### Disinfection and Sterilization: New HICPAC Guidelines

William A. Rutala, Ph.D., M.P.H. University of North Carolina (UNC) Health Care System and UNC at Chapel Hill, NC

#### Disinfection and Sterilization: New HICPAC Guidelines

- **Pr**ovide overview
- Discuss processes and products
- Emerging pathogens and prions
- Special instrument reprocessing issues
- Issues and controversies (e.g. glutaraldehyde exposure time 45m/25°C vs 20m/20°C)

## disinfectionandsterilization.org

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### **Disinfection and Sterilization in Healthcare Facilities**

WA Rutala, DJ Weber, and HICPAC, "In press"

#### Overview

- Last CDC guideline in 1985
- 274 pages (>130 pages preamble, 21 pages recommendations, glossary of terms, tables/figures, >1000 references)
- Evidence-based guideline
- Cleared by HICPAC February 2003

## 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 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**

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.

# **Critical Objects**

- Surgical instruments
- Cardiac catheters
- Implants

### **Chemical Sterilization of "Critical Objects"**

Glutaraldehyde ( $\geq$  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

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

# **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, 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%
Hypochorite (free chlorine)*	650-675 ppm
Glut and phenol/phenate**	1.21%/1.93%

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



## 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:	tables; walls, floors and furniture.
Method:	Low-level disinfection

### Low-Level Disinfection for "Noncritical" Objects

Exposure time <u>&gt;</u> 1 min			
Germicide	Use Concentration		
Ethyl or isopropyl alcohol	70-90%		
Chlorine	100ppm (1:500 dilution)		
Phenolic	UD		
lodophor	UD		
Quaternary ammonium	UD		

UD=Manufacturer's recommended use dilution

# **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
  - 1.21% glut and 1.93% phenol/phenate (HLD-20 m at 25°C)
  - 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)
  - Hypochlorite (650-675ppm free chlorine)
- Ensure antimicrobial activity and material compatibility

## Glutaraldehyde

- Advantages
  - Numerous use studies published
  - Relatively inexpensive
  - Excellent materials compatibility
- Disadvantages
  - Respiratory irritation from vapor
  - Pungent and irritating odor
  - Relatively slow mycobactericidal activity
  - Coagulate blood and fix tissues to surfaces
  - Allergic contact dermatitis

## Ortho-phthalaldehyde

#### Advantages

- Fast acting HLD
- No activation
- Excellent materials compatibility
- Not a known irritant to eyes and nasal passages
- Weak odor

#### Disadvantages

- Stains protein gray
- Cost (\$30/gal);but lower reprocessing costs-soak time, devices per gal)
- Slow sporicidal activity
- Eye irritation with contact
- Exposure may result in hypersensitivity

## **Comparison of Glutaraldehyde and OPA**

- >2.0% Glutaraldehyde
- HLD: 45 min at 25°C
- Needs activator
- 14 day use life
- 2 year shelf life
- ACGIH ceiling limit, 0.05ppm
- Strong odor
- MEC, 1.5%
- Cost \$10/gallon

#### 0.55% Ortho-phthalaldehyde

- HLD: 12 min at 20°C
- No activator needed
- 14 day use life
- 2 year shelf life
- No ACGIH or OSHA limit
- Weak odor
- MEC, 0.3%
- Cost \$30/gallon

#### Comparative Resistance of Mycobacteria to OPA and Glutaraldehyde



Gregory, et al. 1999. Infection Control & Hospital Epidemiology. 20:324-330

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### Ortho-phthalaldehyde (OPA) Contraindications for OPA

- Repeated exposure to OPA, following manual reprocessing of urological instruments, may have resulted in hypersensitivity in some patients with a history of bladder cancer undergoing repeated cystoscopy.
- Out of approximately 1 million urological procedures, there have been reports of 24 patients who have experience 'anaphylaxis-like' reactions after repeated cystoscopy (typically after 4-9 treatments).
- Risk control measures: residues of OPA minimized; and contraindicated for reprocessing of urological instruments used on patients with history of bladder cancer.

