

**Disinfection and Sterilization:
Meeting the CDC Guideline**

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Disinfection and Sterilization

- Provide overview of disinfection and sterilization recommendations
 - Indications and methods for sterilization, high-level disinfection and low-level disinfection
 - Cleaning of patient-care devices
 - Sterilization practices
 - Semicritical equipment: endocavitary probes, endoscopes

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 Spring 2008

**Efficacy of Disinfection/Sterilization
Influencing Factors**

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

Disinfection 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** (or non-germicidal detergent).

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, ozone or chemical sterilization.

Critical Objects
<ul style="list-style-type: none"> ● Surgical instruments ● Cardiac catheters ● Implants

Sterilization of "Critical Objects"
<p style="text-align: center;">Steam sterilization Hydrogen peroxide gas plasma Ethylene oxide Peracetic acid-chemical sterilization Ozone Steam formaldehyde</p>

Chemical Sterilization of "Critical Objects"
<p style="text-align: center;">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%)</p> <hr style="width: 20%; margin-left: auto; margin-right: auto;"/> <p style="text-align: center;">Exposure time per manufacturers' recommendations</p>

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

Semicritical Items
<ul style="list-style-type: none"> ● Endoscopes ● Respiratory therapy equipment ● Anesthesia equipment ● Endocavitary probes ● Tonometers ● Diaphragm fitting rings

High Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 12 m-30m (US), 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%
Hypochlorite (free chlorine)*	650-675 ppm
Glut and phenol/phenate**	1.21%/1.93%

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

Pasteurization

65-77°C for ~30 minutes

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 (or detergent for housekeeping surfaces)

Low-Level Disinfection for "Noncritical" Objects

Exposure time ≥ 1 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

Methods in Sterilization

Sterilization of "Critical Objects"

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Peracetic acid-chemical sterilization
Ozone
Steam formaldehyde

Cleaning

- All used items sent to Central Processing area should be considered contaminated (unless decontaminated in the area of origin)
- Used items handled with gloves (forceps or tongs are sometimes needed to avoid exposure to sharps)
- Decontaminated by a mechanical or manual method to render them safer to handle

Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used as soiled materials become dried onto the instruments.

Cleaning

- Mechanical cleaning machines-automated equipment may increase productivity, improve cleaning effectiveness, and decrease worker exposure
 - Utensil washer-sanitizer
 - Ultrasonic cleaner
 - Washer sterilizer
 - Dishwasher
 - Washer disinfectant
- Manual

Bioburden on Surgical Devices

- Bioburden on instruments used in surgery (Nystrom, 1981)
 - 62% contaminated with $<10^1$
 - 82% contaminated with $<10^2$
 - 91% contaminated with $<10^3$
- Bioburden on surgical instruments (Rutala, 1997)
 - 72% contained $<10^1$
 - 86% contained $<10^2$

Washer/Disinfectant

Rutala WA, Gergen MF, Weber DJ, Unpublished results, 2007

- Five Chambers
 - Pre-wash: water/enzymatic is circulated over the load for 1 min
 - Wash: detergent wash solution (150°F) is sprayed over load for 4 min
 - Ultrasonic cleaning: basket is lowered into ultrasonic cleaning tank with detergent for 4 min
 - Thermal and lubricant rinse: hot water (180°F) is sprayed over load for 1 min; instrument milk lubricant is added to the water and is sprayed over the load
 - Drying: blower starts for 4 min and temperature in drying chamber 180°F

Washer/Disinfectant

Removal/inactivation of inoculum (Exposed) on Instruments

WD Conditions	Organism	Inoculum	Log Reduction	Positives
Routine	MRSA	2.6×10^7	Complete	0/8
Routine	VRE	2.6×10^7	Complete	0/8
Routine	<i>P aeruginosa</i>	2.1×10^7	Complete	0/8
Routine	<i>M terrae</i>	1.4×10^8	7.8	2/8
Routine	GS spores	5.3×10^6	4.8	11/14
No Enz/Det	VRE	2.5×10^7	Complete	0/10
No Enz/Det	GS spores	8.3×10^6	5.5	8/10

