Why do we need to “borrow” so much?
Sterilization guidelines

TJC (regarding IUSS)

- TJC - IC.01.03.01, “The hospital identifies risks for acquiring and transmitting infections.”
  - EP 4 “The hospital reviews and identifies its risks at least annually and whenever significant changes occur …."
- AAMI ST79 Section 11 Quality Process Improvement
  - 11.2.2 Risk Analysis
    - Risk analysis = risk assessment + risk management + risk communication

Common High-Risk Areas

- IUSS (flash sterilization)
- P&P not standardized
- Loaner instrumentation
- Torn wrappers
- No IFUs
- Sets weighing more than 25 pounds
- Sterilization process failures
- Inefficient staff orientation

Tracking Instrumentation

- TJC (regarding IUSS)
  - Review all of the critical aspects of disinfection and sterilization including the tracking of instruments.

- Sterilization guidelines
  - Documentation of cycle information provides a means for tracking items that are processed using IUSS to individual patients

CJD: AORN and AAMI

Track Neurosurgical Instruments

- Do not mix neurosurgical instruments with other specialty instruments.
- Develop a tracking system for instrument trays used in cases of a delayed postoperative CJD diagnosis.
**CJD: Risks with Loaned Devices**

- Borrowed sets at risk for contamination with high-risk tissue (i.e., brain, spinal cord, posterior eye, pituitary tissue)
  - Treat as potentially exposed to high-risk tissues
  - Tracking sets to patients is important
  - Unknown possibility that patient may have CJD
  - Resilience of prions
  - Need additional "lead time" for loaned devices.


**Additional Lead Time for Loaners: Time Recordings When Using Loaned Instruments**

- Facility in Germany
  - Considerable additional burden (esp. first time instruments)
  - Enter and record relevant data etc.
  - QA/staffing analysis time recorded

- Summary
  - New loaned instrument system - 8 trays
  - At least 6.5 hours to process (delivery/receipt – sterile presentation)
  - Post-procedures reprocessed and returned – 5 hours
  - Total approximately 11.5 hours


**Zimmer Manual Orthopedic Surgical Instruments-Cleaning Instructions**

**G. Manual Cleaning/Disinfection Instructions**

1. Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e., pipe cleaner brush).

2. Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.

3. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.

**Zimmer Manual Cleaning Instructions (con’t)**

4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.

5. Repeat the sonication and rinse steps above. (adds another 13 min)

6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

**Immediate Use Steam Sterilization**

- Used only emergently (that cannot be packaged terminally)

- Process in place to ensure:
  - IUSS is not used for implants
  - IFUs are followed (instrument, sterilizer, container cleaning supplies)
  - Sterilizers are maintained
  - Correct monitors are used, evaluated by trained personnel and documented
  - Aseptically transported and cooled prior to use
  - Personnel are monitored for adherence to policy

Implant– IUSS

- IUSS sterilization should not be used for implantable devices (AAMI Intro – Garner and Favero, 1985; CDC, 2003a, 2003b)
- Emergency (when IUSS an implant is unavoidable)
  - BI, and Class 5 chemical integrating indicator (CJ)
- The load should be quarantined until the results of the BI testing are available.
  (CDC, 2003a)
  - Emergency situations - Class 5 CI should be used to release implants
  (AORN – AAMI ST79:40.5.4 and 10.6.2)
- Critical that all implants are traceable to the patient

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 Implantable:
  - Name of implant
  - Name of patient
  - Name of surgeon
  - Reason for premature release
  - What could have prevented the premature release

Process Controls: Start with Multidisciplinary Standardized Loaner Policy

Describe process controls necessary for the management of loaner instrumentation.
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, SPD, SIC, IC, RM, MM etc...
  - Vendors, and
  - Neighboring facilities
- Communication
- Enforcement
  - Controls must be in place
  - Consequences spelled out
- Monitoring

Partnership Must be Developed

- Vendors, Sterile Processing, OR and Surgeons
- Built on mutual trust and collaboration
- Vendors must provide specific instructions
- SPD must keep a record of each set borrowed to include time in and out and other processing specifics

The Joint Commission: Loaner Equipment

- *Clear Policy and procedure
  - Mandate 48 hour lead-time
  - Penalties for noncompliance
  - Follow device manufacturer IFU

The Joint Commission

National Patient Safety Goal (NPSG) 07.05.01
Emphasizes the need to implement evidence-based practices for preventing surgical site infections (SSI).

Element of performance #3
The policies and practices must meet regulatory requirements and be aligned with evidence-based guidelines:
- Centers for Disease Control and Prevention (CDC)
- Association of periOperative Registered Nurses (AORN), and
- Association for the Advancement of Medical Instrumentation (AAMI).

