What’s New in Disinfection and Sterilization of Patient Care Equipment
A Webber Training Teleclass With Dr. William A. Rutala
May 22, 2003

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What’s New in Disinfection and Sterilization of Patient-Care Equipment
William A. Rutala, Ph.D., M.P.H.
University of North Carolina (UNC) Health Care System and UNC at Chapel Hill
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What’s New in Disinfection and Sterilization of Patient-Care Equipment
- New Methods in Disinfection
  - OPA; HP/PA; Glut w/ phenol/phenate; Glut 35⁰C
- New Methods in Sterilization
  - Rapid readout EO B1; new LTST
- Issues (endoscopes/AERs, endocavitary probes, emerging pathogens, flash sterilization, CDC guidelines)

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Disinfection and Sterilization in Healthcare Facilities
WA Rutala, DJ Weber, and HICPAC
- Overview
  - Last CDC guideline in 1985 was 4 pages, 7 references
  - 219 pages (>130 pages preamble, 20 pages recommendations, glossary of terms, tables, >900 references)
  - Evidence-based guideline (search of the literature using Medline)

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Efficacy of Disinfection/Sterilization

Influencing Factors

- Cleaning of the object
- Organic and inorganic load present
- Type and level of microbial contamination
- Concentration of and exposure time to disinfectant/sterilant
- Nature of the object
- Temperature and relative humidity

Disinfection

Objective

To prevent infection by reducing microbial contamination on inanimate objects to a level unlikely to be hazardous

Disinfection and Sterilization

EH Spaulding believed that how an object will be disinfected depended on the object’s intended use.

- CRITICAL - objects which enter normally sterile tissue or the vascular system or through which blood flows should be sterile.
- SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection) that kills all microorganisms but high numbers of bacterial spores.
- NONCRITICAL - objects that touch only intact skin require low-level disinfection.
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### Processing “Critical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification</th>
<th>Critical objects enter normally sterile tissue or vascular system, or through which blood flows.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Object</td>
<td>Sterility</td>
</tr>
<tr>
<td>Level germicidal action</td>
<td>Kill all microorganisms, including bacterial spores.</td>
</tr>
<tr>
<td>Examples</td>
<td>Surgical instruments and devices; cardiac catheters; implants, etc.</td>
</tr>
<tr>
<td>Method</td>
<td>Steam, gas, hydrogen peroxide plasma or chemical sterilization.</td>
</tr>
</tbody>
</table>

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### Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

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### Chemical Sterilization of “Critical Objects”

- Glutaraldehyde (>2.0%)
- Hydrogen peroxide-HP (7.2%)
- Peracetic acid-PA (0.2%)
- HP (1.0%) and PA (0.08%)
- HP (7.5%) and PA (0.23%)
- Glut (0.95%) and Phenolphenate (1.64%)

Exposure times per manufacturers’ recommendations.
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<table>
<thead>
<tr>
<th>Processing “Semicritical” Patient Care Objects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification:</strong> Semicritical objects come in contact with mucous membranes or skin that is not intact.</td>
</tr>
<tr>
<td><strong>Object:</strong> Free of all microorganisms except high numbers of bacterial spores.</td>
</tr>
<tr>
<td><strong>Level germicidal action:</strong> Kills all microorganisms except high numbers of bacterial spores.</td>
</tr>
<tr>
<td><strong>Examples:</strong> Respiratory therapy and anesthesia equipment, GI endoscopes, thermometer, etc.</td>
</tr>
<tr>
<td><strong>Method:</strong> High-level disinfection</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Semicritical Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Endoscopes</td>
</tr>
<tr>
<td>• Respiratory therapy equipment</td>
</tr>
<tr>
<td>• Anesthesia equipment</td>
</tr>
<tr>
<td>• Endocavitary probes</td>
</tr>
<tr>
<td>• Tonometers</td>
</tr>
<tr>
<td>• Diaphragm fitting rings</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>High Level Disinfection of “Semicritical Objects”</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exposure Time:</strong> 12 m-30m, 20°C</td>
</tr>
<tr>
<td><strong>Germicide</strong></td>
</tr>
<tr>
<td>Glutaraldehyde</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde (12 m)</td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
</tr>
<tr>
<td>Hydrogen peroxide and para-acetic acid*</td>
</tr>
<tr>
<td>Glutar and phenylphenate**</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage; **efficacy not verified

