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# Disinfection and Sterilization Guidelines: What You Need to Know

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# Disinfection and Sterilization

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- Provide overview of disinfection and sterilization recommendations
- Review significant revisions
  - Surface disinfection
  - Emerging pathogens (e.g., *C. difficile*) and prions (CJD)
  - Endoscope reprocessing
  - Semicritical equipment: endocavitary probes, applanation tonometers

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**[disinfectionandsterilization.org](http://disinfectionandsterilization.org)**

# Disinfection and Sterilization in Healthcare Facilities

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

## ● 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

# Efficacy of Disinfection/Sterilization

## Influencing Factors

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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 and Sterilization

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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

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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

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- Surgical instruments
- Cardiac catheters
- Implants

# Chemical Sterilization of “Critical Objects”

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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%)

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Exposure time per manufacturers' recommendations

# Processing “Semicritical” Patient Care Objects

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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, endocavitary probes, etc.
Method:	High-level disinfection

# Semicritical Items

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

# High Level Disinfection of "Semicritical Objects"

Exposure Time  $\geq$  12 m-30m (US), 20°C

<u>Germicide</u>	<u>Concentration</u>
Glutaraldehyde	$\geq$ 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%
Hypochlorite (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

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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 (or detergent for housekeeping surfaces)

# Low-Level Disinfection for “Noncritical” Objects

Exposure time  $\geq$  1 min

Germicide

Use Concentration

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Ethyl or isopropyl alcohol

70-90%

Chlorine

100ppm (1:500 dilution)

Phenolic

UD

Iodophor

UD

Quaternary ammonium

UD

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UD=Manufacturer's recommended use dilution

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# Methods in Sterilization

# Sterilization

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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

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- 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

# New Trends in Sterilization of Patient Equipment

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- Alternatives to ETO-CFC  
ETO-CO<sub>2</sub>, ETO-HCFC, 100% ETO
- New Low Temperature Sterilization Technology  
Hydrogen Peroxide Gas Plasma  
Peracetic Acid  
Ozone

# Ethylene Oxide (ETO)

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- 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

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## 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

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## 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

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## 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

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## 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

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- 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

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- 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)

# Flash Sterilization

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- 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

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

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# Sterilization Practices

# Sterilization Monitoring

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Sterilization monitored routinely by combination of physical, 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

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- 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

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- Monitor each load with physical 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

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- 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

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- 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

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- 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 loss 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.

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# Disinfection and Sterilization of Emerging Pathogens

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- 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

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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

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- Provide overview of disinfection and sterilization recommendations
- Review significant revisions
  - Surface disinfection
  - Emerging pathogens (e.g., *C. difficile*) and prions (CJD)
  - Endoscope reprocessing
  - Semicritical equipment: endocavitary probes, applanation tonometers

# Surface Disinfection

## Noncritical Patient Care-CDC, 2007

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- Disinfecting Noncritical Patient-Care Items
  - Process noncritical patient-care equipment with a 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 (such as after each patient use or once daily or once weekly). *Category IB*

# Surface Disinfection

## Environmental Surfaces-CDC, 2007

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- 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*

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*Clostridium difficile*

# Role of the Environment In Transmission

Hota B, Clin Inf Dis 2004;39:1182

Pathogen	Survival	Environmental Data
<i>C. difficile</i>	Months (spores)	3+
VRE	Days to weeks	3+
MRSA	Days to weeks	2-3+
<i>Acinetobacter</i>	33 days	2-3+
<i>P. aeruginosa</i>	7 h	1+

