



disinfectionandsterilization.org

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 Reviewed by OMB Publication in December 2006

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**.



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, ETO, hydrogen peroxide plasma, ozone or chemical sterilization.



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
Object:	Free of all microorganisms except high numbers
Level germicidal action:	Kills all microorganisms except high numbers of
Examples:	Respiratory therapy and anesthesia equipment, GI
Method:	High-level disinfection



"Semicritical Objects"			
Exposure Time ≥ 12 m-3	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%		
Hypochlorite (free chlorine)*	650-675 ppm		
Glut and phenol/phenate**	1.21%/1.93%		







Processing "Noncritical" Patient Care Objects

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







Methods in Sterilization

Sterilization

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









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

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





- New high-level disinfectants (HLD)
 - Superoxidized water
- New chemical sterilants/HLD
 - 3.4% glutaraldehyde with 26% isopropanol
 - 8.3% hydrogen peroxide with 7.0% peracetic acid
- New sterilization process
 - Ozone
- *Limited data in the scientific literature that assesses the antimicrobial activity or material compatibility

Disinfection and Sterilization of Emerging Pathogens

Disinfection and Sterilization of Emerging Pathogens

- Hepatitis C virus
- Clostridium difficile
- Cryptosporidium
- Helicobacter pylori
- E.coli 0157:H7
- Antibiotic-resistant microbes (MDR-TB, VRE, MRSA)
- SARS Coronavirus, avian influenza, norovirus
- Bioterrorism agents (anthrax, plague, smallpox)

Disinfection and Sterilization of Emerging Pathogens

Standard disinfection and sterilization procedures for patient care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood and other body fluids from persons infected with emerging pathogens



Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Prions Spores Mycobacteria Non-Enveloped Viruses Fungi Bacteria Enveloped Viruses







Endoscopes/AERS

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"











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









Disinfection and Sterilization New Research

- Inactivation of Clostridium difficile
- Disinfectants recommended for disinfecting eye examination equipment (e.g., applanation tonometer tips)
- Effectiveness and functional impact of disinfectants on computer keyboards
- Microfiber cloths/mops
- Absorption of QUATS
- Failure to follow disinfection/sterilization principles-patient exposures



Role of the Environment In Transmission Hota B, Clin Inf Dis 2004;39:1182				
Pathogen	Survival	Environmental Data		
C. difficile	Months (spores)	3+		
VRE	Days to weeks	3+		
MRSA	Days to weeks	2-3+		
Acinetobacter	33 days	2-3+		
P. aeruginosa	7 h	1+		

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

Role of the Environment

- 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 culturepositive 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.







High-Level Disinfection C. difficile spores

- 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

Adenovirus 8

A Common Cause of Epidemic Keratoconjunctivitis



Adenovirus 8

- 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 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









Infrared Coagulation (IRC)

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



Infrared Coagulation Testing (Rutala, Gergen, Weber, 2006)					
Inoculum	% Reduction				
~1.6 x 10 ⁷	100				
~9.3 x 10 ⁵	100				
~8.3 x 10 ⁶	100				
	d Coagulation Jutala, Gergen, Weber, 2 Inoculum ~1.6 x 10 ⁷ ~9.3 x 10 ⁵ ~8.3 x 10 ⁶				



Microfiber Cleaning

- Pad contains fibers (polyester and polyamide) that provide a cleaning surface 40 times greater than conventional string mops
- Proposed advantages: reduce chemical use and disposal (disinfectant solution not changed after every third room, clean microfiber per room [washing lifetime 500-1000]); light (~5 lb less than string mop) and ergonomic; reduce cleaning times.
- Does the microfiber provide the same or better removal of microorganisms on surfaces?







Effectiveness of Microfiber Mop

- 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 (Rutala et al, 2006)				
Disinfectant-regular mop	95%			
Disinfectant-Microfiber system	95%			
Disinfectant-Microfiber mop and regular mop bucket	88%			
Detergent-regular mop	68%			











Enterococcus species		Statistics - 1-3-25				
Disinfectant	Efficacy of Disinfectant, by Time of Microbial Challenge and Duration of Disinfectant Exposure, %					
	Challenge at 6 Hours		Challenge at 24 Hours		Challenge at 48 Hours	
	10-min Exposure	60-min Exposure	10-min Exposure	60-min Exposure	10-min Exposure	60-min Exposure
Alcohol	3.05	5.67	12.58	3.31	10.89	5.59
CaviWipes	100.00	100.00	100.00	100.00	100.00	100.00
Clorox Disinfecting Wipes	100.00	100.00	100.00	100.00	100.00	100.00
Sani-Cloth Plus	100.00	100.00	100.00	100.00	100.00	100.00
Sterile water	0.00	0.28	9.69	0.00	0.00	9.09

TABLE 3. Sustained Efficacy of Disinfectants Applied to Keyboard Against Vancomycin-Resistant Enterococcus Species

NOTE. Efficacy was calculated as the percentage difference in the number of colony-forming units on the treated keys, compared with the number of colony-forming units on the control keys. Challenge times are hours since disinfectant exposure.











Failure to Follow Disinfection and Sterilization Principles

Scenario:

Hospital A discovered that for the past 3 days all surgical instruments were exposed to steam sterilization at 132°C for 0 minutes rather than the intended 4 minutes. A central processing technician turned the timer to 0 minutes in error.

Failure to Follow Disinfection and Sterilization Principles

- What do you do?
 - Follow the 14 steps at website disinfectionandsterilization.org (confirm failure, embargo improperly D/S items, investigate the cause, etc)
 - The steps provide a general outline, but each event is unique and you must be flexible and adaptable
 - Communication among key stakeholders is very important
 - Ethical to notify patients if there is a risk-should be upfront and factual
 - Train staff and access processes/practices to minimize recurrence
 - These are stressful events (patients and staff) but the goal is to assess failure and protect patients rather than assessing blame







Rutala WA, Weber DJ. CJD: Recommendations for disinfection and sterilization. Clin Infect 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. MMWR. In press. Rutala WA. APIC guideline for selection and use of disinfectants. Am J Infect Control 1996;24:313

References

- Rutala WA, Peacock JE, Gergen MF, Sobsey MD, Weber DJ. Efficacy of hospital germicides against adenovirus 8, a common cause of epidemic keratoconjunctivitis in health care facilities. Antimicrob Agents Chemother 2006;50:1419
- Rutala WA, White MS, Gergen MF, Weber DJ. Bacterial contamination of keyboards: Efficacy and functional impact of disinfectants. Infect Control Hosp Epidemiol 2006;27:372
- Rutala WA, Weber DJ. Surface disinfection: Should we do it? J Hosp Infect. 2000; 48:S64.