The Joint Commission: 2015 Hospital Accreditation Standards (HAS)

TODAY Investigates: Dirty Surgical Instruments a Growing Problem in the OR 2/22/2012

- Filthy surgical instruments: The hidden threat in America’s operating rooms
  - 2009 rotator cuff repair and 7 other joint surgery patients
    - Arthroscopic shaver & inflow/outflow cannula
    - MFR updated cleaning IFU 10 steps
  - Final step - use a digital scope to visually inspect the insides of handpieces!

http://www.iwatchnews.org/2012/02/22/8207/filthy-surgical-instruments-hidden-threat-americas-operating-rooms
Retained Human Tissue

University of Michigan Health System researchers found that surgical suction tubes retain human tissue and other debris.

http://www.iwatchnews.org/2012/02/22/8207/filthy-surgical-instruments-hidden-threat-americas-operating-rooms

Tissue and Debris in Suction Tips

University of Michigan Health System researchers cut this surgical suction in half, and found the device packed with debris.

http://www.iwatchnews.org/2012/02/22/8207/filthy-surgical-instruments-hidden-threat-americas-operating-rooms

Impossible to Clean

University of Michigan Health System researchers examined the insides of 350 surgery-ready suction tips. All of them contained blood, bone, tissue or rust.

http://www.iwatchnews.org/2012/02/22/8207/filthy-surgical-instruments-hidden-threat-americas-operating-rooms

Tissue and Debris Found in Suction Tips

Centers for Medicare and Medicaid Services

September 4, 2009 - CMS released a memo to state survey agency directors regarding sterilization practices.

"If manufacturers' instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the ASC’s practices should be cited as a violation of 42 CFR 416.44(b)(5)." (CMS, 2009)


Borrowed Instruments Should Not Be Rushed...

Do not take excuses...

- “St. Elsewhere did not get done with the case till 8 pm last night…”
- Avoid the need to use IUSS
- All of your patients deserve the same quality care
Acquisition 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

Delivery of Borrowed Instrumentation

- Items delivered to designated receiving area – DECONTAM
  - Under all circumstances, the instrumentation must be considered contaminated (March 2007 AORN journal – Walter Reed Army Medical Center “Processing the Unknown” – Bio Hazard Containers)
  - Yes, even “pre-sterilized and pre-wrapped” items from another facility need to be reprocessed
  - Wearing proper PPE – check in items

17th Century PPE

- Great Plagues
  - Physicians careful to protect themselves with a “unique costume”
  - Gloves, mask, hat, and long coat
  - Mask resembled a chicken head
  - Large beak contained perfume
  - Clothes of victims destroyed by fire
  - Bodies skewered on poles at least 10 feet long to avoid contact with bearers

Sterilized at Another Hospital – 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.
- Package protected during handling and transportation?
- Do not just trust the other facility protocol.
  - Open, clean, inventory, inspect and resterilize

Inventory & Record all Loaners

“Make it clear …

“If there is no inventory sheet available we will not be responsible for incorrect inventory upon return.”

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Objective 3

IDENTIFY RESOURCES AVAILABLE TO HELP DEVELOP POLICIES AND PROCEDURES AND THE MANAGEMENT OF LOANED MEDICAL DEVICES.

Resources for Management of Loaners

- https://www.iahcsmm.org/resources/loaner-instrument-template.html
- Position Paper on Management of Loaned Instrumentation
- Loaner Instrumentation Sample Template & Procedure
- Loaner Instrument Receipt Document
- AAMI TIR63 2014 - Management of loaned critical and semi-critical medical devices that require sterilization of high-level disinfection.

Orthopedic Council

- Position Paper
  - Well-developed loaner program and written policy
  - Establish standardized receipt and use of all loaners.
- Sample Policy Template
  - Acquisition of loaners
  - OR responsibilities
  - Sales rep responsibilities before surgery and post-surgery
  - Sterile Processing responsibilities
  - Surgical Service responsibilities
- Loaner Instrument Receipt Document
  https://www.iahcsmm.org/resources/loaner-instrument-template.html

IAHCSMM Loaner Updates

- IAHCSMM Ortho Committee
- New Column in Communiqué and Central Source
  - Guidance on loaners
    - Mark Duro (Committee Chair)
    - User-friendly Q&A format

Loaned Instrument Management Program

- Clear and detailed multidisciplinary policies and procedures:
  - Process for requesting and communicating
  - Time requirements for delivery, product testing, and processing
  - Obtaining and reviewing IFU;
  - Delivery requirements;
  - Returning to the lender;
  - Time requirements for vendor retrieval;
  - Inventory requirements;
  - Responsibility for set weighs no more than 25 lb;
  - Method of transport;
  - Documentation of processes and transactions.
Loaners should be delivered directly to the SP decontamination area ASAP, along with any IFU and inventory sheets.

Multiple trays numbered and labeled (patient name, surgeon)

Written recommendations for cleaning, packaging, and sterilization available

Inventory and quality check completed

Multiple trays numbered and labeled (patient name, surgeon)

Trays do not exceed 25 pounds

All instruments in good condition, no rusting, pitting

Container in good condition, no rusting, tape, residue, etc.