Washer/Disinfector				
Removal/Inactivation of Inoculum (Non-Exposed) on Instruments				
WD Conditions	Organism	Inoculum	Log Reduction	Positives
Routine	MRSA	2.6x10 ⁷	Complete	0/8
Routine	VRE	2.9x10 ⁷	Complete	0/8
Routine	<i>P aeruginosa</i>	2.1x10 ⁷	Complete	0/8
Routine	<i>M ferreae</i>	1.2x10 ⁹	7.6	6/8
Routine	GS spores	8.1x10 ⁶	~1	12/12
No Enz/Det	VRE	2.4x10 ⁷	Complete	0/10
No Enz/Det	GS spores	8.7x10 ⁶	1.6	10/10

Washer/disinfectors are very effective in removing/inactivating microorganisms from instruments

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	20-30 min
Textile packs	4 min	5 min

New Trends in Sterilization of Patient Equipment

- 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
- 0.2u bacterial filters may not be suitable for producing sterile water from tapwater
- More expensive (endoscope repairs, operating costs) than HLD
- Point-of-use system, no long-term storage

Ozone

- Advantages
 - Used for moisture and heat-sensitive items
 - Ozone generated from oxygen and water
 - No aeration because no toxic by-products
 - FDA cleared for metal and plastic surgical instruments, including some instruments with lumens
- Disadvantages
 - Sterilization chamber small, 4ft³
 - Limited use and limited microbicidal efficacy data

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 (times, temperatures, gas conc)
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Aerate surgical and medical items that have been sterilized in the ETO sterilizer

Recommendations Methods of Sterilization

- Peracetic acid immersion system can be used to sterilize heat-sensitive items that can be immersed
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)
- Dry heat sterilization (e.g., 340F for 60 minutes) can be used to sterilize items (e.g., powders, oils) that can sustain high temperatures

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 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

Sterilization Practices

Objectives of Monitoring the Sterilization Process

- Assures probability of absence of all living organisms on medical devices being processed
- Detect failures as soon as possible
- Removes medical device involved in failures before patient use

Sterilization Monitoring

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 (Class 1-6)
- 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*
 - Ozone - *G. stearothermophilus*

Packaging

- Once items are cleaned, dried, and inspected, items are wrapped or placed in a rigid container
- Arranged in tray/basket according to guidelines
 - Hinged instruments opened
 - Items with removable parts should be disassembled
 - Heavy items positioned not to damage delicate items
- Several choices to maintain sterility of instruments: rigid containers, peel pouched; sterilization wraps

Packaging Sterilization Wraps

- An effective sterilization wrap would:
 - Allow penetration of the sterilant
 - Provide an effective barrier to microbial penetration
 - Maintain the sterility of the processed item after sterilization
 - Puncture resistant and flexible
 - Drapeable and easy to use
- Multiple layers are still common practice due to the rigors of handling

Recommendations Monitoring of Sterilizers

- Monitor each load with physical and chemical (internal and external) indicators. If the internal indicator is visible, an external indicator is not needed.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer (Class 6 emulating indicators not a substitute).
- Use biological indicators for every load containing implantable items and quarantine items, whenever possible, until the biological indicator is negative.

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. These non-sterile items should be retrieved, if possible, and reprocessed.

Load Configuration

- Place items correctly and loosely into the basket, shelf, or cart of the sterilizer so as not to impede the penetration of the sterilant.

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 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.

