The Spaulding Classification, Disinfection and Sterilization – Is it Time to Reconsider
Dr. Gerald McDonnell, STERIS Corporation
A Webber Training Teleclass

The Spaulding Classification, Disinfection and Sterilization: Is it Time to Reconsider?

Dr. Gerald McDonnell
STERIS Corporation

Hosted by
Prof. Jean-Yves Maillard
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April 28, 2011

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Definitions

- **Cleaning**
  - The removal of contamination from a surface to the extent necessary for further processing or for intended use.

- **Disinfection**
  - The process of reduction of the number of viable microorganisms to a level previously specified
  - Other terms may be used such as ‘sanitization’, ‘pasteurization’ and various levels of disinfection (high, intermediate and low)

- **Sterilization**
  - Validated process to render a product/surface free from viable microorganisms, including bacterial spores.

Spaulding (1972)

- Sterilization is the destruction of all microbial forms
- Disinfection is something less than sterilization
- Can destroy most- and often all-microbial organisms
- 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

1957: Hirschowitz, University of Michigan
First Fiberoptic Endoscopes

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<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></td>
<td>Non-Critical</td>
<td>Cleaning and/or Low/Intermediate Level Disinfection</td>
</tr>
<tr>
<td>Mucous membranes or non-intact skin</td>
<td></td>
<td>Semi-Critical</td>
<td>High Level Disinfection</td>
</tr>
<tr>
<td>Sterile areas of the body, including blood contact</td>
<td></td>
<td>Critical</td>
<td>Sterilization</td>
</tr>
</tbody>
</table>

Microbiology

- The study of microscopic ‘life’ ('micro-organisms')
- Microorganisms
  - Bacteria
  - Viruses
  - Fungi
  - Protozoa
  - Helminths ('worms')
- They are not ‘simple’
  - Complex, diverse, adaptable.....
Life on Earth is overwhelmingly microbial. In fact, the extent of microbial diversity is so great that scientists have difficulties estimating its actual size. Some estimates place the number of microbial species in the range of billions, exceeding the number of species of "large" organisms by several orders of magnitude.

Harvard Magazine, 2007

**Extreme Resistance**

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Resistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thiothrix</td>
<td>Arsenic/Copper Resistance</td>
</tr>
<tr>
<td>Pseudomonas</td>
<td>Biofilm Formation</td>
</tr>
<tr>
<td>Deinococcus</td>
<td>Radiation</td>
</tr>
<tr>
<td>Pyrolobus</td>
<td>Temperature (&gt;85°C)</td>
</tr>
<tr>
<td>Helicobacter</td>
<td>Acidic pH (1-2)</td>
</tr>
<tr>
<td>Geobacillus</td>
<td>All Biocides</td>
</tr>
</tbody>
</table>

**Pathogen Surprises**

- Viruses
- Bacteria
- Mycobacteria
- Protozoa
- Prions

**Virus Structure**

- Non-Enveloped
  - Nucleic Acid
  - Protein
  - Capsid

- Enveloped
  - Envelope
  - Nucleocapsid

**Non-Enveloped Viruses**

<table>
<thead>
<tr>
<th>Virus</th>
<th>Host (s) of Infection</th>
<th>1976 Acquired Immunodeficiency Syndrome (AIDS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Echovirus 3</td>
<td>1966 Poliomyelitis (POL)</td>
<td>Varicella-zoster, cytomegalovirus, herpes zoster, encephalitis, postherpetic neuralgia</td>
</tr>
<tr>
<td>Echovirus 7</td>
<td>1966 Poliomyelitis (POL)</td>
<td>Poliomyelitis, necrotizing fasciitis, postherpetic neuralgia</td>
</tr>
<tr>
<td>Coxsackie A9</td>
<td>1943</td>
<td>Acute meningitis, encephalitis</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>1943</td>
<td>Diarrhea, gastroenteritis</td>
</tr>
<tr>
<td>Adenovirus 37</td>
<td>1943</td>
<td>Acute pneumonia</td>
</tr>
<tr>
<td>Astrovirus</td>
<td>1943</td>
<td>Acute gastroenteritis</td>
</tr>
<tr>
<td>Picornavirus</td>
<td>1943</td>
<td>Hand, foot, mouth disease</td>
</tr>
<tr>
<td>Norovirus</td>
<td>1943</td>
<td>Norovirus gastroenteritis</td>
</tr>
</tbody>
</table>

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Examples: Parvoviruses

- Non-enveloped, hydrophilic
- Small; 18-26nm
- Single stranded, DNA virus
- Highly resistant to disinfection

