Disinfection and Sterilization

William A. Rutala, Ph.D., M.P.H.
University of North Carolina (UNC) Health Care System and UNC at Chapel Hill, NC
Disclosure: ASP, Clorox and Vapotherm
Disinfection and Sterilization

- HICPAC Guideline
- Current issues
  - Norovirus
  - Endocavitary probes
  - Infrared Coagulation
  - Computers
  - Microfiber
  - Vapotherm
Overview

- Last Centers for Disease Control and Prevention guideline in 1985
- 274 pages (>130 pages preamble, 21 pages recommendations, glossary of terms, tables/figures, >1100 references)
- Evidence-based guideline
- Cleared by HICPAC February 2003; delayed by FDA
- Publication expected in late July 2007
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 [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL - objects that touch only intact skin require low-level disinfection.
# 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>
Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants
Chemical Sterilization of “Critical Objects”

- Glutaraldehyde (> 2.0%)
- Hydrogen peroxide-HP (7.5%)
- Peracetic acid-PA (0.2%)
- HP (1.0%) and PA (0.08%)
- HP (7.5%) and PA (0.23%)
- Glut (1.12%) and Phenol/phenate (1.93%)

Exposure time per manufacturers’ recommendations
## Processing “Semicritical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification</th>
<th>Semicritical objects come in contact with mucous membranes or skin that is not intact.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Object</td>
<td>Free of all microorganisms except high numbers of bacterial spores.</td>
</tr>
<tr>
<td>Level germicidal action</td>
<td>Kills all microorganisms except high numbers of bacterial spores.</td>
</tr>
<tr>
<td>Examples</td>
<td>Respiratory therapy and anesthesia equipment, GI endoscopes, endocavity probes, etc.</td>
</tr>
<tr>
<td>Method</td>
<td>High-level disinfection</td>
</tr>
</tbody>
</table>
Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Diaphragm fitting rings
High Level Disinfection of “Semicritical Objects”

Exposure Time ≥ 12 m-30m (US), 20ºC

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>≥ 2.0%</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde (12 m)</td>
<td>0.55%</td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
<td>7.5%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>1.0%/0.08%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>7.5%/0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td>Glut and phenol/phenate**</td>
<td>1.21%/1.93%</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage; **efficacy not verified
## 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 (or detergent cleaning)</td>
</tr>
</tbody>
</table>
Low-Level Disinfection for “Noncritical” Objects

Exposure time $\geq 1$ min

<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
Surface Disinfection
Noncritical Patient Care-CDC, 2007

- Disinfecting Noncritical Patient-Care Items
  - Process noncritical patient-care equipment with an EPA-registered disinfectant at the proper use dilution and a contact time of at least 1 min. *Category IB*
  
  - Ensure that the frequency for disinfecting noncritical patient-care surfaces be done minimally when visibly soiled and on a regular basis. *Category IB*
Surface Disinfection
Environmental Surfaces-CDC, 2007

- Disinfecting Environmental Surfaces in HCF
  - Disinfect (or clean) housekeeping surfaces (e.g., floors, tabletops) on a regular basis (e.g., daily, three times per week), when spills occur, and when these surfaces are visibly soiled. *Category IB*
  
  - Use disinfectant for housekeeping purposes where: uncertainty exists as to the nature of the soil on the surfaces (blood vs dirt); or where uncertainty exists regarding the presence of multi-drug resistant organisms on such surfaces. *Category II*
Disinfection and Sterilization of Emerging Pathogens
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, avian influenza, norovirus
- Bioterrorism 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.
Disinfection and Sterilization

- HICPAC Guideline
- Current issues
  - Norovirus
  - Endocavitary probes
  - Infrared Coagulation
  - Computers
  - Microfiber
  - Vapotherm
Norovirus
Noroviruses

- Norovirus (formerly Norwalk-like viruses-NLV) is a genus within the family *Caliciviridae*. SS-RNA with a capsid structure provides increased resistance to chemical disinfection.
- Causes acute gastroenteritis in humans; fecal-oral transmission primarily, although droplet and fomite transmission may facilitate spread.
- Infective dose as low as 10-100 particles.
- Outbreaks have been reported in hospitals, homes, camps, schools, restaurants, hotels, rehabilitation centers and cruise ships.
- Outbreaks in hospitals have increased in recent years and this may lead to the closure of wards to admissions.
- Human noroviruses cannot be grown in cell culture so feline calicivirus used as a surrogate.
Environmental Contamination
Norovirus

- Hospital-11/36 (31%) environmental swabs were positive by RT-PCR. Positive swabs were from lockers, curtains and commodes and confined to the immediate environment of symptomatic patients. J Hosp Infect 1998;39:39.

