Objective 1

Discuss the issues and concern 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, purchasing)
  - Timeliness
  - Instructions for Use
  - Inventory
  - Set weights
  - Product Testing, etc.
- Consistent standardized approach
  - Define responsibilities
  - Address critical requirements for patient safety

Instruments on Consignment

- Consignment: An arrangement whereby goods are left in the possession of another party to sell.
  - Typically, the consignor receives a percentage of the sale.
- Consignment arrangements typically are in effect for a set period of time.
  - Issues:
    - Space/storage
    - Liability
Problems Inherent with Loaners

Why Do We “Borrow” So Much?
- Ever changing technology
- Multiple cases in the same day
  - Block scheduling
  - Specialty days –
    - Visiting surgeons
    - Training (robotics)
- Procedures done infrequently
  (i.e. pediatrics)
- Cannot afford to purchase everything
- Space/storage issues

Too Expensive to Purchase Every Tray:

Loaner Instrumentation
- Inadequate information (No instructions, inventory lists or pictures)
- Complex instruments (unfamiliar specialty instruments)
- Heavy Instruments
- Frequently requires extended cycle or dry times
- Implants (requiring a BI)

The Joint Commission & AAMI
- 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
  - Risk Assessment can be your best friend in an accreditation survey

Quality Process Improvement
- Addressing and reducing risks
  - Objective is to proactively identify the risks to reduce the likelihood of a process failure.
- Risk Reduction Tools
  - Root Cause Analysis
  - Failure Modes and Effects Analysis (FMEA)
  - Tracers
- The Joint Commission & AAMI
  - 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
  - Risk Assessment can be your best friend in an accreditation survey
Common High-Risk Areas

- Loaner instrumentation
- IUSS
- P&P not standardized
- Torn wrappers
- No IFUs
- Sets weighing more than 25 pounds
- Sterilization process failures
- Inefficient staff orientation, etc…

Immediate Use Steam Sterilization

- Used only emergently
- 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 – Gerner and Fowen, 1986; CDC, 2003a, 2003b)
- Emergency (when IUSS an implant is unavoidable)
  - BI, and Class 5 chemical integrating indicator (CI)
- 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 45.5.4 and 10.8.2)
- Critical that all implants are traceable to the patient

Risk Analysis of the Sterilization Process

- Risky business: Risk analysis in CSSD, written by Sue Klacik
- Published in Healthcare Purchasing News
- Are You Taking Risks When Cleaning Reusable Medical Devices? written by Martha Young, January, 2013
  - In-service article archived at:
    - http://www.3m.com/steri

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*

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

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

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 neuro 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

Process Controls: Start with Standardized Loaner Policy

Describe process controls necessary for the management of loaner instrumentation.
Managing Loaners - Multidisciplinary Team Effort

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

Designated Staff

- Trained and knowledgeable in all aspects of loaner process
- Responsible to interact directly with designated vendor staff
- Be informed about specifics of each loaner agreement

Partnership Must be Developed

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

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: 2016 Hospital Accreditation Standards (HAS)

TODAY Investigates:
Dirty Surgical Instruments a Growing Problem in the OR 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

http://www.iwatchnews.org/2012/02/22/8207/filthy-surgical-instruments-hidden-threat-americas-operating-rooms
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
- Help vendors – need adequate number of loaner sets

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”)
  - 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
  - Clothes of victims destroyed by fire
  - Bodies skewered on poles at least 10 feet long to avoid contact with bears
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, product test and re-sterilize

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](https://www.iahcsmm.org/resources/loaner-instrument-template.html)
- [Position Paper on Management of Loaner Instrumentation](https://www.iahcsmm.org/resources/loaner-instrument-template.html)
- [Loaner Instrumentation Sample Template & Procedure](https://www.iahcsmm.org/resources/loaner-instrument-template.html)
- [Loaner Instrument Receipt Document](https://www.iahcsmm.org/resources/loaner-instrument-template.html)
- AAMI TIR83 2014 - Management of loaned critical and semi-critical medical devices that require sterilization of high-level disinfection.