Semicritical Devices

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*

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

Endoscope Reprocessing, Worldwide

- Worldwide, endoscopy reprocessing varies greatly
 - India, of 133 endoscopy centers, only 1/3 performed even a minimum disinfection (1% glut for 2 min)
 - Brazil, "a high standard ...occur only exceptionally"
 - Western Europe, >30% did not adequately disinfect
 - Japan, found "exceedingly poor" disinfection protocols
 - US, 25% of endoscopes revealed >100,000 bacteria

Schwanze DB. Gastroint Endoscopy 2002;10:216

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

High Level Disinfection of "Semicritical Objects"

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

Germicide	Concentration
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 pheno/phenate**	1.21%/1.93%

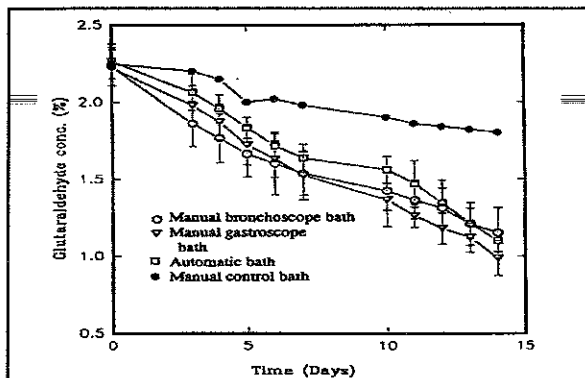
*May cause cosmetic and functional damage; **efficacy not verified

Comparison of Glutaraldehyde and OPA

- | | |
|--|---|
| <ul style="list-style-type: none"> ● >2.0% Glutaraldehyde ● HLD: 45m at 25°C (used 20°m/20C) ● Needs activator ● 14 day use life ● 2 year shelf life ● ACGIH ceiling limit, 0.05ppm ● Strong odor ● MEC, 1.5% ● Cost - \$12/gallon ● Irritant to mucous membranes | <ul style="list-style-type: none"> ● 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 ● Exposure may cause hypersensitivity |
|--|---|

Endoscope Reprocessing Inappropriate Disinfectants

- Do not use the disinfectants below for endoscopes
 - Benzalkonium chloride (Greene WH. Gastroenterol 1974;67:912)
 - 70% alcohol (Elson CO. Gastroenterol 1975;69:507)
 - QUAT (Tuffnell PG. Canad J Publ Health 1976;67:141)
 - Hexachlorophene (Dean AG. Lancet 1977;2:134)
 - Hexachlorophene (Beecham HJ. JAMA 1979;101:3)
 - 70% alcohol (Parker HW. Gastro Endos 1979;25:102)
 - Povidone-iodine (Low DE. Arch Intern Med 1980;107:6)
 - Cetrimonium bromide. (Schliessler KH. Lancet 1980;2:1246)



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

Endoscope Reprocessing

- Process endoscopes (e.g., arthroscopes, cystoscopes, laparoscopes) that pass through normally sterile tissue using a sterilization method before each use; if this is not feasible, provide at least high-level disinfection followed by a sterile water rinse.
- Mechanically cleaned reusable accessories inserted into endoscopes (e.g., biopsy forceps) that break the mucosal barrier and sterilize between each patient.

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

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

Prostate Biopsy Probe

- Evaluated effectiveness of HLD when assembled (needle biopsy holder in probe) and unassembled.
- Inoculated (10^6 - 10^7 *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

Rinse Recommendations for Semicritical Devices

- 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)

Noncritical Items

Surface Disinfection Noncritical Patient Care-CDC, 2008

- 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, 2008

- 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*

Environmental Cleaning in Surgical Services

- Damp dusted before first procedure with disinfectant
- After each surgical procedural, a clean environment should be reestablished
- Operating room equipment and furniture that are visibly soiled should be cleaned with a disinfectant
- Visibly soiled areas on the floor should be cleaned with a disinfectant
- 3ft to 4ft perimeter around the surgical field when soiled

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

Disinfection and Sterilization of Emerging Pathogens

Disinfection and Sterilization of Emerging Pathogens

- Hepatitis C virus
- *Clostridium difficile*
- *Cryptosporidium*
- *Helicobacter pylori*
- *E.coli* O157: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

Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization

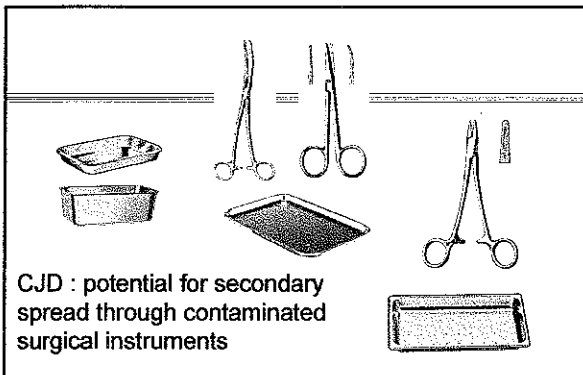
(not in CDC Guideline now but in AORN)

Prion Diseases

- Etiology
 - Prions
 - ◆ Proteinaceous infectious agent
 - ◆ No agent-specific nucleic acid
 - ◆ Host protein converts to pathologic isoform
 - ◆ Accumulates in neural cells, disrupts function
 - ◆ Resistant to conventional D/S procedures

Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

- Prions
- Spores
- Mycobacteria
- Non-Enveloped Viruses
- Fungi
- Bacteria
- Enveloped Viruses



Iatrogenic Transmission of CJD

- Contaminated medical instruments
 - Electrodes in brain (2)
 - Neurosurgical instruments in brain (4)
- Dura mater grafts (>110)
- Corneal grafts (3)
- Human growth hormone and gonadotropin (>130)

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

- 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 LD₅₀ within 1h)

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

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
- Peretz et al. J Virol 2006;80:1. Acidic SDS and SDS+SS-effective
- Fichet et al. JHI 2007;67:278. Gaseous HP-effective

Failure to Follow Disinfection and Sterilization Principles

Failure to Follow Disinfection and Sterilization Principles

- These events are relatively frequent; however, not commonly appreciated
- Human errors
 - Time setting of 132°C steam sterilizer at 0 min rather than 4 min
 - Failure to sterilize critical items after cleaning
 - Exposure time on AER set at 5 min rather than 20 min
- Equipment failures-biopsy port caps not secure
- System problems-unwrapped specula

Failure to Follow Disinfection and Sterilization Principles

Scenario:

Hospital A has been purchased an AER for GI endoscope reprocessing. The AER has been in use for 9 months. The hospital was using >2% glutaraldehyde with an intended exposure time of 20 minutes. It was discovered that the exposure time was incorrectly set at 10 minutes. Endoscopes for 9 months were processed at 10 minutes rather than the recommended 20 minutes.

What Do You Do?

Failure to Follow Disinfection and Sterilization Principles

- Method for assessing patient risk for adverse events
- Although exposure events are often unique, can approach the evaluation of potential failure using a standardized approach
- Propose a sequence of 14 steps that form a general approach to a possible failure of disinfection/sterilization (D/S)
- D/S failure could result in patient exposure to an infectious agent

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.**

USA Hospital's Options

- 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

Occupational Health and Exposure

- Inform each worker of the possible health effects of exposure to infectious agents and/or chemicals
- Educate workers in the proper selection and proper use of PPE
- Ensure that workers wear appropriate PPE to preclude exposure to infectious agents or chemicals
- Establish a program for monitoring occupational exposure to regulated chemicals
- Exclude workers with weeping dermatitis of hands from direct contact with patient-care equipment

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

Summary

- Disinfection and sterilization guidelines must be followed to prevent exposure to pathogens that may lead to infection
- Delivery of sterile products for use in patient care depends not only on the effectiveness of the sterilization process but also on cleaning, disassembling and packaging of the device, loading and monitoring the sterilizer

Disinfection and Sterilization

- Provide overview of disinfection and sterilization recommendations
 - Indications and methods for sterilization, high-level disinfection and low-level disinfection
 - Cleaning of patient-care devices
 - Sterilization practices
 - Semicritical equipment: endocavitary probes, endoscopes

Thank you

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