- Hotel-61/144 (42%) were positive for NLV RNA. Cheesbrough et al. Epid. Infect 2000;125:93.

- Rehabilitation Center-Norovirus detected from patients and three environmental specimens (physiotherapy instrument handle, toilet seat (2-room of symptomatic guest, public toilet) RT-PCR. Epid Infect 2002;129:133-138.

- LTCF-5/10 (50%) of the environmental samples were positive for norovirus by RT-PCR. Wu et al. ICHE 2005;26:802.

Some positive PCR results may represent non-infectious virus.
Environmental Survival
Norovirus

- At 20°C a 9-log$_{10}$ reduction of FCV between 21-28 days in a dried state Doultree et al. J Hosp Infect 1999;41:51
- At 20°C a 9-log$_{10}$ reduction of FCV between 14-21 days in suspension Doultree et al. J Hosp Infect 1999;41:51
- At 20°C a 3-log$_{10}$ reduction in infectivity (two animal caliciviruses) occurred in 1 week. Duizer et al. Appl Env Micro 2004;70:4538.
Role of the Environment
Norovirus

1. Prolonged outbreaks on ships suggest norovirus survives well.

2. Outbreak of GE affected more than 300 people who attended a concert hall over a 5-day period. Norwalk-like virus (NLV) confirmed in fecal samples by RT-PCR. The index case was a concert attendee who vomited in the auditorium. GI illness occurred among members of 8/15 school parties who attended the following day. Disinfection procedure was poor. Evans et al. Epid Infect 2002;129:355.

3. Extensive environmental contamination of a hospital ward.

Suggest transmission most likely occurred through direct contact with contaminated fomites.
Inactivation of Murine and Human Noroviruses

- 25 germicides were evaluated for their ability to inactivate human norovirus on contaminated non-porous inanimate surfaces
- Used a quantitative RT-PCR assay to quantify human norovirus reduction
- As no cell culture model is currently available for human norovirus, we chose a murine norovirus as a surrogate model for human norovirus
- 10µl inoculum of virus was placed on SS disk, allowed to dry, 50µl of the germicide applied, the virus-germicide mixture was neutralized and assayed for infectivity and by RT-PCR.
Inactivation of Murine and Human Noroviruses

<table>
<thead>
<tr>
<th>Disinfectant, 1 min</th>
<th>MNV Log$_{10}$ Reduction</th>
<th>HNV Log$_{10}$ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>2% Glut</td>
<td>&gt;4</td>
<td>0.9-1.6</td>
</tr>
<tr>
<td>Chlorine (1840 ppm)</td>
<td>&gt;3</td>
<td>3.8</td>
</tr>
<tr>
<td>70% Ethanol</td>
<td>&gt;4 (3.3 at 15sec)</td>
<td>2</td>
</tr>
<tr>
<td>65% Ethanol + QUAT</td>
<td>&gt;2</td>
<td>3.6</td>
</tr>
<tr>
<td>Chlorine (5000 ppm)</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>
### Inactivation of Murine and Human Noroviruses


<table>
<thead>
<tr>
<th>Disinfectant, 1 min</th>
<th>MNV Log$_{10}$ Reduction</th>
<th>HNV Log$_{10}$ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>70% Isopropyl alcohol</td>
<td>4.2</td>
<td>2.2</td>
</tr>
<tr>
<td>0.5% Accel H$_2$O$_2$</td>
<td>3.9</td>
<td>2.8</td>
</tr>
<tr>
<td>79% Ethanol + QUAT</td>
<td>3.4</td>
<td>3.6</td>
</tr>
<tr>
<td>QUAT</td>
<td>2.1</td>
<td>0.4</td>
</tr>
<tr>
<td>Phenolic, Ag, 3% H$_2$O$_2$</td>
<td>$\leq$1</td>
<td>$\leq$1</td>
</tr>
</tbody>
</table>
# Inactivation of Murine and Human Noroviruses