# 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

# **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

# "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
  - Deleterious for heat labile instruments
  - Potential for burns

## **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

## **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


### New Trends in Sterilization of Patient Equipment

- Alternatives to ETO-CFC
  ETO-CO<sub>2</sub>, 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/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 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 3.5ft<sup>3</sup> to 7.3ft<sup>3</sup>
- 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, O<sub>2</sub>, H<sub>2</sub>O)
- 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

- 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)

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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, 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

# **Coronavirus (SARS-CoV)**

- Cause one-third of common colds, and Severe Acute Respiratory Syndrome (SARS-CoV)
- Enveloped virus
- Survive on surfaces for hours
- Surfaces possible source of contamination

#### **Disinfection of SARS-CoV and Other Coronaviruses**

- SARS-CoV
  - PVP and 70% alcohol, 2m (Jpn J Vet Res 2004;52:105)
  - 0.5% glutaraldehyde, 2m (Med Micro Imm 2005;194:1)

- Other Coronaviruses
  - PVP, alcohol, glutaraldehyde, CHG, 5% phenolic >3log RF against 229E in 1 m (J Hosp Infect 2004;56:64)
  - QUAT and phenolic not effective
  - PA, OPA, glutaraldehyde, 1:10 chlorine, 70% ethanol >3log RF against porcine TGEV in 1m
  - QUAT, 1:50 chlorine, phenolic, 3% HP, 70% isopro not effective

# Influenza (Avian influenza)

- Avian influenza A (H5N1) virus occurs mainly in birds
- 74 human cases in Vietnam, Thailand and Cambodia resulting in 49 deaths (66% mortality)
- Most cases of bird flu in humans resulted from contact with infected poultry or contaminated surfaces
- Phenolics, a QUAT, a peroxygen, and chlorine effective in inactivating avian influenza (Avian Dis 2003;47:1091)

#### Noroviruses

- Norovirus (formerly Norwalk-like viruses) is a genus within the family Caliciviridae
- Causes acute gastroenteritis in humans
- Outbreaks have been reported in hospitals, homes, camps, schools and cruise ships
- Outbreaks in hospitals have increased in recent years and this may lead to the closure of wards
- This group of viruses cannot be grown in cell culture so feline calicivirus used as a surrogate

# **Inactivation of Feline Caliciviruses**

Sattar SA. J Hosp Infect 2004;56:S64

Disinfectant	Log Reduction	Contact Time (min)
Accel HP (5000 ppm)	>4.7	3
Chlorine dioxide (1000 ppm)	4.5	1
Chlorine (1000 ppm)	>4.5	1
QUAT	4.0	10
75% Ethanol	4.7	10

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## Inactivation of C. difficile

- Handwashing, barrier precautions, and meticulous environmental cleaning with an EPA-registered disinfectant should be effective in preventing the spread of the organism
- In units with high endemic *C. difficile* infection rates or in an outbreak setting, use dilute solutions of 5.25-6.15% sodium hypochlorite (e.g., 1:10 dilution of bleach) for routine disinfection. (Category II)
- Glutaraldehyde reliably kills C. difficile spores using exposure times of 5-20 min

# Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization

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#### CJD



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# 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

#### **Prion Diseases**

- Etiology
  - Prions (proteinaceous infectious agent)
    - ◆No agent-specific nucleic acid
    - Host protein (PrP<sup>c</sup>) converts to pathologic isoform (PrP<sup>sc</sup>); PrP gene resides on chromosome 20
    - Mutation in this gene may trigger transformation
    - Accumulates in neural cells, disrupts function, cell death
    - Resistant to conventional D/S procedures

# **latrogenic Transmission of CJD**

- Contaminated medical instruments
  - Electrodes in brain (2)
  - Neurosurgical instruments in brain (4?)
- Implantation of contaminated grafts
  - Dura mater grafts (114)
  - Corneal grafts (2)
- Use of human growth hormone (139) and gonadotropin (4)

### **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





CJD : potential for secondary spread through contaminated surgical instruments



### **CJD and Medical Devices**

- World Health Organization, 2000
  - When instruments contact high infectivity tissue, single-use instruments recommended.
  - If single-use instruments not available, maximum safety attained by destruction of re-usable instruments.
  - Where destruction is not practical, reusable instruments must be decontaminated by immersion in 1N NaOH and autoclaved (121°C/30m), cleaned, rinsed and steam sterilized.
  - After decontamination by steam and NaOH, instruments can be cleaned in automated mechanical reprocessor.