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### Processing “Noncritical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification:</th>
<th>Noncritical objects will not come in contact with mucous membranes or skin that is not intact.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Object:</td>
<td>Can be expected to be contaminated with some microorganisms.</td>
</tr>
<tr>
<td>Level germicidal action:</td>
<td>Kill vegetative bacteria, fungi and lipid viruses.</td>
</tr>
<tr>
<td>Examples:</td>
<td>Bedpans; crutches; bed rails; EKG leads; bedside tables; walls, floors and furniture.</td>
</tr>
<tr>
<td>Method:</td>
<td>Low-level disinfection</td>
</tr>
</tbody>
</table>

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### Low-Level Disinfection for “Noncritical” Objects

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Use Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl or isopropyl alcohol</td>
<td>70-90%</td>
</tr>
<tr>
<td>Chlorine</td>
<td>100ppm (1:500 dilution)</td>
</tr>
<tr>
<td>Phenolic</td>
<td>UD</td>
</tr>
<tr>
<td>Iodophor</td>
<td>UD</td>
</tr>
<tr>
<td>Quaternary ammonium</td>
<td>UD</td>
</tr>
</tbody>
</table>

UD=Manufacturer’s recommended use dilution

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### Use of Disinfectants for Noncritical Items/Surfaces

- Disinfect noncritical medical equipment with disinfectant at the proper use-dilution and a contact time of at least 30 to 60 sec.
- Frequency for disinfecting items/surfaces should comply with facility policies and minimally when visibly soiled and on a regular basis.
- Disinfect noncritical patient-care items if used on a patient on Contact Precautions before use by another patient.
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New Methods in Disinfection

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New FDA-Cleared Sterilants

- "Old"
  - ≥ 2% Glut, 7.5% HP, 1.0% HP and 0.08% PA
- New
  - 0.55% ortho-phthalaldehyde (HLD-12 m)
  - 7.35% HP and 0.23% PA (HLD-15 m)
  - 2.5% Glut (HLD-5 m at 35°C)
- Ensure antimicrobial activity and material compatibility

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Ideal HLD/Chemical Sterilant

- Rapid HLD (≤ 10 min) and rapid sporicidal activity
- No disinfectant residue after rinsing
- Excellent material compatibility
- Long shelf-life
- Nontoxic (no odor or irritation issues)
- No disposal problems
- Monitor minimum effective concentration

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**Glutaraldehyde**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerous use studies published</td>
<td>Respiratory irritation from vapor</td>
</tr>
<tr>
<td>Relatively inexpensive</td>
<td>Pungent and irritating odor</td>
</tr>
<tr>
<td>Excellent materials compatibility</td>
<td>Relatively slow mycobactericidal activity</td>
</tr>
<tr>
<td>Coagulate blood and fix tissues to surfaces</td>
<td>Allergic contact dermatitis</td>
</tr>
</tbody>
</table>

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**Ortho-phthalaldehyde (OPA)**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast acting HLD</td>
<td>Stains protein gray</td>
</tr>
<tr>
<td>No activation</td>
<td>Cost ($30/gal)</td>
</tr>
<tr>
<td>Excellent materials compatibility</td>
<td>Eye irritation with contact</td>
</tr>
<tr>
<td>Not a known irritant to eyes and nasal passages</td>
<td>Slow sporicidal activity</td>
</tr>
<tr>
<td>Weak odor</td>
<td></td>
</tr>
</tbody>
</table>

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**Comparison of Glutaraldehyde and OPA**