---

**Heat exposure conditions**

<table>
<thead>
<tr>
<th>disinfectant</th>
<th>Contact time</th>
<th>disinfectant reduction (log.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol (70%)</td>
<td>10 mins</td>
<td>≤1</td>
</tr>
<tr>
<td>QUAT (0.05%)</td>
<td>10 mins</td>
<td>≤1</td>
</tr>
<tr>
<td>Bleach (1:10)</td>
<td>10 mins</td>
<td>0.6 to 3</td>
</tr>
<tr>
<td>2% glutaraldehyde</td>
<td>20 mins</td>
<td>3 to 4</td>
</tr>
<tr>
<td>0.5% DPA</td>
<td>10 mins</td>
<td>3 to 4</td>
</tr>
<tr>
<td>0.2% PAA (at 20°C)</td>
<td>10 mins</td>
<td>≥4</td>
</tr>
</tbody>
</table>

**Disinfectant**

- Parvoviruses
- Polio
- Adeno
- Vaccine

- **Examples:**
  - Polio
  - Adeno
  - Vaccine

**Resistance…..is futile?**

- Intrinsic (Natural)
  - Cell wall surface
  - Spore formation
  - Biofilm formation
- Acquired
  - Mutations
  - Plasmid/transposon acquisition
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**Mycobacterium**
- Slow to very slow growing bacteria, acid-fast, generally Gram+, aerobic, rod-shaped
- Typical pathogens: *M. tuberculosis, M. leprae, M. avium*
- Atypical: *M. chelonae, M. gordonae, M. fortuitum*
- Commonly found in water

**Glutaraldehyde-Resistance**
- van Klinger and Pullen (1993)
- Repeated isolation from a washer-disinfector
- Netherlands
- Used 2% glutaraldehyde
- *Isolated Mycobacterium chelonae*
- Not inactivated at 60 min exposure to 2% GTA
- Griffiths *et al.* (1997)
- *Isolated* Mycobacterium chelonae
- From multiple washer-disinfectors in the UK
- Used 2% glutaraldehyde
- Misidentification and iatrogenic infections
- Not inactivated at 60 min exposure to 2% GTA

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**M. chelonae strains**

**“Hybrid” mycobacteria strains**

2% Glutaraldehyde

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**Keratitis**
- *M. abscessus*
- *M. chelonae*

**Surgical Site Infections**
- *M. abscessus*
- *M. chelonae*
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USA Study
- Washer-Disinfectors (USA)
  - 3 tested
  - Post cleaning-disinfection-rinsing cycles
  - Disinfectants
    - 2.5% glutaraldehyde at 25C
    - 2.3% glutaraldehyde at 35C
    - 0.55% OPA at 25C
- Microbiology
  - Rinse water (100mL) and swab sites (10)
  - Culturing
    - Mesophilic, aerobic bacteria: TSA agar, 30C, 7 days
    - Mycobacteria: 7H11 agar, 30C, 7-14 days
  - Analysis
    - Identification
    - Biocide sensitivity
    - Resistance investigations

Results
- All washer-disinfectors contaminated post-disinfection cycles
- Range of bacteria identified
  - Many could not be sub-cultured
  - Identifications
    - Mycobacterium
    - Methylobacterium

Contamination Sources
- Contaminated rinse water
  - Same organisms found in the rinse water/lines
- Inadequate disinfection
- Biofilm development
  - Organisms sensitive to disinfectant when isolated
- Disinfectant resistance
  - Mycobacterium

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**Summary**

- Mycobacteria can develop high resistance to aldehyde (glutaraldehyde and OPA) disinfectants
- Can survive normal high level disinfection
- Resistance appears to be due to changes in cell wall structure
  - e.g., deficient in porin proteins (MspA, MspA/C)
- Cross-resistance observed to antibiotics
  - e.g., rifampicin, vancomycin, tetracycline, clarithromycin
- Other impacts
  - Increased pathogenicity

**Protozoa**

- One of the most abundant forms of microorganisms
- Often difficult to cultivate and diagnose under laboratory conditions
- Pathogen examples
  - *Giardia*
  - *Cryptosporidium*
  - *Plasmodium*
  - *Acanthamoeba*

**Oocyst Disinfection**

<table>
<thead>
<tr>
<th>Biocide</th>
<th><em>C. parvum</em> activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>+</td>
</tr>
<tr>
<td>ETO</td>
<td>+</td>
</tr>
<tr>
<td>VHP</td>
<td>+</td>
</tr>
<tr>
<td>Gas Plasma</td>
<td>+</td>
</tr>
<tr>
<td>SYSTEM 1</td>
<td>+</td>
</tr>
<tr>
<td>Liquid Peroxide</td>
<td>+/-*</td>
</tr>
<tr>
<td>Liquid PAA</td>
<td>+/-*</td>
</tr>
<tr>
<td>2% Glutaraldehyde</td>
<td>-</td>
</tr>
<tr>
<td>0.55% OPA</td>
<td>-</td>
</tr>
</tbody>
</table>

