Objectives

- Understand the importance of compliance with national standards in infection prevention
- Review methods to prevent cross contamination and improve patient safety by proper reprocessing and handling of devices
- Discuss the importance of certification and competencies for all processing personnel

Surgical Site Infections

- Most patients who have surgery do not develop an infection.
- Infections develop in about 1 to 3 out of every 100 patients who have surgery.
- According to the CDC, each year, U.S. hospitals experience 1.7 million health-care associated infections (HAIs), causing roughly 99,000 deaths at a cost of $37-$45 billion dollars.

Surgical Site Infections*

- An estimated 40 to 60 percent of these infections are preventable.
- 38% of all nosocomial infections in surgical patients are surgical site infections.
- 4 to 16% of all nosocomial infections are SSI.
- 2 to 5% of operated patients will develop SSI.
- SSI increases the patients length of stay in the hospital by an average of 7.5 days

*Safe Care Campaign webpage

The Joint Commission

- Uses two (2) sources for processing areas:
  - CDC Guideline for Disinfection and Sterilization in HCFs (2008)
How Does Sterile Processing Impact?
- Guardian of spread of infection via medical devices and equipment
- Responsible for majority of processing of devices used throughout hospital
- Patient safety dependent upon sterile processing personnel performing their functions competently

Transport of Soiled Items
- If not performed correctly contamination can occur with
  - patients
  - employees
  - environment
- All items must be confined and contained
- Look throughout the facility – all departments vulnerable!

Transport of Soiled Items
- Use of closed or covered carts
- Plastic tote bins
- Plastic bags (for non-sharps)
  - Contents must be labeled as biohazard
- Do not transport instruments in solution
  - can create spills
- Transport containers must be cleaned after each use

Improper Transport of Soiled Instruments
Decontamination Area

- Cleaning is the FIRST step in the sterilization process
- Must be done correctly
- Must have the device manufacturer’s written instructions for cleaning the device
- Must follow the instructions each time
- Temperature 60-65°F, humidity 30-60%
daily.
- Negative pressure, 10 air exchanges/hour
- Verified annually by Engineering

Risks

- Failure to properly clean a device can
  - Result in device failure at the time of use
  - Prevent sterilization or high level disinfection from occurring
  - Cause rusting, corrosion of the instrument or device
  - Liability for the facility
  - Pain, suffering for the patient, possibly death

Acceptable?

Decontamination Area

- SPD technician needs to read and follow the instructions carefully
- Must use correct detergent
  - some detergents can deteriorate materials or cause allergic reactions in patients
  - cannot just use any detergent - only those tested by the device manufacturer as safe for their device and the patient
  - Enzymes have maximum water temperature – best if below 110°F. How to monitor?

Damaged Container from High Alkaline Detergents
Decontamination Area

- Must use and measure the detergent correctly
- Use a measuring cup to measure the detergent
- Use a gallon jug to measure the water level in the sink (mark level)
- Detergents (when concentrated) can be high in pH

Decontamination Area

- If detergents not diluted properly, damage to the instrument/device can result and/or the device may not be properly cleaned
- Correct cleaning implements needed.
- Lumens especially problematic
  - must have correct size (diameter) and length of brush to thoroughly clean inside lumens
  - Formation of biofilms

Decontamination Area

- Ineffective Cleaning
- Must have sufficient processing equipment to get the job done correctly
- SPD personnel need to be competent in the use of all processing equipment
- Need for specialty equipment (e.g. endoscopic instrument cleaners)
- Document the efficacy of the process (cleaning effectiveness testing) at least weekly

Decontamination Area

- Standard Precautions
  - all items must be treated as if infected
  - SPD technicians need to be protected from blood and other body fluids by wearing personal protective equipment to meet the task
  - cuffed, heavy duty gloves, *(fitted at wrist)*
  - head cover, shoe covers (water repellent), impervious gown face shield and impervious mask when aerosols present

Decontamination Area

- Standard Precautions
  - avoid injuries from sharps (needles, sharp instruments)
  - Use metal mesh gloves (e.g. Kevlar) or sponge stick to sort through instruments
  - No counting of instruments in Decontam!
Problem Areas