<table>
<thead>
<tr>
<th>Glutaraldehyde</th>
<th>Ortho-phthalaldehyde</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0% Glutaraldehyde</td>
<td>0.55% Ortho-phthalaldehyde</td>
</tr>
<tr>
<td>HLD: 45 min at 25°C</td>
<td>HLD: 12 min at 20°C</td>
</tr>
<tr>
<td>Needs activator</td>
<td>No activator needed</td>
</tr>
<tr>
<td>14 day use life</td>
<td>14 day use life</td>
</tr>
<tr>
<td>2 year shelf life</td>
<td>2 year shelf life</td>
</tr>
<tr>
<td>ACGIH ceiling limit, 0.05ppm</td>
<td>No ACGIH or OSHA limit</td>
</tr>
<tr>
<td>Strong odor</td>
<td>Weak odor</td>
</tr>
<tr>
<td>MEC, 1.5%</td>
<td>MEC, 0.3%</td>
</tr>
<tr>
<td>Cost - $13/gallon</td>
<td>Cost - $30/gallon</td>
</tr>
</tbody>
</table>

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OPA Research

- Afra and Sitter, 1994. OPA eliminated all microorganisms from 100 different endoscopes used in a clinical setting.
- Gregory et al., 1999. OPA achieved a 6 log reduction of M. bovis in 5.5 min compared to 32 min for glutaraldehyde.
- Walsh et al., 1999. OPA effective against glutaraldehyde-resistant M. chelonae strains.

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Comparative Resistance of Mycobacteria to OPA and Glutaraldehyde

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OPA Label Claims Worldwide

1. Europe, Asia, Latin America
   5 min at 20°C
2. Canada, Australia
   10 min at 20°C
3. United States
   12 min at 20°C

1. Antimicrobial tests support 5 min exposure time.
2. Canadian regulatory authority requires 6-log reduction in mycobacteria (5.6 m) and only 5 min intervals.
3. FDA requires 6-log reduction of mycobacteria suspended in organics and dried onto scope without cleaning.

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Minimum Effective Concentration
Chemical Sterilant

- Dilution of chemical sterilant occurs during use
- Test strips are available for monitoring MEC
- Test strips for glutaraldehyde monitor 1.5%
- Test strip not used to extend the use-life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used (used daily, test at least daily)
- Record results

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Hydrogen Peroxide

- Advantages
  - No activation required
  - Enhanced removal of organisms
  - No disposal issues
  - No odor or irritation issues
  - Does not coagulate blood or fix tissues to surfaces
  - Use studies published
- Disadvantages
  - Material compatibility concerns for brass, zinc, copper, and nickel/silver plating (cosmetic and functional damage)
  - Eye damage with contact
**Peracetic Acid/Hydrogen Peroxide**

- **Advantages**
  - No activation required
  - No odor or irritation issues
  - Effective in the presence of organic matter

- **Disadvantages**
  - Material compatibility issues for lead, brass, copper, zinc (cosmetic and functional damage)
  - Limited clinical use
  - Potential for eye and skin damage

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**Disinfection and Sterilization of Emerging Pathogens**

- Hepatitis C virus
- Clostridium difficile
- Cryptosporidium
- Helicobacter pylori
- E.coli 0157:H7
- Antibiotic-resistant microbes (MDR-TB, VRE, MRSA)
- SARS Coronavirus
- Bioterrorist agents (anthrax, plague, smallpox)
Disinfection and Sterilization of Emerging Pathogens

Standard disinfection and sterilization procedures for patient care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood and other body fluids from persons infected with emerging pathogens.