Orthopedic Council

- [Position Paper](https://www.iahcsmm.org/resources/loaner-instrument-template.html)
  - Well-developed loaner program and written policy
  - Establish standardized receipt and use of all loaners.
- [Sample Policy Template](https://www.iahcsmm.org/resources/loaner-instrument-template.html)
  - 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](https://www.iahcsmm.org/resources/loaner-instrument-template.html)
- [Column in Communiqué and Central Source](https://www.iahcsmm.org/resources/loaner-instrument-template.html)
  - Guidance on loaners
    - Mark Duro (Committee Chair)
    - User-friendly Q&A format

- 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

TIR 63:2014 - Management of loaned critical and semi-critical medical devices that require sterilization or HLD

- 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

“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.”


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.

Receiving of purchased or loaner items

- 5.2 Policies and procedures for the receipt of purchased or loaner items should be developed, implemented, and audited.
  - Audits should be scheduled and documented.
  - Loaners should be delivered directly to the SP decontamination area ASAP, along with any IFU and inventory sheets.


**IAHCSMM position paper and policy on loaners**

- 2 business days
- 3 business days for new sets

SHC ©
Lead Time for Loaner – 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.

Lead Time for Loaners - AORN

- AORN – Guidelines for Sterilization
  - XIV.d. Personnel should coordinate requests for loaned instrumentation in sufficient time for loaned items to be processed by conventional terminal sterilization methods.
  - XIV.d.2. Late receipt of loaned instruments should not be used to justify IUSS.

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,
    - processing (i.e., cleaning, decontaminating, inspecting, packaging, sterilizing) and
    - post procedure processing and pick-up

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.

Product Quality Assurance Testing (ST79 10.9)

- Multiple BIs and Class 5 CIs and an evaluation of post-sterilization moisture content
  - Wrapped sets - BIs and Class 5 CIs at each end of the tray and among the instruments
  - Containment devices - BIs and Class 5 CIs in each corner, the center, each layer and any other areas recommended by the containment device manufacturer
  - Any test results that indicate a problem, such as positive BIs, unresponsive CIs or wet packs, shall be thoroughly investigated and product use discontinued until the problem is resolved.
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.

Total of 49 minutes
- Automated cleaning using a washer/disinfector alone may not be effective

Can be 50+ trays
Multiple Cases Needing Loaned Devices

AAMI TIR 63:2014 Documentation

4.8.2 Documentation
- Date and time of procedure
- Requisition with description of item(s)
- Receipt of devices
- Shipment record including IFU
- Reconciliation of return shipment post use and reprocessing
- Method of return
- Record of decontamination prior to release

4.8.3 Receipt Documentation (receiving facility)
- Receipt data and time
- Receipt location
- Sender’s name
- Sender rep name and contact info
- Description and catalog number of each device
- Surgeon
- Date of procedure
- Manufacturer’s IFU
- Weight of loaned instruments sets

Loarer Check List
- SPD notified of loaners prior to receiving them
- Received in facility (decontam) at least 2 business days before scheduled case
- Inventory list available
- 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.
Loaners Needed for a Scheduled Case

Does NOT constitute an emergency situation!

Accountability and Record Keeping

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)

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

Inventory & Record all Loaners

Make it clear …

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

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
Receive New Order – Print and Save

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
- FINALLY!
  - Simple solution to a complex issue
  - Comprehensive vendor coordination
  - Cloud based platform
  - Utilize mobile technologies to help solve loaner instrumentation issues
- Can be used with or without a current barcode system!
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 for all to see
- 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
- Strong P&P created in collaboration
  - Consistently followed
  - Consequences spelled out
  - Reference which standards used
- Adequate time is necessary to properly reprocess
  - Preferable at least 24 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
- Product testing should be done if new sets
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](https://www.iahcsmm.org/resources/loaner-instrument-template.html)
  - Position Paper on Management of Loaner Instrumentation
  - Loaner Instrumentation Sample Template & Procedure
  - Loaner Instrument Receipt Document

#1 Thing to remember

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