WATER QUALITY IN ENDOSCOPE REPROCESSING

Christina Bradley
Hospital Infection Research Laboratory
City Hospital
Birmingham, UK
CONTROLS ASSURANCE IN INFECTION CONTROL

Decontamination of medical devices

Validate washer disinfectors using HTM 2030, with particular emphasis on ensuring that the cleaning process is effective

HSC 1999/179
ENDOSCOPE WASHER DISINFECTORS: PROBLEMS

- Disinfectant concentration
- Machine contamination
- Water quality
- Maintenance
- Validation
Water is used for

- Preparation of detergent
- Preparation of disinfectant
- Final rinsing
Water: potential problems

- Chemical residues
- Particulates
- Micro-organisms
- Endotoxins
The Importance of Water Quality

- Water will effect
  - Cleaning performance
  - Rinsing
    - Device compatibility
    - Device/procedure safety
    - Microbial contamination levels
Water

- Tap water is not sterile
- Rising main water rarely used
  - Holding tanks become contaminated
  - Mycobacterium spp., Pseudomonas spp., fungi, etc
- Contaminated scopes
  - False positive microbiology
- Infection
Source of contamination

- Incoming water – inadequately treated
- Water treatment system
- Endoscope washer disinfector – formation of biofilm
Water treatment methods

- Filtration – 0.22μm
- Reverse Osmosis
- Addition of biocides
- Ultraviolet light
- Combination of methods
Machine contamination

Due to:

- Inadequate cleaning, disinfection and maintenance of machine
- Static water remaining in tanks and pipework
- Poor quality water supply
- Biofilm within the machine
Problems

- Pseudomonas species
  - machine contamination, water treatment
- Atypical mycobacteria
  - misdiagnosis of infection, resistant strains
Pseudomonas

- Bronchoscopes
  - 30% of specimens taken with scopes yielded Pseudomonas
- Loose biopsy port cap
- 3 deaths probably due to outbreak
- Instruments removed from service
- Was Pseudomonas in the water?
  - Rinse water negative on culture

Srinivasan NEJM 2003; 348: 221-7
M chelonae

- 7 patients
- M chelonae from BAL fluid
- Same organism isolated from WD
  - Detergent dispenser
- Previously rinsed with tap water
- EO and discontinuation of use of tap water ended problem

Nye et al JHI 1990 16; 257-261
Fungi

- AFOS washer disinfector
- Flexible cystoscopes
- Mains water via PVC pipes
- Daily decontamination
  - 1% hydrogen peroxide
- Culture
  - pigmented fungi, Ps aeruginosa,
- Piping changed
  - Biofilm, bacteria free rinse water not used

Phillips et al. IHI 1998; 40: 250-1
M. xenopi

- Spinal infections post disc operations
  - 58 cases of M. xenopi spinal infection
- “No infection control procedure existed at the time of investigation”
- Percutaneous nucleotomy
  - Nucleotome cleaned in tap water
  - Disinfected in glutaraldehyde – 10 mins
  - Rinsed in tap water  
  
  Astagneau et al Lancet: 2001; 747-51
Health Technical Memorandum 2030
Management policy
Washer-disinfectors

30/80
HTM 2030

- States levels for
  - Total Viable Count (TVC)
  - Environmental mycobacteria
  - Bacterial endotoxin
HTM 2030 - Water treatment

- Filtration (0.22 µm)
- Heat disinfection
- Reverse osmosis
- Ultraviolet light
- Addition of biocides
HTM 2030 Water quality

- **Reverse osmosis**
  - Disinfectant diluent, final rinse water
- **RO/0.22 µm filtered, heat or UV**
  - Post disinfection/sterilization rinsing for critical applications
- **Sterile purified**
  - Post disinfection/sterilization rinsing for critical applications
HTM 2030

Water quality - TVC

For WDs in which the product is rinsed after disinfection there should be no organisms per 100 ml

All other water services supplied to WDs should have <100 cfu/100ml

(Weekly test)
HTM 2030

Water quality – environmental mycobacteria

For endoscope WDs in which the product is rinsed after the disinfection stage there should be no mycobacteria detected

(Yearly test)
HTM 2030

Water quality - endotoxins

“When the intended use of the WD is for products that will be used invasively e.g. surgical instruments the water used for the final rinse should be tested for bacterial endotoxins (LAL test)”

(Yearly test)
EN ISO 15883
Washer Disinfectors

- Part 1 – General requirements
- Part 2 – Thermal washer disinfectors for surgical instruments, anaesthetic equipment, holloware etc
- Part 3 – Thermal washer disinfectors for human waste containers
- Part 4 – Chemical washer disinfectors for thermo-labile equipment
- Part 5 Test soils for demonstrating cleansing efficacy
EN ISO 15883 (Part 1)

- Final rinse water should contain <10 cfu/100ml sample and shall be free from legionellae, Pseudomonas aeruginosa and mycobacteria
- Recommended weekly test
EN ISO 15883 (Part 1)

- If a requirement for the level of bacterial endotoxins is stated in other parts of EN 15883 then the LAL test with a sensitivity of 0.25 EU/ml should be used.

- Endotoxins are not mentioned in EN 15883-4.
Validation of decontamination

Numerous tests are described in HTM 2030 but at the minimum, the user must ensure:

- All channel irrigation occurs
- Disinfectant is within minimum effective concentration
- Quality of water is adequate
Water testing

- Who will carry out the testing?
- How are the samples transported to the laboratory?
- Who receives the results?
- Are the results presented in an understandable format?
- Who will take action dependant on the results?
- What action will be taken in the event of contamination being detected?
Is there a problem?
Action if water is contaminated

- **Low counts**
  - Alcohol flush. ? Antibiotic prophylaxis

- **High counts**
  - Suspend high risk procedures (ERCP etc)
  - Double strength disinfect

- **Continued problem**
  - Change filters
  - Disinfect machine/water treatment system
  - Get manufacturer to strip down machine

Risk assessment
Type of procedure

- Higher risk
  - ERCP
  - Bronchoscopy
  - Cystoscopy

- Lower risk
  - Upper and lower GI
Water Sampling

# Suggested Action Levels


<table>
<thead>
<tr>
<th>Aerobic cfu/100 ml</th>
<th>Interpretation/action</th>
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<tbody>
<tr>
<td>0</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>1-9 (achieved on a regular basis)</td>
<td>Acceptable – counts under reasonable control</td>
</tr>
<tr>
<td>10-100</td>
<td>Unsatisfactory – investigate and super chlorinate</td>
</tr>
<tr>
<td>&gt;100</td>
<td>Unacceptable – take WD out of action</td>
</tr>
</tbody>
</table>
Things to consider?

- Should we be carrying out weekly TVC’s on final rinse water?
- Is the presence of >10 cfu/ml TVC in rinse water significant?
- Are endotoxins an issue?
- What level of endotoxin can cause harm to a patient?
- What level of endotoxin remains on the instrument?
- Should we risk assess depending on use of device?
- Is there a departmental action plan summarising action to be taken?
- Are the methods for collecting samples and interpreting results clearly defined?
Summary

- Inferior water quality can potentially cause problems
- Washer disinfectors and water treatment systems should be well maintained
- Washer disinfectors should be tested in accordance with National Guidelines
- All staff should receive adequate training
Thank you for listening