Water for Reprocessing of Medical Devices
Dr. Michelle Alfa, St. Boniface Hospital
A Webber Training Teleclass

Water for Reprocessing of Medical Devices:
My cup runneth over ... but is it enough?

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Cleaning Medical Devices

What you don’t know can hurt you!!

Medical Procedures:
Device Reprocessing

- First: Do no Harm
- 60’s – 70’s:
  Age of Aquarius and Free Love???
- New Millenium:
  Age of the Internet and Litigation!!
  (The Public are informed and demanding more of HealthCare)

Current Challenges:

- Device Design & Manufacturer’s Validated Cleaning Instructions
- Reprocessing Personnel Competency
- Water Quality... is it really an issue???

Cleaning of Medical Devices:
Who is responsible for What??

- Manufacturer’s validate that instrument can be reliably cleaned and sterilized/disinfected and is therefore re-usable.
- Users verify that cleaning equipment is working and that in-hospital cleaning methods are consistently performed.

Water Quality Impacts:

- Impact on Medical Devices:
  Damage: pitting, corrosion, loss of function
  Reduction in cleaning efficacy
  Interference with disinfection/sterilization efficacy
- Impact on patient:
  Infection transmission
  Adverse reaction; inflammation, fever

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Impact on Medical Devices:
- Discoloration

Impact on Medical Devices:
- Corrosion

Impact on Device:
- Inefficient Device Reprocessing
  - Same cleaning process, different quality of water
  - Washer-disinfectors
    - increased foaming
    - blocking of spray jets

Water-associated Microorganisms
- Coliforms
  - e.g., E. coli
- Cryptosporidium, Giardia
- Enteric viruses
- Pseudomonas and other pseudomonads
- Legionella
- Mycobacterium

Residuals on Medical Devices
- Contact with mucosal surfaces; e.g. flexible endoscopes
- Contact with sterile body site; e.g. MIS accessory devices
- Contact with ocular tissues; e.g. cataract surgery instruments

Orthopaedic Instruments
- Crud from between coils
- Alternative: solid shaft

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Hand pieces: residual crud

- Under side-panel
- Inside connector ring

Patient-used (no side-panel): unclean

Patient-used repeatedly; side-panel removed

New Developments:
Manufacturer’s Instructions:

- AAMI ST81, EN ISO 17664, (CSA 17664)
  Guidance documents now require medical device manufacturers provide at least one manual and one automated validated cleaning protocol

- USERS: refuse to order/pay for medical device until validated cleaning protocol provided by manufacturer

“Show Me the MONEY”!!

- STERILE Crud!!!
  - Acetabular reamers
  - Electronic drill handpieces
- No “infection” risk → so what is the issue?
- Water quality... least of our worries!
- Cost/Benefit: What is realistic???

Residuals:
Ineffective cleaning/rinsing

- Foreign organic material
  - Endotoxin (LPS) from dead bacteria
  - Blood and other organic debris from previous patient or from cleaning process (e.g. enzymatic detergent residuals, water organisms etc).
- Can it get “Out/Off” of device into patient??

What evidence exists that sterile crud is problematic?

LPS adsorbed on surface of particulate wear debris contributes to inflammatory reactions that lead to aseptic loosening of implants

Toxic Anterior Segment Syndrome

- Cataract surgery (current outbreak in USA)
- Early onset (12-24 hrs post-surgery) inflammation → pain, blurred vision (limbus-to-limbus corneal edema)
- Non-infectious toxic agent enters anterior segment of eye during surgery and causes inflammatory reaction.
- Residual LPS (from tap water rinse) or residual organic material (e.g. enzymatic detergent) in cataract surgery instruments (e.g. Phaco tips)
- Cleaning and rinsing with sterile distilled water critical for ophthalmic surgery instruments.


Ultrasound Transducer Assemblies; Biopsies

- FDA Alert: "Use sterile water for rinsing or removing residual germicides from devices which have been processed using liquid chemical germicides. Do not rinse reprocessed device with tap water, which may recontaminate the device."

http://www.fda.gov/cdrh/safety/061906-ultrasoundtransducers.html

What to do....What to do???

....Just when you thought the water was safe!!!!

AAMI TIR34:

Water for the reprocessing of medical devices

Association for the Advancement of Medical Instrumentation

Abstract: This Technical Information Report (TIR) covers the selection and maintenance of effective water quality suitable for reprocessing medical devices. It provides guidelines for selecting the water quality necessary for the reprocessing of categories of medical devices and addresses water treatment equipment, water distribution and storage, quality control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations.

Four Essential Steps

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Assessment of water quality</td>
</tr>
<tr>
<td>2</td>
<td>Implementation of water treatment process</td>
</tr>
<tr>
<td>3</td>
<td>Assurance of proper water quality for the various stages in medical device reprocessing</td>
</tr>
<tr>
<td>4</td>
<td>Ongoing monitoring of water quality</td>
</tr>
</tbody>
</table>

Water Quality Document: AAMI

- Big picture issues:
  - water assessment
  - tap water: needs treatment or not
- Water quality for various stages/types of medical device reprocessing
  - tap water
  - softened water
  - Deionized, or Highly treated water (e.g. treated with deionization, carbon filter, reverse osmosis & sub-micron filtration)
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AAMI FDS/TIR34

<table>
<thead>
<tr>
<th>Category of Water</th>
<th>Type of Testing</th>
<th>Sample Site</th>
<th>Suggested Frequency of Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Heterotrophic plate count</td>
<td>Reprocessing area, storage tanks (if used), immediately downstream of water treatment process</td>
<td>Monthly or quarterly</td>
</tr>
<tr>
<td>Critical</td>
<td>LAL test</td>
<td>Reprocessing area</td>
<td>On installation, modification, or repair of the high-purity water treatment system or when persistent increased microbial levels are detected by heterotrophic plate counts, ATP, or TOC.</td>
</tr>
<tr>
<td>Semicritical</td>
<td>pH meter and colorimetric dipsticks</td>
<td>Reprocessing area</td>
<td>Monthly or quarterly</td>
</tr>
<tr>
<td>Semicritical</td>
<td>pH meter</td>
<td>Reprocessing area</td>
<td>Monthly or quarterly</td>
</tr>
<tr>
<td>Noncritical</td>
<td>pH meter</td>
<td>Reprocessing area</td>
<td>Monthly or quarterly</td>
</tr>
</tbody>
</table>

Ongoing Monitoring of Water: Impact on Device Reprocessing Personnel??

Conclusions

- What is “Water Quality”? - Chemical content - Microbial content - Organic content
- Adverse Effects:
  - Devices: Do you see problems (e.g., rusting, spotting)?
  - Patients: infections, inflammatory response
- Basic 4 steps
  - Assess, Treat (if necessary), Assure, Maintain
- Common water qualities used
  - Potable, Softened, Deionized, Highly Treated (e.g. RO, distilled)
- Monitoring Water Quality

Water Issues aren't all BAD!

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