# Environmental Contamination

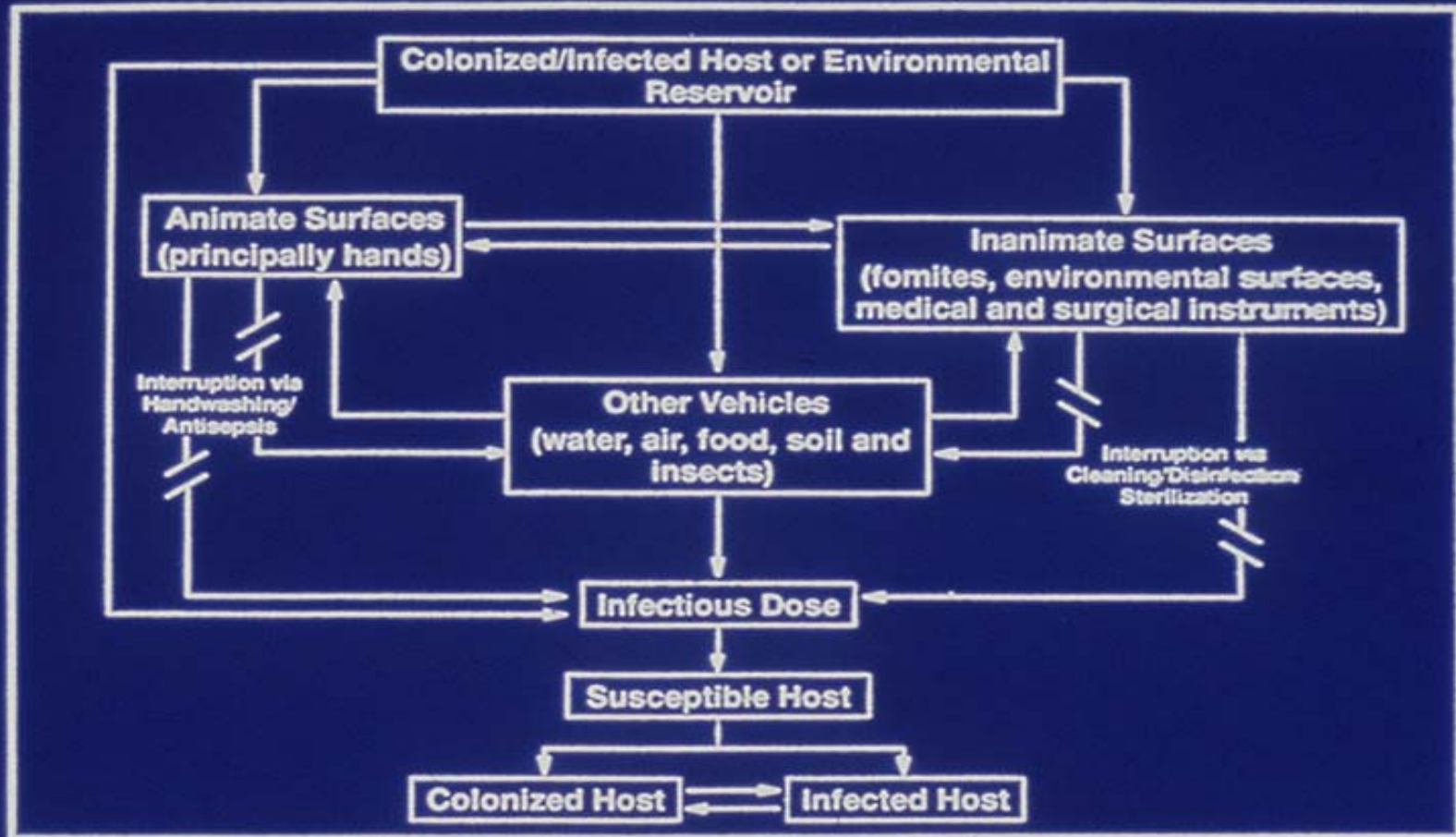
## *C. difficile*

- 25% (117/466) of cultures positive (<10 CFU) for *C. difficile*. >90% of sites positive with incontinent patients. Samore et al. Am J Med 1996;100:32.
- 31.4% of environmental cultures positive for *C. difficile*. Kaatz et al. Am J Epid 1988;127:1289.
- 9.3% (85/910) of environmental cultures positive (floors, toilets, toilet seats) for *C. difficile*. Kim et al. J Inf Dis 1981;143:42.
- 29% (62/216) environmental samples were positive for *C. difficile*. 8% (7/88) culture-negative patient, 29% (11/38) positive cultures in rooms occupied by asymptomatic patients and 49% (44/90) in rooms with patients who had CDAD. NEJM 1989;320:204
- 10% (110/1086) environmental samples were positive for *C. difficile* in case-associated areas and 2.5% (14/489) in areas with no known cases. Fekety et al. Am J Med 1981;70:907.

# Role of the Environment

## *C. difficile*

- The presence of *C. difficile* on the hands correlated with the density of environmental contamination. Samore et al. Am J Med 1996;100:32.
  - 0-25% environmental sites positive-0% hand cultures positive
  - 26-50% environmental sites positive-8% hand cultures positive
  - >50% environmental sites positive-36% hand cultures positive
- 59% of 35 HCWs were *C. difficile* positive after direct contact with culture-positive patients.
- *C. difficile* incidence data correlated significantly with the prevalence of environmental *C. difficile*. Fawley et al. Epid Infect 2001;126:343.
- Environmental contamination does not play a major role in nosocomial CDAD in some endemic situations. Cohen et al. Clin Infect Dis 1997;24:889.