<table>
<thead>
<tr>
<th>Antiseptic, 1 min</th>
<th>MNV Log(_{10}) Reduction</th>
<th>HNV Log(_{10}) Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol Hand Spray</td>
<td>3.2</td>
<td>2.5</td>
</tr>
<tr>
<td>Ethanol Based Rub</td>
<td>1.9</td>
<td>2.1</td>
</tr>
<tr>
<td>Iodophor (10%)</td>
<td>0.8</td>
<td>0.5</td>
</tr>
<tr>
<td>4% CHG</td>
<td>0.1</td>
<td>0.3</td>
</tr>
<tr>
<td>0.5% Triclosan</td>
<td>1.3</td>
<td>0.2</td>
</tr>
<tr>
<td>1% PCMX</td>
<td>0</td>
<td>2.4</td>
</tr>
</tbody>
</table>
## Inactivation of Feline Caliciviruses

Sattar SA. *J Hosp Infect* 2004;56:S64

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>Log Reduction</th>
<th>Contact Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accel HP (5000 ppm)</td>
<td>&gt;4.7</td>
<td>3</td>
</tr>
<tr>
<td>Chlorine dioxide (1000 ppm)</td>
<td>4.5</td>
<td>1</td>
</tr>
<tr>
<td>Chlorine (1000 ppm)</td>
<td>&gt;4.5</td>
<td>1</td>
</tr>
<tr>
<td>QUAT</td>
<td>4.0</td>
<td>10</td>
</tr>
<tr>
<td>75% Ethanol</td>
<td>4.7</td>
<td>10</td>
</tr>
</tbody>
</table>
Control Measures
Norovirus

- Containment of infectious persons
- Symptomatic staff instructed to remain home for 48 hours after symptoms resolve
- Rigorous environmental cleaning procedures
- Implementation of strict contact precautions
- Soap and water for hand hygiene should be considered rather than alcohol-based hand rubs
- During clusters, surfaces should be disinfected with an agent shown to have efficacy (e.g., hypochlorite, 5000 ppm)
- Ward closed to admissions (possibly); treat entire ward as isolation
Endocavitary Probe Covers

- Sterile transvaginal probe covers had a very high rate of perforations before use (0%, 25%, 65% perforations from three suppliers)

- A very high rate of perforations in used endovaginal probe covers was found after oocyte retrieval use (75% and 81% from two suppliers) but other investigators found a lower rate of perforations after use of condoms (0.9-2.0%)

- Condoms superior to probe covers for ultrasound probe (1.7% condom, 8.3% leakage for probe covers)
Endocavitary Probes

- Probes - Transesophageal echocardiography probes, vaginal/rectal probes used in sonographic scanning
- Probes with contact with mucous membranes are semicritical
- 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) should be performed
Infrared Coagulation (IRC)

- IRC is a widely used method for treating hemorrhoids. The procedure involves applying infrared light to compress and seal hemorrhoid veins.
- The manufacture sells a sterile disposable sheath and states removing and soaking lightguides between procedures is no longer required.
- The manufacturer also states that the lightguide is damaged by immersion in a disinfectant (as the lightguide is not sealed at the end and disinfectant gets between the quartz glass and the covering).
Infrared Coagulation (IRC)

- CDC guideline (In press) recommends immersion for reprocessing endocavitary probes with covers because integrity of the cover is compromised.
- Since the lightguide cannot be immersed we investigated an alternative procedure:
  - Wipe the probe for 2 minutes with 1:10 bleach (5000 ppm)
  - Wipe probe with sterile water and let air dry.
## Infrared Coagulation Testing


<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Inoculum</th>
<th>$\log_{10}$ Reduction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Mycobacterium terrae</em></td>
<td>$7.8 \times 10^6$</td>
<td>6.9</td>
</tr>
</tbody>
</table>
Wiping the non-immersible IRC probe for 2 min with 5000 ppm chlorine was effective in removing/inactivating microorganisms from the instruments.
Noncritical Patient Equipment
Computer Keyboards, ICHE April 2006

