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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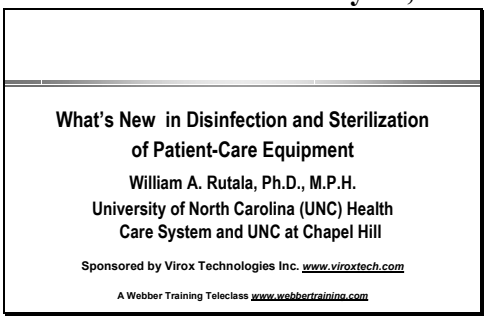

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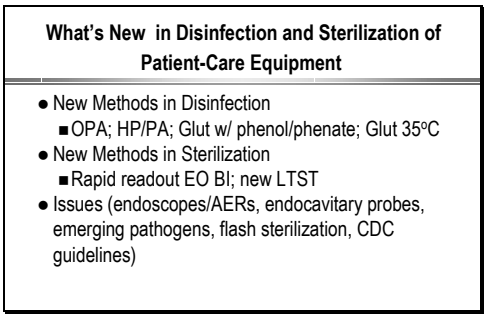

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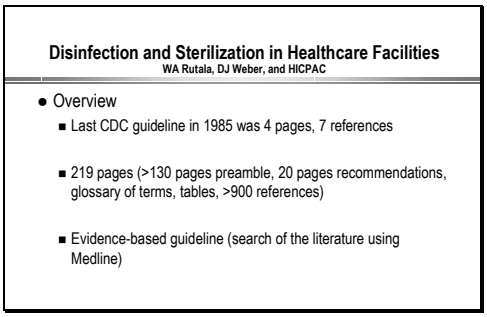

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Efficacy of Disinfection/Sterilization
Influencing Factors

- 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

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Disinfection

Objective

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

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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**.

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Processing "Critical" Patient Care Objects

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

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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 (7.5%)
Peracetic acid-PA (0.2%)
HP (1.0%) and PA (0.08%)
HP (7.5%) and PA (0.23%)
Glut (0.95%) and Phenol/phenate (1.64%)

Exposure time per manufacturers' recommendations

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Processing "Semicritical" Patient Care Objects

Classification:	Semicritical objects come in contact with mucous membranes or skin that is not intact.
Object:	Free of all microorganisms except high numbers of bacterial spores.
Level germicidal action:	Kills all microorganisms except high numbers of bacterial spores.
Examples:	Respiratory therapy and anesthesia equipment, GI endoscopes, thermometer, etc.
Method:	High-level disinfection

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Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Diaphragm fitting rings

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High Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 12 m-30m, 20°C

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde (12 m)	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Glut and phenol/phenate**	0.95%/1.64%

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

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Processing "Noncritical" Patient Care Objects

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

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Low-Level Disinfection for "Noncritical" Objects

Exposure time ≤10 min

Germicide	Use Concentration
Ethyl or isopropyl alcohol	70-90%
Chlorine	100ppm (1:500 dilution)
Phenolic	UD
Iodophor	UD
Quaternary ammonium	UD

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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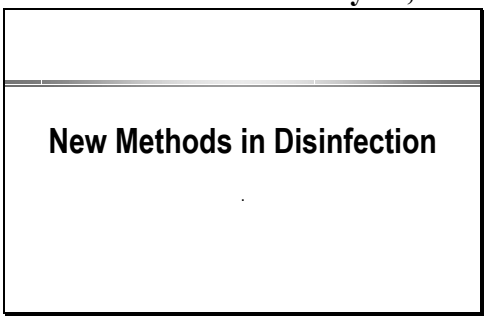

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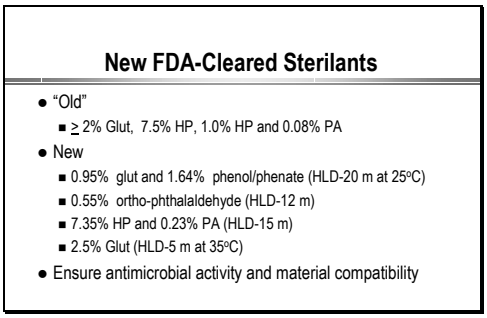

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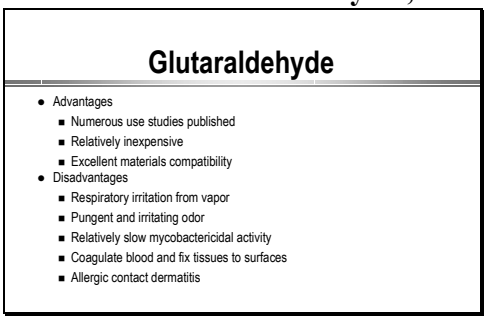