**FIGURE.** Transmission of infectious agents via animate and inanimate surfaces (modified from reference 25).

# Disinfectants and Antiseptics

*C. difficile* spores at 10 and 20 min, Rutala et al, 2006

- ~4 log<sub>10</sub> reduction (3 *C. difficile* strains including BI-9)
  - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50, ~1,200 ppm)
  - Clorox Clean-up, ~1,910 ppm chlorine
  - Tilex, ~25,000 ppm chlorine
  - Steris 20 sterilant, 0.35% peracetic acid
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde
  - Aldahol, 3.4% glutaraldehyde and 26% alcohol

# Control Measures

## *C. difficile*

- Handwashing (soap and water) , contact precautions, and meticulous environmental cleaning (disinfect all surfaces) with an EPA-registered disinfectant should be effective in preventing the spread of the organism. McFarland et al. NEJM 1989;320:204.
- 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)
- For semicritical equipment, glutaraldehyde (20m), OPA (12m) and peracetic acid (12m) reliably kills *C. difficile* spores using normal exposure times

# High-Level Disinfection

## *C. difficile* spores

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- 2% glutaraldehyde is effective against *C. difficile* at 20 minutes
- 0.55% ortho-phthalaldehyde is effective against *C. difficile* at 10 minutes
- Steris 20 is effective against *C. difficile* at 10 and 20 minutes

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# Adenovirus 8

A Common Cause of Epidemic Keratoconjunctivitis

# Adenovirus 8

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- Adenovirus is extremely hardy when deposited on environmental surfaces and may be recovered from plastic and metal surfaces for more than 30 days
- Elimination of adenovirus from inanimate surfaces and ophthalmic instruments is essential in preventing outbreaks of epidemic keratoconjunctivitis
- Unfortunately, no reports that validate CDC recommendations for disinfecting tonometer tips. CDC. MMWR 1985; 34:533.

# CDC, 1985

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- Applanation tonometers-Soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine (~1:10 household bleach)
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol

# Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- Ineffective  $<2 \log_{10}$  reduction
  - Bactoshield (4% CHG)
  - Vesphene (phenolic)
  - 70% isopropyl alcohol
  - 3% hydrogen peroxide
  - TBQ (0.06% QUAT)
  - Novaplus (10% povidone iodine)
  - Soft 'N Sure (0.5% triclosan)
  - Acute-Kare (1% chloroxylenol)
  - Sterilox (218 and 695 ppm chlorine)
  - Dettol (4.8% chloroxylenol)
  - Accel TB (0.5% accelerated hydrogen peroxide)
  - Microcyn (~80 ppm chlorine)

# Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- ~4 log<sub>10</sub> reduction
  - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50)
  - Clorox Clean-up, ~1,910 ppm chlorine
  - Clorox disinfecting spray (65% ethanol, 0.6% Quat)
  - Steris 20 sterilant, 0.35% peracetic acid
  - Ethanol, 70%
  - Lysol disinfecting spray (79.6% ethanol, 0.1% Quat)
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde

# CDC Guidelines

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- CDC, 1985. Applanation tonometers-soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol
- CDC, 2007. Wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5000 ppm chlorine or 70% ethyl alcohol. Category II.
- These results emphasize the proper selection of disinfectants for use in disinfecting semicritical items (e.g., applanation tonometers)

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# Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization

# Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

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Prions

Spores

Mycobacteria

Non-Enveloped Viruses

Fungi

Bacteria

Enveloped Viruses



CJD : potential for secondary spread through contaminated surgical instruments

# Risk Assessment for Special Prion Reprocessing: Patient, Tissue, Device

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- High-Risk 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
- High-Risk Tissue
  - Brain, spinal cord, eyes
- High-Risk Device
  - Critical or semicritical

# 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 LD<sub>50</sub> within 1h)

\*VHP reduced infectivity by 4.5 logs (Lancet 2004;364:521)

# Inactivation of Prions

## Recent Studies

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- 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

# GI ENDOSCOPES AND BRONCHOSCOPES

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- 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