- Scheduling of cases back-to-back in OR does not permit sufficient time to properly clean instruments per manufacturer’s instructions
- Loaner instruments do not arrive in sufficient time to properly clean them
- Lack of in-servicing from loaner companies for SPD staff
- Inadequate training and for use of decontamination equipment and all decontamination activities
- Not performing competency assessments annually
- **Rigid containers not WASHED after each use**

Problem Areas

- New, more sophisticated instruments that defy cleaning
- We are negligent when we do not follow procedures
- How do we defend this action?
- Need to get Risk Management, Process Improvement and IP involved

Challenges for Cleaning

For Other Cleaners

- SonicCheck
- Cartwash check
- Robotic arm check
- Temp check

AAMI ST-79

- Weekly cleaning effectiveness testing for all mechanical cleaners

Handwashing
Handwashing
- One of the most important parts of infection control!
- Needs to be performed frequently and correctly
  - before starting work, after using bathroom, after removing gloves, before and after eating, before changing tasks, when handling sterile packages, when applying dust covers, after removing PPE
- Use of hand sanitizers in clean areas (e.g. case carts)

Sterilization
- Effective sterilization requires
  - proper cleaning
  - proper assembly
  - proper packaging materials and methods
  - proper loading of the sterilizer
  - proper sterilization method

Sterilization
- The correct sterilization methodology is required
- Steam - should always be used unless otherwise directed by the device manufacturer
- Requires contact with all surfaces of the device

Sterilization
- Effective sterilization requires
  - proper sterilization parameters
  - proper handling after sterilization
  - These factors are affected by sterile processing personnel
  - Errors in one or more tasks can result in a non-sterile device

Sterilization
- Multi-part items should be disassembled
- No metal against metal (e.g. basins inside basins) unless wicked with absorbent material to draw steam between surfaces
- Autoclave carts need to be kept clean
  - Debris from carts can enter into packs
Dusty, Soiled Autoclave Carts

Risks - Sterilization
- Improper loading of sterilizers can result in sterilization failure
- Items must be loaded to ensure adequate contact with the sterilant - no overloading!
- For steam, all items that can retain water should be tilted on their side

What's Wrong with This?

Are these Loaded Correctly????

This is Correct Loading

Sterilization
- Place linen items on top shelves of sterilizer and metal items on bottom
- Place peel packs inside basket - place on edge
- Need lot control number to track devices in the event of a sterilization failure
Lot Control Sticker

Wet Packs
- Need to know if packs are dry at the end of the cycle
- We do not hold inside sterilizer with door open to DRY, but to COOL
- Perform dry studies of heaviest trays

Wet Packs
- After sterilization/cooling open and observe for
  - "dew" on instruments
  - Moisture in towel/mat
  - Water inside tray (look under instruments!)
- Need to resolve

Sterilization
- All sterilization cycles must be monitored to ensure all sterilization parameters were met
  - include chemical indicator inside all packs/trays
  - include biological test at least weekly-preferably daily and with all implants
  - read and sign sterilizer printout/chart at the end of each cycle and before items removed
    - Many technicians do not know how to properly interpret a printout but sign it anyway

Sterilization
- Need sterilization log to document all items processed in each load (for recall)
- Records should be specific
- All sterilization records (logs, printouts/charts, BI test results, etc.) should be retained according to facility’s attorney recommendations
- Prep/Packaging/Sterilization Area – temperature 68-73°F, humidity 35-60%; ideal is 50%
- Sterilizer Access area – 75-85°F.
- Monitor and document daily
- Positive pressure, 10 air exchanges/hour
**Sterilization**
- After sterilization
  - Steam - requires thorough cooling of devices to prevent re-contamination by hands
  - Pores open on packaging until cool
  - Items should remain untouched on sterilizer cart for 30 minutes to 2 hours!
  - All packs/devices should be handled as little as possible after sterilization

**Infrared Thermometer**

**QA Testing**
- Pre-vacuum sterilizers require a Bowie-Dick air removal test daily
- Determines sterilizer’s ability to remove air from packs and chamber in a specified time frame
- Cannot use pre-vacuum cycle unless the test passes

**Biological Testing**
- BI testing at least weekly, preferably daily and with all implant sets
- Uses *geobacillus* stearothermophilus spore
- All implant loads must be monitored with a BI test pack containing a Class V chemical integrator
- Implants must be quarantined until result of the BI known
- If needed before BI test result, release using an Early Release form (AAMI ST-79 Annex)