- Degree of microbial contamination
- Efficacy of disinfectants
- Cosmetic and functional effects of disinfectants on appearance of the letters or the keyboards
Disinfection of Computer Keyboards

- All tested products were effective (>95%) in removing and/or inactivating the test pathogens (MRSA, P. aeruginosa). No functional/cosmetic damage.
- Disinfectants included: 3 quaternary ammonium compounds, 70% isopropyl alcohol, phenolic, chlorine (80ppm)
- At present, recommend that keyboards be disinfected daily (for 5 sec) and when visibly soiled
Microfiber Cleaning

- Pad contains fibers (polyester and polyamide) that provide a cleaning surface 40 times greater than conventional string mops.

- Proposed advantages: reduce chemical use and disposal (disinfectant solution not changed after every third room, clean microfiber per room [washing lifetime 500-1000]); light (~5 lb less than string mop) and ergonomic; reduce cleaning times.

- Does the microfiber provide the same or better removal of microorganisms on surfaces?
# Effectiveness of Microfiber Mop

(Rutala et al, AJIC, June 2007)

<table>
<thead>
<tr>
<th>Cleaning Method</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disinfectant-regular mop</td>
<td>95%</td>
</tr>
<tr>
<td>Disinfectant-Microfiber system</td>
<td>95%</td>
</tr>
<tr>
<td>Disinfectant-Microfiber mop and regular mop bucket</td>
<td>88%</td>
</tr>
<tr>
<td>Detergent-regular mop</td>
<td>68%</td>
</tr>
<tr>
<td>Detergent-Microfiber system</td>
<td>95%</td>
</tr>
<tr>
<td>Detergent-Microfiber mop and regular mop bucket</td>
<td>80%</td>
</tr>
</tbody>
</table>
The microfiber system demonstrated superior microbial removal compared to cotton string mops when used with a detergent cleaner.

The use of a disinfectant did not improve the microbial elimination demonstrated by the microfiber system.

Use of a disinfectant did significantly improve microbial removal when a cotton string mop was used.
Vapotherm 2000i

- Delivers humidified oxygen via nasal cannula
- Widely used by pediatric and neonatal clinicians
- Portable, multi-use device
- Voluntary recall in December 2005
- Reintroduced January 2007

Diagram from Vapotherm, Inc
**Ralstonia Species Contamination Associated with Vapotherm Respiratory Gas Humidifier**

- Up to 32 hospitals reported potential *Ralstonia* (e.g., *Ralstonia mannitolilytica*) contamination over a ten month period in 2005
- Ten states showed a similar genetic strain of *Ralstonia*
- Up to eight potential patient infections reported to CDC using a physician reporting tool
- 38 confirmed cases; 92% (35) exposed to Vapotherm; 8 infections; 1 possible contribution to death
- During the investigation (Jan-Oct 2005) timeframe Vapotherm sold over 100,000 delivery tubes
Potential Source of Contamination
- Contamination of machine interior during initial calibration with unfiltered water

Potential Source of Contamination
- Contamination of vapor-transfer cartridge, a component of the device, during manufacture

Corrective Action
- All devices in distribution were recalled to the manufacturer’s facility and disinfected with 1000 ppm chlorine dioxide for 1 hour (>6 log reduction *M. terrae*). Tested 65 units with water; 63 negative, 2 gram-positives.

Corrective Action
- Manufacture of new devices uses filtered water and drying
- Vapor-transfer cartridges now ETO sterilized
**Potential Source of Contamination**
- Contamination of either the device, vapor-transfer cartridge, or both during use

**Corrective Action**
- A new, closed system was developed and only sterile water is used for humidification
- Vapor-transfer cartridge, previously multiuse, is for single patient and discarded after 30 days

**Potential Source of Contamination**
- Failure to remove bacteria during routine decontamination

**Corrective Action**
- Disinfect (PA/HP or QUAT for 10 min, 6 log reduction Sa, Pa, Ec) between patients or after every 30 days in a single patient
Summary

