Disinfection and Sterilization:
Current Issues and New Technologies

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Disclosure: Clorox, Advanced Sterilization Products

Disinfection and Sterilization: Current Issues and New Technologies

- Disinfection and sterilization principles
- Current issues
  - Critical-cleaning with washer disinfectors, Class 6 chemical indicator, flash sterilization, ozone, VHP, ETO, prions
  - Semicritical items-*C. difficile* spores, laryngoscopes, new AERs/HLDs, endocavitary
  - Noncritical-surface disinfection
    - Accelerated hydrogen peroxide (AHP)
    - Norovirus and *C. difficile* spores (HP vapor)
    - Microfiber
    - Computers-sustained antimicrobial activity, touchscreen cleaning
    - Germicides-MRSA inactivation by disinfectants, technique
    - Green products

disinfectionandsterilization.org

Disinfection and Sterilization

EH Spaulding believed that how an object will be disinfected/sterilized 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**.

Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

Sterilization of "Critical Objects"

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Peracetic acid (0.2%)-chemical sterilization

Ozone

Vaporized hydrogen peroxide

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 (US), 20°C

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde (12 m US)	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	≥7.35%/≥0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Glut and phenol/phenate	1.21%/1.93%
Glut and alcohol	3.4%/26% IPA

*May cause cosmetic and functional damage

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

Critical Items/Sterilization

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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 disinfector
- 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 Disinfector

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 Disinfector

Removal/Inactivation of Inoculum (Exposed) on Instruments

WD Conditions	Organism	Inoculum	Log Reduction	Positives
Routine	MRSA	$2.6x10^7$	Complete	0/8
Routine	VRE	$2.6x10^7$	Complete	0/8
Routine	*P aeruginosa*	$2.1x10^7$	Complete	0/8
Routine	*M terrae*	$1.4x10^8$	7.8	2/8
Routine	GS spores	$5.3x10^6$	4.8	11/14
No Enz/Det	VRE	$2.5x10^7$	Complete	0/10
No Enz/Det	GS spores	$8.3x10^6$	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	*P aeruginosa*	$2.1x10^7$	Complete	0/8
Routine	*M terrae*	$1.2x10^8$	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

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.

Types of Sterilization Monitoring Devices

- Chemical Indicators
  - External chemical indicators
    - Class 1 (process indicator, indicator tape)-outside of every package
  - Internal chemical indicators
    - Class 2 (Bowie Dick)-routine testing of vacuum; within a test pack daily in an empty sterilizer
    - Class 3 (single variable indicator; temperature, ETO conc)-may be used as internal monitor
    - Class 4 (multi-variable indicator)-may be use as internal monitor

Types of Sterilization Monitoring Devices

- Chemical Indicators
  - Internal chemical indicator
    - Class 5 (integrating indicator)-may be used as internal monitor, suppose to mimic the behavior of a biological indicator (BI)
    - Class 6 (emulating indicator)-suppose to emulate or mimic the behavior of a biological indicator; are cycle-specific (need a emulating indicator designed to validate a 10 min/270F cycle and a different indicator to validate a 3 min/270F). No professional organization (e.g., AORN) has recommended the use of Class 6 emulating indicator as a substitute for biological indicators and there are no data that demonstrate that it mimics a BI at suboptimal sterilization times.

Flash Sterilization
AORN, CDC Guidelines

- Flash sterilization 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)
- Do not used flash sterilization for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time

Flash Sterilization
What is the definition?

- In 1942, Underwood defined flash sterilization as 3 minutes at 250°F for instruments when there is an "extreme emergency".
- In 1969, Perkins redefined flash sterilization to the current definition of an unwrapped item at 270°F for 3 minutes in a gravity sterilizer.