**Qualification Testing**
- After major repair
  - 3 BIIs on each type of cycle (if both used)
  - 3 Bowie Dick tests
  - All must be negative before sterilizer put back into use
  - Control vials and BI vials MUST be from the same lot # and documented on the BI log
  - Follow IFUs, 3-hour BI test recommends the control vial be incubated 48 hours to get a visual read

**Sterile Storage**
- Sterilized items should be properly stored to prevent contamination
- Need segregated area
  - Temperature 68-75°F (AAMI)
  - Humidity should not exceed 70%
  - 4 air exchanges/hour - positive pressure
  - Monitor and document daily
Sterile Storage
- SPD technicians need to keep all storage locations clean and disinfected
  - clean at least monthly
  - check integrity of packaging of all items
  - Clean shelves and storage bins
- Keep all items 8 in. (20.32 cm) to 10 in. (25.40 cm) above floor
- Keep at least 2 in. (5.08 cm) from outside wall

Abraded Wrapper
- Keep packs and items away from fire sprinkler heads (18”)
- Need to limit traffic
- All personnel entering area must be properly attired (scrub suit or cover gown, head cover) to keep contaminates to a minimum

Process Improvement
- Need a system of process improvement monitoring to ensure compliance with all stated policies
- Report to Infection Prevention
- Correct deficiencies
- Need tracking system to document processes and verify productivity of department

Sterile Storage
- Keep packs and items away from fire sprinkler heads (18”)
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PI for Infection Prevention
- # Positive Bls steam
- # Printouts not signed
- # Incomplete BI log information/cycles not documented
- # Implants not monitored with a BI
- # Implants released early without form
- # Instances non-compliance with CJD protocols
- # Instances non-compliance with sterilization IFUs
- # Instances of wet packs
- # Instances not compliant with BI policy
PI for Infection Prevention

- # Instances items released before cool
- # Instances damaged packaging
  **Sterrad (Low Temp. Gas Plasma)**
  - # Instances non-compliance with BI policy
  - # Positive BIs
  - # Cycles not documented
  - # Printouts not signed
  - # Instances IFUs not followed

PI for Infection Prevention

- # OR cases
- Cycles with instruments
  - % flashed
- # Cycles with implants
- # Cycles with BIs
- # Cycles not documented
- # Printouts not signed

PI for Infection Prevention

- Decontamination
  - # Cleaning Verification Failures
  - # Instances of non-compliance with IFUs
  - Vendor non-compliance (loaners)
  - Complaints of bioburden in trays

PI for Infection Prevention

- High Level Disinfection
  - # Instances MEC testing not performed before each use of HLD
  - # Instances QA testing of strips not performed
  - # Instances devices not documented on log
  - # Instances temp of HLD not documented

PI for Infection Prevention

- GI/Endo
  - # Instances non-compliance with storage of scopes
  - # Instances failed to trace scope to patient
  - # Instances printout not signed
  - # Instances alcohol flush not documented
  - # Cleaning effectiveness tests that failed

Risk Reduction

- Develop Policies and Procedures for all practices
- Keep Policies and Procedures current
- **Reference Policies and Procedures AAMI standards and other relevant agencies (e.g. EPA, FDA)**
- Implement a system to monitor staff compliance with policies and procedures
- Ensure staff education and training - document
- Assess staff competencies annually - document
Conclusions

- Sterile Processing has a major impact on infection control and patient safety
- Devices used in surgery must be sterile and safe when used
- Sterile Processing staff need to be knowledgeable in all aspects on processing to ensure the safety of the device

Spread the Word

- All states should require certification for sterile processing personnel in hospitals and surgery centers
- Certification elevates the competency levels of the practitioners
- Win-win for everyone!

Conclusions

- Sterile Processing personnel need to be educated in the proper processing methods
- The SPD Department needs adequate facilities to perform essential services
- The SPD Department needs to be kept clean with daily damp mopping of floors
  - routine cleaning of vents, ceilings, walls

Conclusion

- JC and CMS very informed
- Know the standards and expect compliance
- We need to be PROACTIVE not REACTIVE
- THANK YOU!