Continuing Education Contact Hours

- Participants must complete the entire presentation/seminar to achieve successful completion and receive contact hour credit. Partial credit will not be given.
- All of the presenters are employees of STERIS Corporation and receive no direct compensation other than their normal salaries for participation in this activity.
- STERIS Corporation is an approved provider of continuing nursing education by the California Board of Registered Nursing, provider number CEP 11681 for 1.0 contact hour along with IAHCSMM and CBSPD.
- STERIS Corporation is providing the speakers and contact hours for this activity. However, products referred to or seen during this presentation do not constitute a commercial support by the speakers.

Learning Objectives

- Review the processing of devices and common causes of adverse patient reactions
- Describe recent examples of infections and other complications due to inadequate reprocessing of devices used for surgical and therapeutic procedures
Infections

- Surgical site: an infection of the incision or organ/space operated on during a surgical procedure
- Other device-associated

What could we be missing?

Surgical devices
- Reported vs non-reported
- Source of infection, often unknown

Non-surgical devices
- e.g., flexible endoscopes (GI) and other semi-critical or non-critical devices

Latent infections
- Some infections can take years to develop
- Mycobacteria, prions

Other complications
- Toxicity-related events
- Tissue damage
- Device breakage
Slide 16

**TASS**

A toxin problem
‘Toxic Anterior Segment Syndrome’
• Inflammation
• Cataract surgery
• Inadequate cleaning, chemical/organic material residuals (e.g., from water)

Slide 17

**Orthopaedic Implant Sets**

Slide 18
Spaulding (1972)

Cleaning is essential
- "If it's not clean, it can not be disinfected or sterilized"

Sterilization is the destruction of all microbial forms
- Can destroy most and often all microorganisms

Disinfection is something less than sterilization
- Can destroy most and often all microorganisms

Microbial resistance (3 groups)
- Most vegetative bacteria/fungi, large/medium lipid viruses
- Tubercle bacilli, small non-lipid viruses
- Bacterial spores

Levels of germicidal (disinfection) action (3 groups)
- Low level
- Intermediate level
- High level

<table>
<thead>
<tr>
<th>Patient Contact</th>
<th>Examples</th>
<th>Device Classification</th>
<th>Minimum Inactivation Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact skin</td>
<td>Non-Critical</td>
<td>Cleaning and/or Low/Intermediate Level Disinfection</td>
<td></td>
</tr>
<tr>
<td>Mucous membranes or non-intact skin</td>
<td>Semi-Critical</td>
<td>High Level Disinfection</td>
<td></td>
</tr>
<tr>
<td>Sterile areas of the body, including blood contact</td>
<td>Critical</td>
<td>Sterilization</td>
<td></td>
</tr>
</tbody>
</table>
Retained Tissue in Arthroscopy

- 7 organ/space surgical site infections after arthroscopic procedures
- Surgeries performed with a rigid arthroscope and shaver
- Infections caused by *P. aeruginosa*

Tosh et al. ICHE 32:1179, 2011
Slide 25

Investigation

62 of 388 environmental cultures cultured P. aeruginosa
- Sink, water, drains,
- None from the scope or shaver

P. aeruginosa isolated from patients and from the decontamination sink and suction bottles had the same genetic (PFGE) profile

Slide 26

Observations

- Shaver and accessories steam sterilized
- Arthroscope gas plasma sterilized
- Borescope evaluation of shaver cannula and handpiece

Slide 27

Retained tissue
Cleaning concern
Slide 28

Hypothesis
Bacteria within the residual tissue survived the sterilization processes

Slide 29

Manufacturer's Cleaning Instructions
Length of enzymatic soak was about 1 minute:

• Manufacturer's instructions recommended 10-15 min.