# **Risk Assessment: Patient, Tissue, Device**

#### • Patient

- Known or suspected CJD or other TSEs
- Rapidly progressive dementia
- Familial history of CJD, GSS, FFI
- History of dura mater transplant, cadaver-derived pituitary hormone injection
- Tissue
  - High risk-brain, spinal cord, eyes
- Device
  - Critical or semicritical

### 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 or special prion reprocessing
- Low risk patient, high risk tissue, critical/semicritical device-conventional D/S
- High risk patient, high risk tissue, noncritical deviceconventional disinfection

#### CJD: Disinfection and Sterilization Conclusions

- Critical/SC-cleaning with 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 LD<sub>50</sub> within 1h)
- \*VHP reduced infectivity by 4.5 logs (Lancet 2004;364:521)

# **CJD: Instrument Reprocessing**

- Special prion reprocessing by combination of NaOH and steam sterilization
  - Immerse in 1N NaOH for 1 hour; remove and rinse in water, then transfer to an open pan and autoclave for 1 hour
  - Immerse in 1N NaOH for 1 hour and heat in a gravity displacement sterilizer at 121°C for 30 minutes
- Combined use of autoclaving in sodium hydroxide has raised concerns of possible damage to autoclaves, and hazards to operators due to the caustic vapors.
- Risk can be minimized by the use of polypropylene containment pans and lids.

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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

#### **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.

#### Inactivation of Prions Recent Studies

- Yan et al. Infect Control Hosp Epidemiol 2004;25:280.
  - Enzymatic cleaner (EC)-no effect
- Fichet et al. Lancet 2004;364:521.
  - Phenolic (Environ LpH), alkaline cleaner (AC), EC+VHP-effective
- Baier et al. J Hosp Infect 2004;57:80. AC-effective
- Lemmer et al. J Gen Virol 2004;85:3805.
  - SDS/NaOH, AC, 0.2% PA, 5% SDS-effective (in vitro)
- Jackson et al. J Gen Virol 2005;86:869. E (Pronase, PK)-effective
- Race R and Raymond G. J Virol 2004;78:2164.
  - Environ LpH-effective

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## Endoscopes/AERS

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#### **Murphy Was an ICP!**

#### Murphy's Law

#### "Whatever can go wrong will go wrong"

#### Corollary

"...in the worst possible way at the worst possible time"

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#### **ENDOSCOPE CHANNELS**



#### **GI ENDOSCOPES AND BRONCHOSCOPES**

- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI 10<sup>9</sup> in/10<sup>5</sup> out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to crosstransmission
- 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

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

## **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



## **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

#### **Rinse Water for HLD**

- Endoscopes-After HLD, rinse endoscopes and flush channels with sterile water, filtered water, or tapwater followed by a rinse with 70-90% ethyl or isopropyl alcohol
- Other Semicritical Devices-After HLD, use sterile water, filtered water, or tapwater followed by an alcohol rinse for devices that contact upper respiratory tract (II).
  - No recommendation for sterile or filtered water versus tapwater alone for devices that contact mm of rectum or vagina.





#### 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





# 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

#### **Special Instrument Reprocessing Issues**

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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
- 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

## **Endocavitary Probe Covers**

- Sterile transvaginal probe covers had a very high rate pf 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)



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### **Prostate Biopsy Probe**

- Evaluated effectiveness of HLD when assembled (needle biopsy holder in probe) and unassembled.
- Inoculated (10<sup>6</sup>-10<sup>7</sup> *P.aeruginosa*): internal lumen/outside surface of needle biopsy holder; internal lumen of probe with and without needle biopsy holder in place
- Conclusion: HLD achieved when unassembled but not when assembled





## **HBV and Blood Glucose Monitoring**

- Three outbreaks of HBV in LTC associated with glucose monitoring (MMWR; 2005:54-220)
- Assign separate glucometers to individual patients. If a glucometer must be reused for another patient, the exterior surfaces of the device must be disinfected.
- Disinfect with disinfectant with TB or HBV/HIV claim, or a dilute bleach solution of 1:10-1:100 concentration.
- Directions vary by manufacturer: alcohol damages light emitting diodes (LED) readout; QUATs may damage metal parts.