Endoscopes/AERS

GI ENDOSCOPES AND BRONCHOSCOPES
- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use
- High-level disinfection recommended minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission

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GI ENDOSCOPES AND BRONCHOSCOPES

- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI 10^9 in/10^5 out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- In the inanimate environment, although the incidence remains very low, endoscopes represent a risk of disease transmission

TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents Salmonella sp. and P. aeruginosa
  - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
  - 90 infections transmitted
  - M. tuberculosis, atypical Mycobacteria, P. aeruginosa

ENDOSCOPE REPROCESSING

- Source of contaminations for infections (36 outbreaks) transmitted by GI endoscopes from 1974-2001:
  - Cleaning-3 (12%)
  - Disinfection-19 (73%)
  - Rinse, Dry, Store-3 (12%)
  - Etiology unknown-11

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ENDOSCOPE INFECTIONS
- Infections traced to deficient practices
  - Inadequate cleaning (clean all channels)
  - Inappropriate/ineffective disinfection (time exposure, perfuse channels, test concentration)
  - Failure to follow recommended disinfection practices (tapwater rinse)
  - Flaws in design of endoscopes or AERs

ENDOSCOPES

<table>
<thead>
<tr>
<th>Type of Endoscope</th>
<th>Number Cultured</th>
<th>Number of Cultures &gt;100,000 Bacteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI</td>
<td>71</td>
<td>17 (23.9%)</td>
</tr>
<tr>
<td>Arthroscope/</td>
<td>17</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Cystoscope</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


ENDOSCOPE DISINFECTION
- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immers scope and perfuse HLD/sterilant through all channels for at least 12 min
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube and channels
- STORE-prevent recontamination

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Automated Endoscope Reprocessors (AERs)

- Advantages: automate and standardize reprocessing steps, reduce personnel exposure to chemicals, filtered tap water
- Disadvantages: failure of AERs linked to outbreaks, does not eliminate precleaning, does not monitor HLD concentration
- Problems: incompatible AER (side-viewing duodenoscope), biofilm buildup, contaminated AER, inadequate channel connectors
- MMWR 1999;48:557. Used wrong set-up or connector
- Must ensure exposure of internal surfaces with HLD/sterilant

ENDOSCOPE SAFETY

- Ensure protocols equivalent to guidelines from professional organizations (APIC, SGNA, ASGE)
- Are the staff who reprocess the endoscope specifically trained in that job?
- Are the staff competency tested at least annually?
- Conduct IC rounds to ensure compliance with policy

Endocavitary Probes

- Probes—Transesophageal echocardiography probes, vaginal/rectal probes used in sonographic scanning
- Probes with contact with mucous membranes are semicritical, probes in contact with sterile tissue are critical
- Guideline recommends that a new condom/probe cover should be used to cover the probe for each patient and since covers may fail (1-80%), HLD (semicritical probes) or sterilization (critical probes) should be performed

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New Methods in Sterilization

Sterilization
The complete elimination or destruction of all forms of microbial life and is accomplished in healthcare facilities by either physical or chemical processes

“Ideal” Sterilization Method

- Highly efficacious
- Rapidly active
- Strong penetrability
- Materials compatibility
- Non-toxic
- Organic material resistance
- Adaptability
- Monitoring capability
- Cost-effective

Schneider PM. Tappi J. 1994;77:115-119
Steam Sterilization

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Least affected by organic/inorganic soils
  - Rapid cycle time
  - Penetrates medical packing, device lumens

- Disadvantages
  - Detrimental for heat labile instruments
  - Potential for burns

Minimum Steam Sterilization Times

<table>
<thead>
<tr>
<th>Item</th>
<th>Minimum exposure</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped items</td>
<td>4 min</td>
<td>30 min</td>
</tr>
<tr>
<td>Textile packs</td>
<td>4 min</td>
<td>5 min</td>
</tr>
</tbody>
</table>

Flash Sterilization

- Flash originally defined as sterilization of an unwrapped object at 132°C for 3 min at 27-28 lbs pressure in gravity
- Flash used for items that must be used immediately
- Acceptable for processing items that cannot be packaged, sterilized and stored before use
- Because of the potential for serious infections, implanted surgical devices should not be flash sterilized unless unavoidable (e.g., orthopedic screws)
Flash Sterilization

- When flash sterilization is used, certain parameters should be met: item decontaminated, exogenous contamination prevented; sterilizer function monitored by mechanical, chemical, and biological monitors
- Do not used flash sterilization for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time