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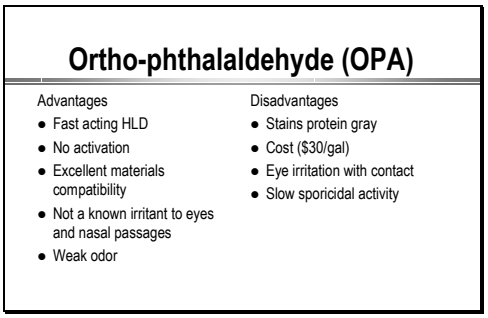

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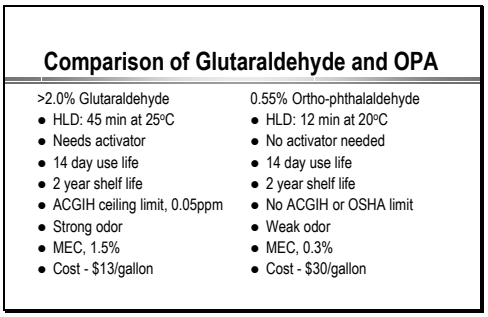

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OPA Research

- Alfa and Sitter, 1994. OPA eliminated all microorganisms from 100 different endoscopes used in a clinical setting.
- Gregory et al, 1999. OPA achieved a 6 $\log_{10}$ 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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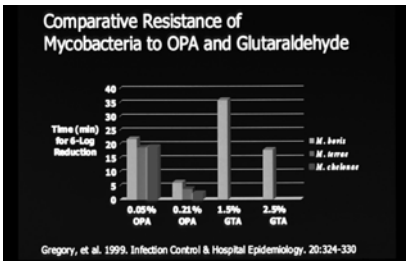

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OPA Label Claims Worldwide

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 (5.5 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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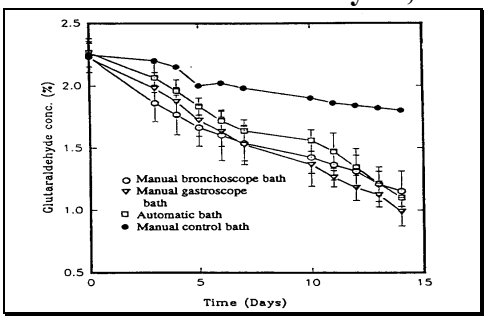

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Minimum Effective Concentration Chemical Sterilant

- 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

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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

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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)

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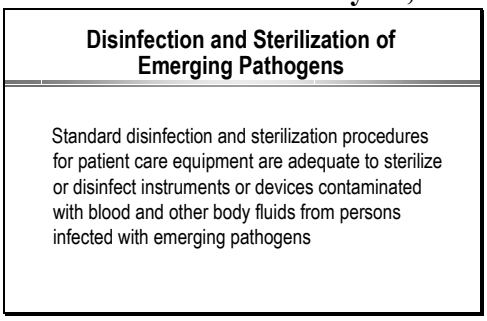

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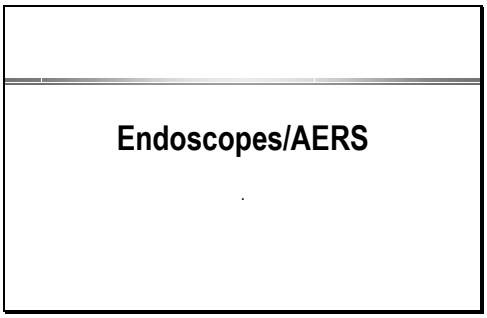

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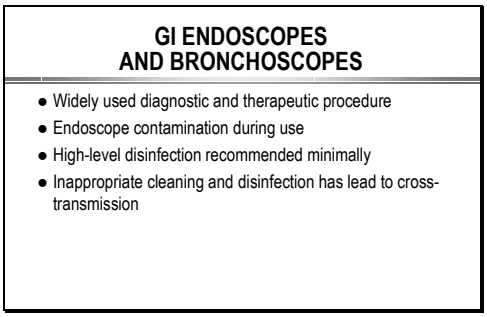

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GI ENDOSCOPES AND BRONCHOSCOPES

- 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

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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*

Spach DH et al Ann Intern Med 1993: 118:117-128 and Weber DJ et al Gastroint Dis 2002;87

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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 is design of endoscopes or AERs

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ENDOSCOPES

Bacterial cultures from the internal channels of endoscopes

Type of Endoscope	Number Cultured	Number of Cultures ≥100,000 Bacteria
GI	71	17 (23.9%)
Arthroscope/ Cystoscope	17	0 (0%)

Kaczmarek RG et al, Am J Med 1992;92:257-261.