Manufacturer's instructions recommended brushing
• Lumens only rinsed with running water

Slide 30

Intervention
• Adopted manufacturer procedures
• Improved work flow
• Increased training and certification of processing staff
• Implemented instrument tracking
• Routine borescope evaluation of suction channel

Post-Script
King et al, Arthroscopy 22:1046, 2006
After reprocessing and ETO sterilization, 13 of 27 (48%) shaver blades had detectable protein and 17 (63%) had detectable nucleic acid
Slide 31

Continued Focus on Cleaning

- Microbial and toxicity risk
- Improvements in cleaning instructions
- Attention to detail in reprocessing instructions
- Staff competency is essential
- Cleaning endpoint verification
  - Visual and another method


Slide 32

Slide 33

Cystoscopy and Pseudomonas

Urology clinic

23 *P. aeruginosa* infections post-cysto
- Urinary tract infection and/or bacteremia

5 environmental cultures positive for *P. aeruginosa*
- 3 endoscopes, rinse bath, cleaning brush

4 available cultures from patients and the environmental cultures had genetically (PFGE) identical profiles

Slide 34

Reprocessing Area Review

- Scope cleaned right before a case, not afterwards
- Environmental surfactant disinfectant used
- Distal end only soaked in disinfectant
- Rinse water used for 2 weeks or until odiferous
- No alcohol final rinse
- No written procedures

Scope reprocessor had no training and no regular competency assessments

---

Slide 35

Interventions

- Disinfection process 'cleaned up.'
- No further infections, as of the time of publication
- Joint SUNA/AUA white paper on reprocessing flexible cystoscopies, 2009
  http://www.suna.org/resources/cystoscopyWHPaper.pdf

Hypothesis: “Multiple deviations from manufacturer and best practice recommendations” allowed contamination of endoscopes.

---

Slide 36

- Approximately 11 million gastrointestinal endoscopies are performed annually in the United States
- Contaminated endoscopes have been linked to more health care-associated infections than any other medical device
- Several guideline-issuing organizations assert that the risk of endoscopy-associated infection (EAI) is only 1 in 1.8 million procedures

---
Slide 37

But....
- Audits have documented widespread lapses in infection control involving medical equipment
- Inspections determined that certain endoscopy equipment was not properly reprocessed for up to several years
- Direct observations in a multisite study revealed that endoscopes were virtually never reprocessed in accordance with guidelines
- Implications are unknown because no epidemiologic studies have determined the risk of infections with reprocessing quality

Ofstead et al, AJIC 41: 734-6, 2013

Slide 38

Paper Conclusion
- Evidence indicates that current risk estimates are inaccurate, outdated, based on flawed methodology, and can have profound effects on patients
- Current low risk estimates are used to justify the lack of reporting, routine monitoring, patient notification, and laboratory testing following a lapse
- There remains a need for epidemiologic studies to accurately estimate the risks of infections and other complications

Ofstead et al, AJIC 41: 734-6, 2013

Slide 39

Non-infectious Outbreaks
Usually acute onset
- Less than 24 hours after exposure
- But sometimes can be over an extended time (e.g., implant rejection)

Causes often related to lapses in best practice

Microbiology work up negative
- Endotoxin may be suspected

Epidemiology work up is similar to infectious cause
**Glutaraldehyde colitis**

- 3 cases of colitis several hours post sigmoidoscopy
- Recently 2% glutaraldehyde replaced 0.2%
- Rigorous rinsing of sigs instituted → another case → further investigation
- Glutaraldehyde odor strong in endoscopy room
- Source: glutaraldehyde in water bottle tubing

Conclusion: tubing not well rinsed

West et al, Gastroenterology 108:1250, 1995
Slide 43

Keratitis
- M. abscessus
- M. chelonae

Surgical Site Infections
- M. abscessus
- M. chelonae

---

Slide 44

Atypical Mycobacteria Epidemic
(Rio de Janeiro 2006 / 2007)

<table>
<thead>
<tr>
<th>Procedures</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholecystectomy</td>
<td>64.6%</td>
</tr>
<tr>
<td>Appendectomy</td>
<td>4.7%</td>
</tr>
<tr>
<td>Diagnosis laparoscopy</td>
<td>3.8%</td>
</tr>
<tr>
<td>Oophoroplasty</td>
<td>3%</td>
</tr>
<tr>
<td>Myomectomy</td>
<td>2%</td>
</tr>
<tr>
<td>Arthroscopy</td>
<td>2%</td>
</tr>
<tr>
<td>Histerectomy</td>
<td>2%</td>
</tr>
</tbody>
</table>

Surgical Procedure (n = 1051)