- Alternatives to ETO-CFC
  ETO-CO₂, ETO-HCFC, 100% ETO
- New Low Temperature Sterilization Technology
  Hydrogen Peroxide Gas Plasma
  Peracetic Acid

Ethylene Oxide (ETO)

- Advantages
  - Very effective at killing microorganisms
  - Penetrates medical packaging and many plastics
  - Compatible with most medical materials
  - Cycle easy to control and monitor
- Disadvantages
  - Some states (CA, NY, TX) require ETO emission reduction of 90-99.9%
  - CFC (inert gas that eliminates explosion hazard) banned after 1995
  - Potential hazard to patients and staff
  - Lengthy cycle/aeratation time
Hydrogen Peroxide Gas Plasma Sterilization

Advantages:
- Safe for the environment and health care worker; it leaves no toxic residuals
- Fast - cycle time is 45-73 min and no aeration necessary
- Used for heat and moisture sensitive items since process temperature 50°C
- Simple to operate, install, and monitor
- Compatible with most medical devices

Disadvantages:
- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about 3.5ft³ to 7.3ft³
- Endoscopes or medical devices with lumens or channels >40 cm or a diameter of <3 mm cannot be processed at this time in the US
- Requires synthetic packaging (polypropylene) and special container tray

Sterrad 50, 100S: New Plasma Sterilizers

Characteristics:
- Hydrogen peroxide (HP) gas plasma sterilizer
- Plasma is ionized or partially ionized gas
- Sterrad 50 (44 L sterilization chamber) is smaller than other plasma units; cycle time is 45 min; contains single shelf for placement of instruments in rectangular chamber
- 50 and 100S consists of two HP diffusion-plasma stage cycles
- Effective in killing 10⁶ B. stearothermophilus spores in lumens

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Evaluation of Low Temperature Sterilization Technologies

- Sporidical activity of Sterrad systems was assessed by inoculating flat stainless steel carriers with $10^6$ Geobacillus stearothermophilus spores (Bss).
- These carriers were aseptically placed in 40 cm long stainless steel lumens of varying diameters (1mm, 2 mm or 3 mm).

Comparative Evaluation of the Sporicidal Activity of New Low-Temperature Sterilization Technologies

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>3mm</th>
<th>2mm</th>
<th>1mm</th>
<th>3mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>EO+HCFC</td>
<td>0/50</td>
<td>0/40</td>
<td>0/40</td>
<td>0/50</td>
</tr>
<tr>
<td>Sterrad 100S</td>
<td>0/50</td>
<td>0/40</td>
<td>0/40</td>
<td>0/40</td>
</tr>
<tr>
<td>Sterrad 50</td>
<td>0/30</td>
<td>0/30</td>
<td>0/30</td>
<td>0/30</td>
</tr>
<tr>
<td>Sterrad 100</td>
<td>2/40</td>
<td>3/40</td>
<td>37/50</td>
<td>0/40</td>
</tr>
</tbody>
</table>


Conclusions

- All sterilization processes effective in killing spores.
- Cleaning removes salts and proteins and must precede sterilization.
- Failure to clean or ensure exposure of microorganisms to sterilant (e.g. connectors) could affect effectiveness of sterilization process.
Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization

Epidemiology of CJD in the US
- Degenerative neurologic disorder
- CJD (a prion) incidence
  - One death/million population
  - No seasonal distribution, no geographic aggregation
  - Both genders equally affected
  - Age range 50-80+ years, average 67
- Long incubation, rapid disease progression after onset
- Prions resistant to conventional disinfection/sterilization

Iatrogenic Transmission of CJD
- Contaminated medical instruments
  - Electrodes in brain (2)
  - Neurosurgical instruments in brain (4)
- Dura mater grafts (114)
- Corneal grafts (2)
- Human growth hormone (139) and gonadotropin (4)
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**CJD and Medical Devices**

- Six cases of CJD associated with medical devices
  - 2 confirmed cases-depth electrodes; reprocessed by benzene, alcohol and formaldehyde vapor
  - 4 cases-CJD following brain surgery, index CJD identified-1, suspect neurosurgical instruments
- Cases occurred before 1980 in Europe
- No cases since 1980 and no known failure of steam sterilization