*Depends on temperature, concentration and contact time

Barbee et al., 1999
Sell et al., 1999
Quilez et al., 2005

**Cryptosporidium parvum**

- **Acantameoba Cyst**

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>Contact Time</th>
<th>Disinfectant Reduction (Log₁₀)</th>
<th>Collection Strains</th>
<th>Hospital Isolates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hot water (55°C)</td>
<td>10 mins</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Hot water (60°C)</td>
<td>10 mins</td>
<td>&gt;5</td>
<td>&gt;5</td>
<td></td>
</tr>
<tr>
<td>Bleach (1/10)</td>
<td>10 mins</td>
<td>2 to &gt;5</td>
<td>0 to &gt;3.5</td>
<td>1 to &gt;5</td>
</tr>
<tr>
<td>2% Glutaraldehyde</td>
<td>20 mins</td>
<td>&gt;5</td>
<td>&gt;5</td>
<td></td>
</tr>
<tr>
<td>0.55% OPA</td>
<td>10 mins</td>
<td>2 to 3</td>
<td>1 to 4</td>
<td></td>
</tr>
<tr>
<td>2% Hydrogen Peroxide</td>
<td>10 mins</td>
<td>&gt;5</td>
<td>&gt;5</td>
<td></td>
</tr>
<tr>
<td>0.2% PAA (at 55°C)</td>
<td>10 mins</td>
<td>&gt;5</td>
<td>&gt;5</td>
<td></td>
</tr>
</tbody>
</table>

Coulon et al., 2010. Journal of Clinical Microbiology, 48, 2689-2697.

**Acantameoba Trophozoites**

- Trophozoites in suspension

**Cryptosporidium parvum**

Coulon et al., 2010. 2% glutaraldehyde, 20 mins
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More that just Protozoa

Amoebal Trophozoite
Amoebal Cysts

Prion Diseases

- What are ‘Prions’?
- Still debated!
- Proteins
- Appear to be devoid of nucleic acid
- Identified as the causative agents for a group of central nervous system diseases
  - TSEs
  - CJD, vCJD

Infection Control Concerns

- 100% fatal
- Transmissible
- Medical/surgical devices
- Tissues, including blood
- Environment
- ‘Resistance’
- Cleaning
- Disinfection/Sterilization

Cleaning

<table>
<thead>
<tr>
<th>Method</th>
<th>‘Log’ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Washing + Steam Sterilization¹</td>
<td>~5.5</td>
</tr>
<tr>
<td>Kleenzyme</td>
<td>~4.5</td>
</tr>
<tr>
<td>Enzyme Cleaner 2</td>
<td>~1</td>
</tr>
<tr>
<td>Kleenzyme + Steam Sterilization²</td>
<td>~6.5</td>
</tr>
<tr>
<td>Enzyme Cleaner 2 + Steam Sterilization²</td>
<td>~3.0</td>
</tr>
</tbody>
</table>

¹134°C x 18 mins
²121°C x 20 mins


Alkaline Cleaning

<table>
<thead>
<tr>
<th>Method</th>
<th>‘Log’ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamo100 (1.6%; 43°C; 15 mins)</td>
<td>&gt;5</td>
</tr>
<tr>
<td>Prolystica Alkaline 2x (0.4%; 5 mins, 65°C) + steam sterilization (134°C; 4 mins)</td>
<td>&gt;5</td>
</tr>
<tr>
<td>Prolystica Alkaline 10x (0.04%; 5 mins, 65°C) + steam sterilization (134°C; 4 mins)</td>
<td>&gt;5</td>
</tr>
</tbody>
</table>


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Chemical Sterilization

<table>
<thead>
<tr>
<th>Method</th>
<th>Test Parameters</th>
<th>'Log' Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>V-Pro 1</td>
<td>1, 3 or 6 pulses at ~1.6mg/L gas under vacuum</td>
<td>&gt;5</td>
</tr>
<tr>
<td>Gas Plasma (STERRAD 10X)</td>
<td>1 or 2 Advanced Cycles at ~ 8mg/L gas under vacuum</td>
<td>&gt;5</td>
</tr>
<tr>
<td>Gas Plasma (STERRAD 100S)</td>
<td>2 or 4 pulses at ~ 8mg/L gas under vacuum</td>
<td>~1</td>
</tr>
</tbody>
</table>


Conclusions

The A. Denver Russell Memorial Lecture