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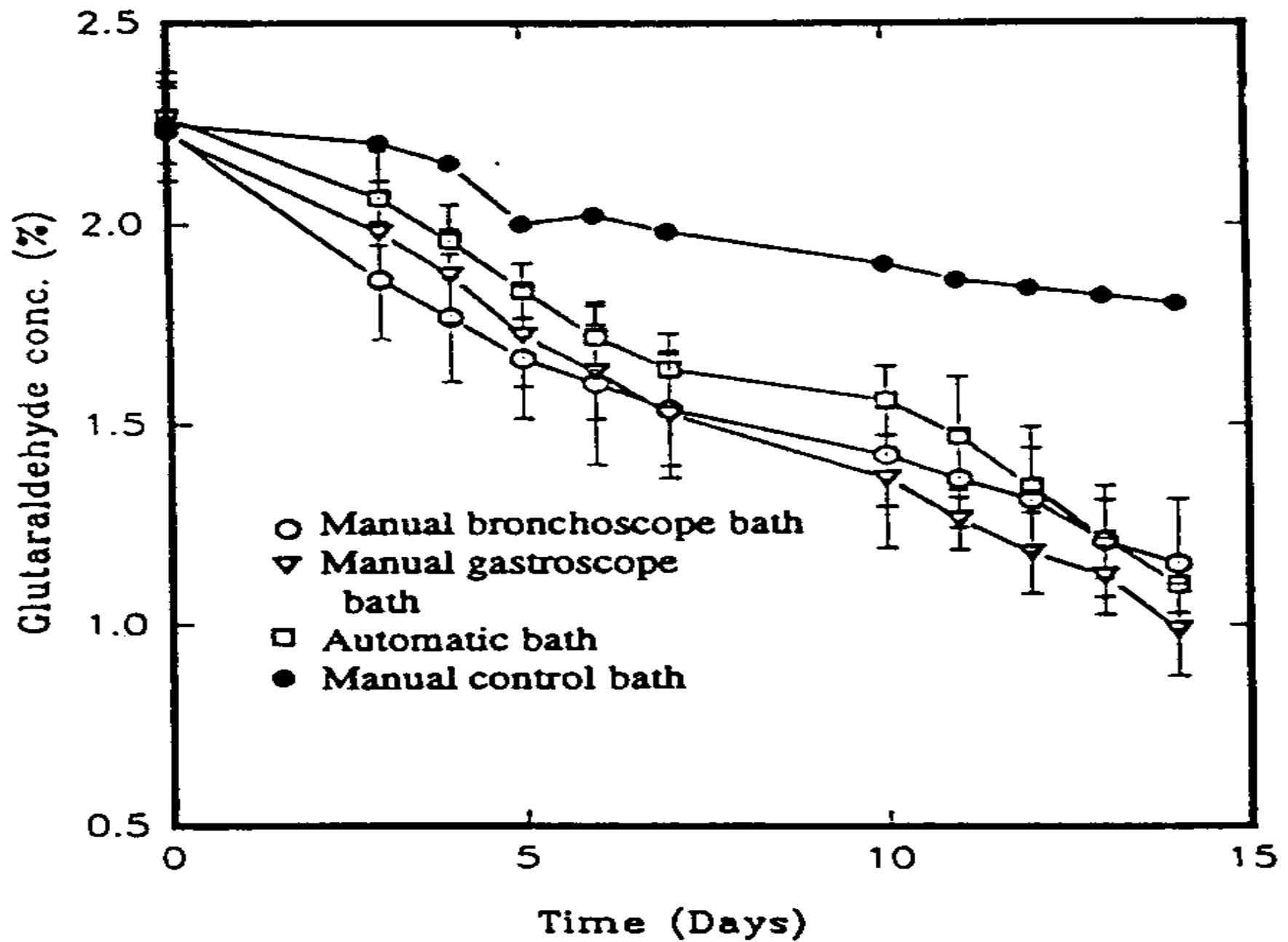
- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents *Salmonella sp.* and *P. aeruginosa*
  - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
  - 90 infections transmitted
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*

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

# ENDOSCOPE DISINFECTION

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- 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



# Minimum Effective Concentration Chemical Sterilant

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- 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. Check solution each day of use (or more frequently) using the appropriate indicator.
- Record results

# ENDOSCOPE SAFETY

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- 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
- Perform microbiologic testing of the endoscope or rinse water-no recommendation (unresolved issue)

# Endocavitary Probes

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- 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

# Rinse Recommendations for Semicritical Devices

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- Use sterile water, filtered water or tapwater followed by an alcohol rinse for semicritical equipment that contact mucous membranes of the upper respiratory tract (e.g., nose pharynx, esophagus). *Category II*
- No recommendation to use sterile or filtered water rather than tapwater for rinsing semicritical equipment that will have contact with the mucous membranes of the rectum (rectal probes) or vagina (vaginal probes)

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# Reuse of Single Use Devices

# FDA Developments

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- 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.**

# USA Hospital's Options

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- 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 non-premarket requirements)
- Option 3-avoid reuse of SUDs

# Recommendations

## Quality Control

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- 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
  - Conduct infection control rounds in high-risk areas (GI)

# Disinfection and Sterilization

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- Provide overview of disinfection and sterilization recommendations
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**Thank you**

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