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**Risks: Patient, Tissue, Device**

- **Patient**
  - Known or suspected CJD or other TSEs
  - Rapidly progressive dementia
  - Dura mater transplant, HGH injection
- **Tissue**
  - High risk-brain, spinal cord, eyes
- **Device**
  - Critical or semicritical

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CJD: potential for secondary spread through contaminated surgical instruments

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CJD: Recommendations for Disinfection and Sterilization
- High risk patient, high risk tissue, critical/semicritical device-special prion reprocessing
- High risk patient, low/no risk tissue, critical/semicritical device-conventional D/S
- Low risk patient, high risk tissue, critical/semicritical device-conventional D/S
- High risk patient, high risk tissue, noncritical device-conventional disinfection

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CJD: Disinfection and Sterilization Conclusions
- Cleaning with steam sterilization is effective
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, 121°C 30 m)
  - 134°C for 18m (prevacuum)
  - 132°C for 30-60m (gravity)
- No low temperature sterilization technology effective
- Four disinfectants (e.g., chlorine) effective (4 log10 decrease in LD50 within 1h)

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CJD: Disinfection and Sterilization Conclusions
- Epidemiologic evidence suggest nosocomial CJD transmission via medical devices is very rare
- Guidelines based on epidemiologic evidence, tissue infectivity, risk of disease via medical devices, and inactivation data
- Risk assessment based on patient, tissue and device
- Only critical/semicritical devices contaminated with high-risk tissue from high risk patients requires special treatment

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Prevent Patient Exposure to CJD

**Question:** How do hospitals minimize patient exposure to neurosurgical instruments from a patient who is later given a diagnosis of CJD?

**Answer:** Consider using the reviewed sterilization guidelines for neurosurgical instruments used on patients undergoing brain biopsy when a specific lesion (e.g., tumor) has not been demonstrated. Alternatively, neurosurgical instruments used in such cases could be disposable.

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Sterilization Practices

Sterilization monitored routinely by combination of mechanical, chemical, and biological parameters

- Mechanical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters present
- Biological - Bacillus spores that directly measure sterilization
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**Biological Monitors**

- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus* (formerly *B. subtilis*)
- ETO - *B. atrophaeus*
- New low temperature sterilization technologies
  - Plasma sterilization (Sterrad) - *B. atrophaeus*
  - Peracetic acid - *G. stearothermophilus*

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**Attest EO Rapid Readout: A New Rapid Readout BI for EO**

**Characteristics**

- EO widely used as a low temp sterilization process
- A new BI designed for rapid and reliable monitoring
- Fluorescent change detected within 4 hrs
- Visual pH color change of media within 96 hrs
- Rapid readout BI detects presence of spore-associated enzyme and growth of *B. atrophaeus* (subtilis) spores
- Enzyme always detected whenever viable spores present

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**Attest EO Rapid Readout: A New Rapid Readout BI for EO**

**Characteristics**

- Rapid Readout EO BI used to monitor 100% EO, EO-CFC, EO-HCFC. Not tested in EO-CO2 mixtures.
- Self-contained BI makes it easy to use in department where sterilizer located.
- Data show 7 day growth positives detected by fluorescence with 4 hours (quarantine 4 h, no recalls)
- Indicator available outside US but not yet FDA cleared

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Hosted by Paul Webber  paul@webbertraining.com
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What’s New in Disinfection and Sterilization of Patient-Care Equipment

- New Methods in Disinfection
  - OPA; HP/PA; Glut w/ phenol/phenate; Glut 35°C
- New Methods in Sterilization
  - Rapid readout EO BI; new LTST
- Issues (endoscopes/AERs, endocavitary probes, emerging pathogens, flash sterilization, CDC guidelines)

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Thank you

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- Rutala WA. APIC guideline for selection and use of disinfectants. Am J Infect Control 1996;24:313