- D/S guidelines must be followed to prevent exposure to pathogens that may lead to infection
- During clusters, surfaces potentially contaminated with norovirus should be disinfected with an agent shown to have efficacy (e.g., hypochlorite, 5000 ppm)
- Computer keyboards can be effectively disinfected
- Wiping a non-immersible probe (IRC) with 5000 ppm chlorine for 2 min was effective in eliminating mycobacteria
- Vapotherm has instituted several control measures to prevent transmission of infection associated with its use
Disinfection and Sterilization

- HICPAC Guideline
- Current issues
  - Norovirus
  - Endocavitary probes
  - Infrared Coagulation
  - Computers
  - Microfiber
  - Vapotherm
Thank you
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.
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
  - Deleterious for heat labile instruments
  - Potential for burns

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

Advantages

● Safe for the environment and health care worker; it leaves no toxic residuals
● Fast - cycle time is 28-52 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
Hydrogen Peroxide Gas Plasma Sterilization

Disadvantages

- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about 3.5ft³ to 7.3ft³
- Endoscopes or medical devices restrictions based on lumen internal diameter and length (see manufacturer’s recommendations); expanded claims with NX
- Requires synthetic packaging (polypropylene) and special container tray
Steris System Processor

Advantages

- Rapid cycle time (30-45 min)
- Low temperature (50-55°C) liquid immersion sterilization
- Environmental friendly by-products (acetic acid, O₂, H₂O)
- Fully automated
- No adverse health effects to operators
- Compatible with wide variety of materials and instruments
- Suitable for medical devices such as flexible/rigid scopes
- Simulated-use and clinical trials have demonstrated excellent microbial killing
Steris System Processor

Disadvantages

- Potential material incompatibility (e.g., aluminum anodized coating becomes dull)
- Used for immersible instruments only
- Biological indicator may not be suitable for routine monitoring
- One scope or a small number of instruments can be processed in a cycle
- More expensive (endoscope repairs, operating costs) than HLD
- Point-of-use system, no long-term storage
Conclusions
Sterilization

- 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
Recommendations
Methods of Sterilization

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)
Sterilization Practices
Sterilization Monitoring

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

- Physical - 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
Biological Monitors

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

- Monitor each load with mechanical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items.
Recommendations
Monitoring of Sterilizers

Following a single positive biological indicator used with a method other than steam, treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator.
Recommendations
Storage of Sterile Items

- Sterile storage area should be well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.
- Sterile items should be stored so that packaging is not compromised
- Sterilized items should be labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and the expiration date (if applicable)
Recommendations
Storage of Sterile Items

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g., tear, wetness). Packages should be evaluated before use for lose of integrity.

- Time-related shelf life (less common) considers items remain sterile for varying periods depending on the type of material used to wrap the item/tray. Once the expiration date is exceeded the pack should be reprocessed.
Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization
Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

- Prions
- Spores
- Mycobacteria
- Non-Enveloped Viruses
- Fungi
- Bacteria
- Enveloped Viruses
CJD: potential for secondary spread through contaminated surgical instruments
CJD: Disinfection and Sterilization
Conclusions

- Critical/Semicritical-devices contaminated with high-risk tissue from high risk patients requires special prion reprocessing
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, 121°C 30 m)
  - 134°C for 18m (prevacuum)
  - 132°C for 60m (gravity)
- No low temperature sterilization technology effective*
- Noncritical-four disinfectants (e.g., chlorine, Environ LpH) effective (4 log decrease in LD₅₀ within 1h)

*VHP reduced infectivity by 4.5 logs (Lancet 2004;364:521)
Inactivation of Prions
Recent Studies

  - Enzymatic cleaner (EC)-no effect
  - Phenolic (Environ LpH), alkaline cleaner (AC), EC+VHP-effective
  - SDS/NaOH, AC, 0.2% PA, 5% SDS-effective (in vitro)
  - Environ LpH-effective
Endoscopes/AERS
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 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
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
References

- Rutala WA, Weber DJ, HICPAC. CDC guideline for disinfection and sterilization in healthcare facilities. MMWR. In press.
- Rutala WA. APIC guideline for selection and use of disinfectants. Am J Infect Control 1996;24:313
References