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ENDOSCOPE DISINFECTION

- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse 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

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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

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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

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Sterilization

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

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"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

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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

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Minimum Steam Sterilization Times

Time at 132°C in Prevacuum Sterilizer

Item	Minimum exposure	Minimum drying time
Wrapped instruments	4 min	30 min
Textile packs	4 min	5 min

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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)

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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

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New Trends in Sterilization of Patient Equipment

- Alternatives to ETO-CFC
  ETO-CO_2, ETO-HCFC, 100% ETO
- New Low Temperature Sterilization Technology
  Hydrogen Peroxide Gas Plasma
  Peracetic Acid

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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

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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

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Hydrogen Peroxide Gas Plasma Sterilization

Disadvantages

- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about $3.5ft^3$ to $7.3ft^3$
- 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

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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 10^6 *B. stearothermophilus* spores in lumens

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Evaluation of Low Temperature Sterilization Technologies

- Sporicidal 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)

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

	Units Positive/Units Tested			
Sterilization Method	LTU, 3mm	LTU, 2mm	LTU, 1mm	SL, 3mm
EtO-HCFC	0/50	0/40	0/40	0/50
Sterrad 100S	0/50	0/40	0/40	0/40
Sterrad 50	0/30	0/30	0/30	0/30
Sterrad 100	2/40	3/40	37/50	0/40

Rutala WA and DJ Weber. AJIC 1998;26:393-398. Rutala WA et al. ICHE 1999;26:393.

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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

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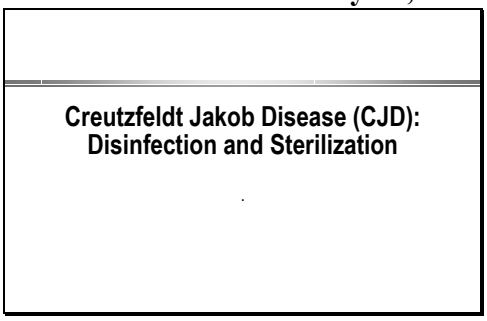

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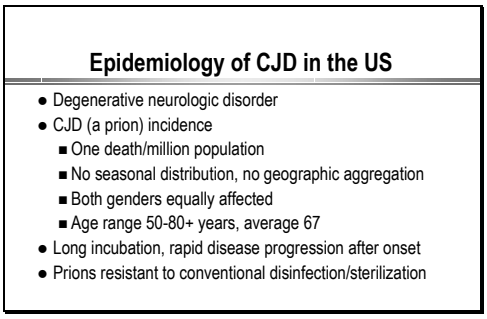

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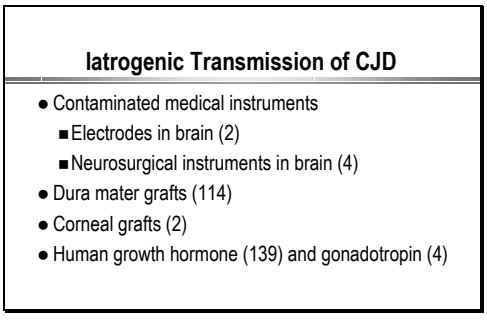

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CJD and Medical Devices

- 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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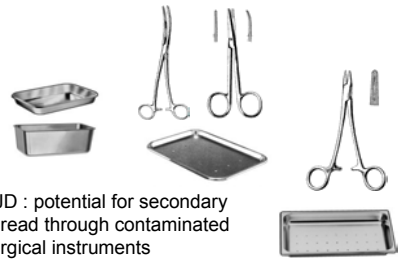

CJD : potential for secondary spread through contaminated surgical instruments

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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, 121ºC 30 m)
  - 134ºC for 18m (prevacuum)
  - 132ºC for 30-60m (gravity)
- No low temperature sterilization technology effective
- Four disinfectants (e.g., chlorine) effective (4 $\log_{10}$ decrease in LD_{50} 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

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Sterilization Monitoring

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-CO_2 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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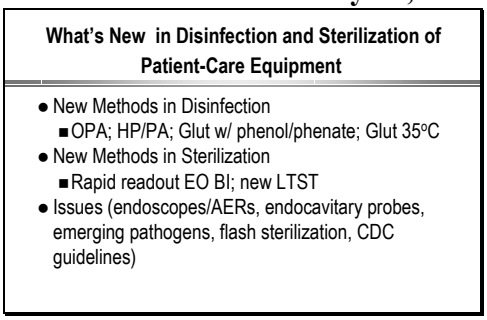

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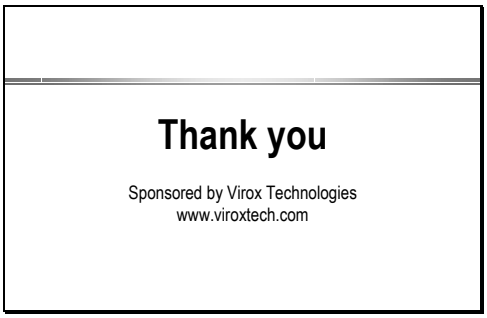

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