TIR 63:2014

Loaned Medical Devices

Processes for the request, receipt, return, and documentation

4.2 Roles and responsibilities of the Sender

4.3 Roles and responsibilities of the receiver

Communication

Financial responsibility

Device responsibility

4.8 Tracking and documentation

Reprocessed according to IFU

Good working order

Required components are present

Product Testing AAMI ST79

10.9 Periodic product quality assurance testing of routinely processed items

Establish programs to periodically test routinely sterilized items.

Before newly purchased or loaner sets are used, determine if existing product testing is applicable to these sets

Not applicable to these sets, then product testing should be performed before use
Lead Time for Loaner Equipment - AORN

- AORN – 2015 Guidelines for Cleaning and Care of Surgical Instruments
  - Policy to include time requirements for:
    - preprocedure delivery,
    - product testing, and
    - processing (ie, cleaning, decontaminating, inspecting, packaging, sterilizing) and
    - post procedure processing and pick-up

AORN 2015 Guidelines for Cleaning and Care of Surgical Instruments

Lead Time for Loaner Equipment – AAMI

- AAMI TIR63 Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection
  - The medical device(s) should arrive at the agreed-upon time to allow the receiving facility to follow its procedures for inspecting, inventorying, in-servicing, and reprocessing.


- Guidelines
  - Environmental Cleaning,
  - Hand Hygiene,
  - Surgical Attire,
  - Cleaning and Processing Flexible Endoscopes
  - High-Level Disinfection,
  - Cleaning and Care of Surgical Instruments,
  - Selection and Use of Packaging Systems for Sterilization, and
  - Sterilization
  - Competency Verification Tools and Job Descriptions
  - Customizable Policy and Procedure Templates available


AORN

- “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.”

Ortho team meeting loaner form

- Specifies who/when it was ordered.

Loaners Needed for a Scheduled Case

- Does NOT constitute an emergency situation!
Accountability and Record Keeping

Vendor accountable for sterilizing instructions
- Do not take vendor rep’s word for cleaning and sterilization instructions
- Fax or e-mail directly from the Co.
- Proactive approach (Mike Murphy – Iowa)
  - Call surgeon at home – instruments will not be ready for AM case

Vendor
- Allow sufficient time to permit in-house reprocessing of instruments
- Provide written inventory of all items on the tray(s)
  - Quantity
  - Catalog number and description (pictures preferred)

Tracking Concerns with Loaner Sets
- Record delivery times
- Document QA
- Track location & sterilization
- Identify special cleaning/sterilization needs
- Monitor status in department (Receipt/Return)
- Track quality of service provided by vendor
- Produce management reports

Bar Code Capabilities
- Collect order, receipt and return information
- Track loaner trays individually
- Track loaner system as a group
- Management reports:
  - By vendor
  - By physician
  - By date used

Loaner Module Main Screen
- Loaner documentation and review of all previous orders

Receive New Order – Print and Save
- Print a Bar Code Label
- Print Case Info Labels
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 person responsible for returning to supplier
  - Record
    - Date,
    - Item, and
    - Signature
  - Maintain records

New Vendor Coordination for Loaners

- Simple solution to a complex issue
- Comprehensive vendor coordination
- Cloud based platform
- Utilizing mobile technologies to help solve loaner instrumentation issues
- Consolidates:
  - Logistics,
  - Confirmation and communication through one dashboard accessible by all members of the surgical team:
    - SP,
    - OR,
    - Surgeon,
    - Vendor

Loaner Platform

- User friendly dashboard
- Color coded calendar
- ETA – estimated tray arrival
- Visual representation
  - Secured level of identity
  - Tied to specific case
  - Who should be there today
    - Names and pictures of vendors etc.

Case Details

- See all information around all loaned set
- Case details:
  - Surgeon,
  - Patient (ID number)
  - Procedure time and room
  - People involved with the case
  - Number of trays

Communication

- Well documented communication
- Paper trail
  - Electronic comments (chain of messages)
- Reps must be invited or self-invite
- Tray delivery
  - When
  - Where
  - How many
  - Set weights
Tray Details

- Count sheets
- Instructions for use (IFU)
- Vendor and staff verification signature
- Add technique guide
- Ability to capture photos
  - Save time and counting
  - Can pinch and zoom photos

Scan X-Ray Vision

- See photos of tray
  - Is this the correct tray?
  - Does this tray have the “thing-a-ma-jig” in it?

Summary

- P&P needs to be created in collaboration and followed
- Adequate time is necessary to properly reprocess
  - Preferable at least 48 hours before the procedure is scheduled
- All loaners must be considered contaminated
- MFG validated processing instructions must be followed
- Documentation is necessary to trace items to patients
- Implants must have BI results prior to use

References

- AAMI TIR63 2014 - Management of loaned critical and semi-critical medical devices that require sterilization of high-level disinfection.
- https://www.iahcsmm.org/resources/loaner-instrument-template.html
  - Position Paper on Management of Loaned Instrumentation
  - Loaner Instrumentation Sample Template & Procedure
  - Loaner Instrument Receipt Document

#1 Thing to remember

- It is all about patient safety
- A major responsibility of health care providers is to minimize patient risks.