## **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? Yes






## **Effectiveness of Microfiber Mop**

- Test conditions with a EPA-registered disinfectant: compared routine mop and bucket; microfiber mop and bucket; microfiber mop and system bucket. Twenty-four replicates per condition.
- Conducted RODAC sampling before and after floor disinfection (5 samples per room)
- New disinfectant solution for each test condition
- Dry time varied from 2 (routine mop and bucket)-8 (microfiber mop and bucket) minutes

## **Effectiveness of Microfiber Mop**

Disinfectant-regular mop	95%
Disinfectant-Microfiber system	95%
Disinfectant-Microfiber mop and regular mop bucket	88%
Detergent-regular mop	68%



### **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 after 300 wipes.
- 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

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# Issue/Controversy

"Science-based" guideline versus "policy-based" guideline

### "Science-based" or "Policy-based" Guideline

- Science-based-recommendations based of peer-reviewed scientific studies
- Policy-based-recommendations based on EPA and FDA regulations and registration claims
  - High-level disinfection with glutaraldehyde for 20m/20° (at least 33 studies support 20m/20°) vs 45m/25°;
  - Low-level disinfection for at least 60 sec (at least 14 studies support 60 sec) vs 10 min

### "Science-based" or "Policy-based" Guideline

- FDA registration protocol does not allow cleaning
- Must kill 10<sup>5</sup>-10<sup>6</sup> Mtb, dried on scope, in presence of 2% horse serum, and in absence of cleaning.
- All professional organization guidelines, 10-20 min glutaraldehyde
- When guidelines followed, no evidence of disease transmission
- Unresolved, but "science-based' recommendation with recognition of FDA/EPA policies.

#### Disinfection and Sterilization: New HICPAC Guidelines

- **Pr**ovide overview
- Discuss processes and products
- Emerging pathogens and prions
- Special instrument reprocessing issues
- Issues and controversies (e.g. glutaraldehyde exposure time 45m/25°C vs 20m/20°C)

#### Disinfection and Sterilization: New HICPAC Guidelines

- Sterilization practices
  - Monitoring
  - Storage of sterile items
  - Reuse of single use items
- Disinfection of noncritical surfaces
  - Patient care items
  - Housekeeping surfaces

# Thank you

## References

- Rutala WA, Weber DJ. CJD: Recommendations for disinfection and sterilization. Clin Inf Dis 2001;32:1348
- Rutala WA, Weber DJ. Disinfection and sterilization: What clinicians need to know. Clin Infect Dis 2004;39:702
- Rutala WA, Weber DJ, HICPAC. CDC guideline for disinfection and sterilization in healthcare facilities. In press.
- Rutala WA. APIC guideline for selection and use of disinfectants. Am J Infect Control 1996;24:313

### **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.
- Following a positive biological indicator with steam sterilization, objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or procedure is defective or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the suspect load.

### **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.

## **Reuse of Single Use Devices**

### **FDA Developments**

- August 2000, FDA issued final SUD Enforcement Guidance. Hospitals and TPR regulated the same as original equipment manufacturer (OEM).
- A device labeled for single-use only that is reprocessed is considered as a new device. Hospital is considered the manufacturer.
- As a new device, all federal controls regarding the manufacture and marketing of the device apply.

### Hospital's Options: USA

- Option 1-Comply with enforcement guidance (August 14, 2000) and continue to reprocess SUDs
- Option 2-Use Third Party Reprocessor (premarket requirements new for TPR as they have been using nonpremarket requirements)
- Option 3-avoid reuse of SUDs

### Recommendations Quality Control

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency, staff should:
  - hands-on training
  - all work supervised until competency is documented
  - competency testing should be conducted at commencement of employment and regularly
  - review written reprocessing instructions to ensure compliance

### **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 1 min
- 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

### Detergents or Disinfectants for Surface Disinfection

- Process noncritical patient-care equipment with a EPAregistered disinfectant or disinfectant/detergent at the proper use dilution and a contact time of at least 1 min.
- Use disinfectant for housekeeping purposes when uncertain if cleaning personnel not able to: distinguish soiled areas containing blood from dirt; or determine when MDROs are likely in the environment.