Flash Sterilization

- Flash sterilization principles as defined by Underwood/Perkins and perpetuated by professional organizations are no longer applicable as the longstanding concerns have changed over the past 40 years. Historically, these issues included:
  - Lack of a timely biological indicator to monitor performance (now 1 hr) ;
  - Possibility for contamination of processed items during transportation to the Operating Rooms (containers ensure aseptic delivery to the OR);
  - Sterilization cycle parameters are minimal (extended exposure times) .
- And while no compromise with patient safety can be tolerated, prohibitions and principles regarding flash sterilization should be reassessed by professional organizations.
- Proposal: comply with current recommendations but recommendations should change to define what cycles/conditions are suboptimal.

Sterilization of "Critical Objects"

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Peracetic acid-chemical sterilization

Ozone

- Advantages
  - Used for moisture and heat-sensitive items
  - Ozone generated from oxygen and water (oxidizing)
  - No aeration because no toxic by-products
  - FDA cleared for metal and plastic surgical instruments, including some instruments with lumens
- Disadvantages
  - Sterilization chamber small, $4ft^3$
  - Limited use (material compatibility/penetrability/organic material resistance?) and limited comparative microbicidal efficacy data

V-PRO™1, Vaporized Hydrogen Peroxide

- Advantages
  - Safe for the environment and health care worker; it leaves no toxic residuals
  - Fast - cycle time is 55 min and no aeration necessary
  - Used for heat and moisture sensitive items (metal and nonmetal devices)
- Disadvantages
  - Sterilization chamber is small, about $4.8ft^3$
  - Medical devices restrictions based on lumen internal diameter and length-see manufacturer's recommendations, e.g., SS lumen 1mm diameter, 125mm length
  - Not used for liquid, linens, powders, or any cellulose materials
  - Requires synthetic packaging (polypropylene)
  - Limited use and limited comparative microbicidal efficacy data

Document ETO Sterilizer Loads

Federal Register, December 28, 2007

- The new regulation requires the following actions:
  - Make sure to run full loads in the ETO sterilizer
  - Run partial sterilizer loads if it's medically necessary to do so (left to discretion of hospitals; keep records)
  - Document every sterilizer load, and when loads are not full, note the medical reasons and who authorized them (CSP, Adm, MD)
- EPA estimates that the new rule will prevent 2-9 tons of ETO from being released into the air nationwide
- Hospitals have until December 29, 2008 to comply

Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization

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

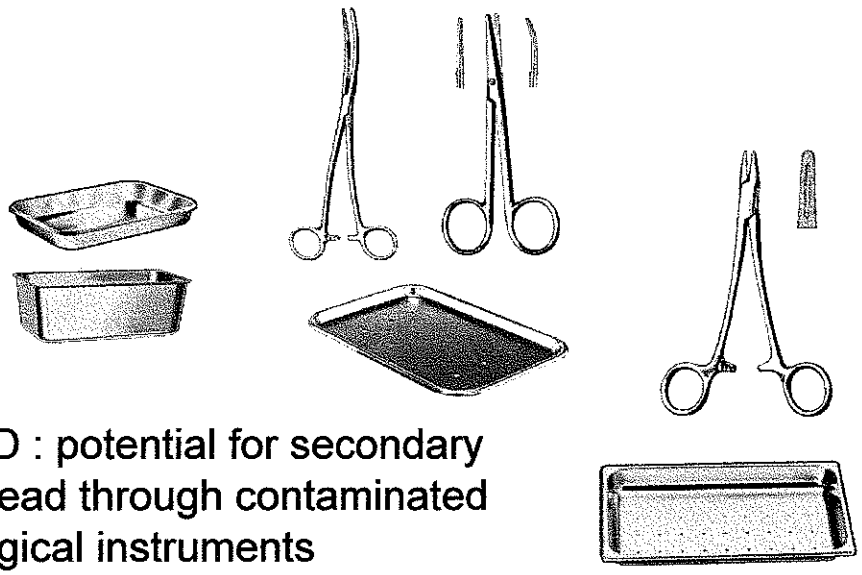
Fungi

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)



CJD : potential for secondary spread through contaminated surgical instruments

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)
- APIC/SHEA guideline on prions
- No low temperature sterilization technology effective*
- Noncritical-four disinfectants (e.g., chlorine, Environ LpH) effective (4 log decrease in LD_{50} 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
- Yan et al. Zentr Steril 2008;16:26-34 HP Gas Plasma effective (Sterrad NX)

Prion Disease Transmission: Can We Apply Standard Precautions to Prevent Risks?