---

Slide 45

Duarte, 2009
Table 1. Bacterial strains identified from washer-disinfectors

<table>
<thead>
<tr>
<th>Bacterial Strains</th>
<th>Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycobacterium neoaurium</td>
<td>Water Port</td>
</tr>
<tr>
<td>Mycobacterium chelonae</td>
<td>Final Rinse</td>
</tr>
<tr>
<td>Mycobacterium gordonae</td>
<td>Cold Tap Spigot</td>
</tr>
<tr>
<td>Mycobacterium gordonae</td>
<td>Hot Tap Spigot</td>
</tr>
<tr>
<td>Mycobacterium gordonae</td>
<td>Post-Clean Rinse</td>
</tr>
<tr>
<td>Mycobacterium avium</td>
<td>Post Wash - Rinse Suction Line</td>
</tr>
<tr>
<td>Mycobacterium mucogenicum</td>
<td>Fluid Sample - Tap Water</td>
</tr>
<tr>
<td>Mycobacterium mucogenicum</td>
<td>Detergent/Prewash</td>
</tr>
<tr>
<td>Mycobacterium mucogenicum</td>
<td>Rinse 2</td>
</tr>
<tr>
<td>Mycobacterium mucogenicum</td>
<td>Rinse 3</td>
</tr>
<tr>
<td>Mycobacterium mucogenicum</td>
<td>Final Rinse</td>
</tr>
<tr>
<td>Mycobacterium abscessus/chelonae</td>
<td>Feed Water Hose</td>
</tr>
<tr>
<td>Mycobacterium abscessus/chelonae</td>
<td>Hot Tap Spigot</td>
</tr>
<tr>
<td>Mycobacterium abscessus/chelonae</td>
<td>Glutaraldehyde Line</td>
</tr>
<tr>
<td>Mycobacterium abscessus/chelonae</td>
<td>Feed Water Hose</td>
</tr>
<tr>
<td>Methylobacterium fujisawaense</td>
<td>Post Wash - Rinse Suction Line</td>
</tr>
<tr>
<td>Methylobacterium rhodesianum</td>
<td>Detergent/Prewash</td>
</tr>
<tr>
<td>Methylobacterium radiotolerans</td>
<td>Rinse 2</td>
</tr>
<tr>
<td>Methylobacterium extorquens</td>
<td>Detergent/Prewash</td>
</tr>
<tr>
<td>Bacillus megaterium</td>
<td>Feed Water Hose</td>
</tr>
<tr>
<td>Paenibacillus alginolyticus</td>
<td>Hot Tap Spigot</td>
</tr>
</tbody>
</table>

Fisher et al. (2012) AJIC
Endophthalmitis and Orthopedic Infections

15 orthopedic and 5 ophthalmology cases
• Serious infections

Variety of bacteria: coagulase negative staphylococci, Bacillus sp, E. faecalis, coliforms

Where would you start the investigation?

After investigation dead-ends, focused on sterile pack storage

Reports of broken and missing items
10 Surgical packs were damp or discolored and taken out of service

10 dry packs were chosen at random
• 20 cultured; 11 grew coagulase negative staphylococci and/or Bacillus sp

Sterile Processing Review
• Not well maintained
• No gowns, gloves or masks in clean area
• Staff in street clothes
• No hand washing sinks in clean area
• Autoclave drainage inadequate
• Insufficient dry time or cooling time for packs
• Carts were corroded
• No covers on sterile packs

Overall insufficient drying and maintenance of sterile packs

Compromised Sterile Packaging (damp packs or rapid cooling)

Intervention and recommendations included
• Tightening of practices in sterile processing
• Adequate cooling and drying
• Weekly audit, internal
• Routine visits, external, IPs
• Upgrade staff attire
• Increase environmental cleaning
Slide 55

Conclusions

• Reusable medical devices, including surgical devices, require strict attention to reprocessing instructions

• The full reprocessing cycle should be considered, each step being important

• Infections and other complications have occurred due to inadequate reprocessing of devices

• These are under-reported

Slide 56

Evaluation and Registration

• Thank you for attending this CE activity

• Please complete and submit the evaluation form

• For more information on the CE credentialed programs offered, go to http://university.steris.com

Slide 57

STERIS University Customer Website
Customer site launched July 18, 2011

“The largest catalogue to date of STERIS’s highly flexible and territory-specific, including webinars, seminars, online modules, published papers and self-study articles, all in one easily accessible location. Education comes to learners at their convenience.”

“STERIS Launches New Healthcare Education Portal”

“STERIS University promises to be a ‘Knowledge Factory’ for healthcare professionals”