Gerald McDonnell July 2008

- Alkaline detergents and some enzymes are good at removing and breaking down prions from surfaces
- Alkaline detergents vary dramatically on pH, alkalinity, contact time, concentration, temperature and compatibility with device material.
- In Europe some detergents are CE marked as "Prion Inactivating Detergents"
- These technologies will be available and may eliminate "special prion reprocessing"

Instruments contaminated with high-risk tissue from a high-risk patient require "special prion reprocessing". New technologies may alter the need for "special prion reprocessing" in the future.

Semicritical Items/HLD

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C. difficile spores

Disinfectants and Antiseptics

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

- ~4 $\log_{10}$ 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, 0.2% peracetic acid
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde
  - Aldahol, 3.4% glutaraldehyde and 26% alcohol

Semicritical Equipment

- Reprocessing semicritical items has been shown to have a narrow margin of safety
- Generally, the narrow margin of safety attributed to high microbial load and complex instruments with lumens
- Any deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection
- Problems encountered with reprocessing semicritical equipment often related to improper cleaning

Errors in designing and reprocessing semicritical items continue and place patients at risk of infection

Automatic Endoscope Reprocessors (AERs)

- Manual cleaning of endoscopes is prone to error.
- AER Advantages: automate and standardize reprocessing steps, reduce personnel exposure to chemicals, filtered tap water
- AER 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; used wrong set-up or connector MMWR 1999;48:557
- Must ensure exposure of internal surfaces with HLD/sterilant

Automatic Endoscope Reprocessors

- EvoTech-integrates cleaning (FDA-cleared claim) and disinfection. Automated cleaning comparable to manual cleaning. All residual data for cleaning of the internal channels as well as external insertion tube surfaces were below the limit of $<8.5 ug/cm^2$
- Reliance-requires a minimal number of connections to the endoscope channels and uses a control boot (housing apparatus the creates pressure differentials to ensure connectorless fluid flow through all channels that are accessible through the endoscope's control handle channel ports). Data demonstrate that the soil and microbial removal effected by Reliance washing phase was equivalent to that achieved by optimal manual cleaning. Alfa, Olson, DeGagne. AJIC 2006;34:561.

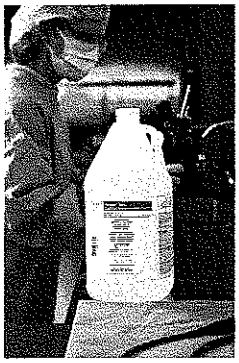
Reprocessing of Rigid Laryngoscopes

JHI 2008, 68:101; ICHE 2007, 28:504; AJIC 2007, 35: 536

- Limited guidelines for reprocessing laryngoscope's blades and handles
- Many hospitals consider blade as semicritical (HLD) and handle as noncritical (LLD)
- Blades linked to HAIs; handles not directly linked to HAIs but contamination with blood/OPIM suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCHC-blades-Steris, handle [without batteries]-Sterrad); blade/handle with batteries-Sterrad

Resert™ XL HLD

- High Level Disinfectant – under review by the FDA
- 2% hydrogen peroxide
  - pH stabilizers
  - Chelating agents
  - Corrosion inhibitors
- Efficacy (claims need verification)
  - Sporicidal, virucidal, bactericidal, tuberculocidal, fungicidal
- HLD: 8 mins at 20°C
- Odorless, non-staining, ready-to-use
- No special shipping or venting requirements
- Manual or automated applications
- 12-month shelf life, 14 days reuse
- Material compatibility/organic material resistance?



*The Accelerated Hydrogen Peroxide technology and logo are the property of Virox Technologies, Inc. Modified from G McDonnell. AJIC 2006;34:571

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%)
- Ineffectiveness of probe covers (latex condoms and probe sheaths) in preventing contamination of endocavitary, 68.4%
- 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

Noncritical Items/LLD

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