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# DISINFECTION AND STERILIZATION: CURRENT ISSUES AND NEW TECHNIQUES, THE US VIEW

David J. Weber, MD, MPH  
Professor of Medicine, Pediatrics, and Epidemiology  
Associate Chief of Staff, UNC Health Care  
University of North Carolina, NC, US

# DISCLOSURES

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- Speaker's bureau
  - Johnson and Johnson
  - Clorox
- Special thanks to Dr. William Rutala for slides

# Disinfection and Sterilization: Current Issues and New Technologies

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- Spaulding classification
- Recommended sterilants and disinfectants, CDC/HICPAC
  - Critical devices
  - Semicritical device
  - Non-critical devices
- Endoscopes continue to be the highest risk devices used in hospitals
  - New guidelines for cleaning and disinfection
- Improving room cleaning and disinfection
  - Room decontamination-UV and HPV
  - Self disinfecting surfaces

# DISINFECTION AND STERILIZATION IN HEALTHCARE FACILITIES

## ■ Overview

- Last Centers for Disease Control and Prevention guideline in 1985
- Current Guidelines: 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
- Published in November 2008

# 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**.

# Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Most Resistant



Least Resistant

Prions

Spores

Mycobacteria

Non-Enveloped Viruses

Fungi

Bacteria

Enveloped Viruses



# 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, ozone, HPV or chemical sterilization



# “Ideal” Sterilization Method

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- Highly efficacious
- Rapidly active
- Strong penetrability
- Materials compatibility
- Non-toxic
- Organic material resistance
- Adaptability
- Monitoring capability
- Cost-effective

# Sterilization of "Critical Objects"

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Steam sterilization

Ethylene oxide

Hydrogen peroxide gas plasma

Peracetic acid (0.2%)-chemical sterilization?

Ozone

Vaporized hydrogen peroxide

Steam formaldehyde

# 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 (Sterrad System)

## 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

## 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>
- STERRAD booster may required to process long narrow lumen (see manufacturer's recommendations); expanded claims with NX
- Requires synthetic packaging (polypropylene) and special container tray

# Ozone

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## ■ 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<sup>3</sup>
- Limited use (material compatibility/penetrability/organic material resistance?) and limited microbicidal efficacy data

# V-PRO™1, Vaporized Hydrogen Peroxide

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## ■ 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<sup>3</sup>
- 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

# 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:	Endoscopes, respiratory therapy and anesthesia equipment, thermometers, tonometers, endocavity probes, diaphragm fitting rings, etc.
Method:	High-level disinfection

# High Level Disinfection of "Semicritical Objects"

Exposure Time  $\geq$  8m-30m (US), 20°C

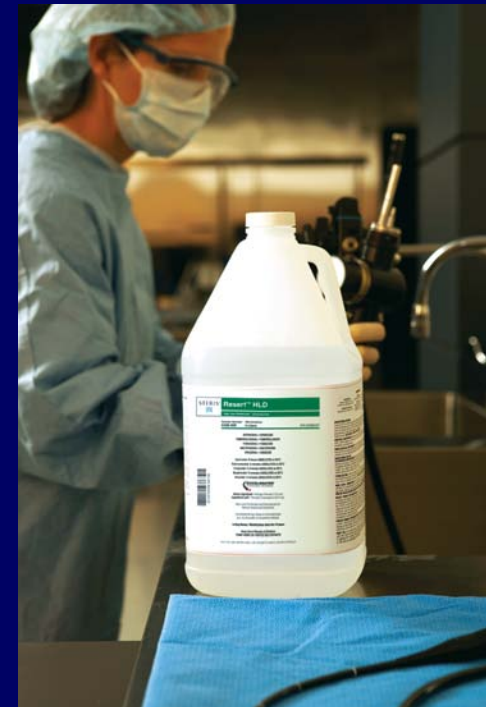
Germicide	Concentration
Glutaraldehyde	$> 2.0\%$
Ortho-phthalaldehyde (12 m US)	0.55%
Hydrogen peroxide*	7.5%
Accelerated hydrogen peroxide	2.0%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	$> 7.35\% / > 0.23\%$
Hypochlorite (free chlorine)*	650-675 ppm
Glut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

\*May cause cosmetic and functional damage



# Resert™ XL HLD

- High Level Disinfectant
- 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

# ENDOSCOPES

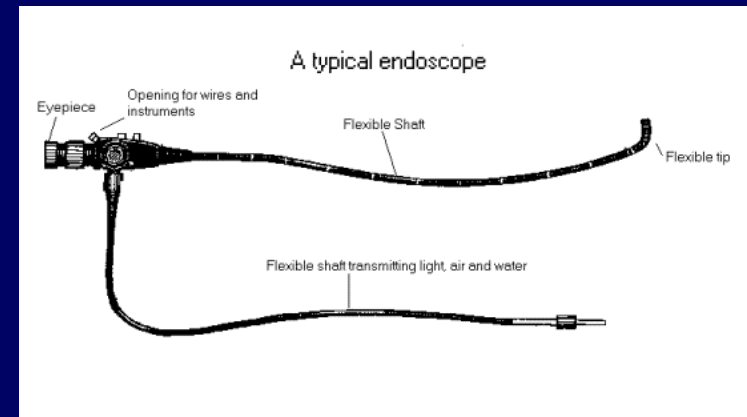
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- Gastrointestinal endoscopy
  - >70 outbreaks (>6000 patients exposed, >400 patients contaminated)
  - 70% agents *Salmonella sp.* and *P. aeruginosa*
  - Clinical spectrum ranged from colonization to death (~2%)
- Bronchoscopy
  - >50 outbreaks (>2000 patients exposed, >750 patients contaminated)
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*
  - Pseudo-outbreaks more common than outbreaks

Seoane-azques E, et al. Endosocpe 2007;39:742-745

# FEATURES OF ENDOSCOPES THAT IMPAIR CLEANING AND DISINFECTION

- Usually heat sensitive
- Long narrow lumens
- Cross-connections
- Mated surfaces
- Sharp angles
- Springs and valves
- Occluded dead ends
- Absorbent material
- Rough or pitted surfaces



# ENDOSCOPY-ASSOCIATED OUTBREAKS, 1974-2004

Type of intervention	United States		Other countries		Total	
	No. of outbreaks	No. of patients exposed	No. of outbreaks	No. of patients exposed	No. of outbreaks	No. of patients exposed
Bronchoscopy	15	4001	12	1969	27	5970
Cystoscopy	2	773	1	152	3	925
ERCP	4	554	7	2432	11	2986
Lower GI endoscopy	4	4179	6	748	10	4927
Upper GI endoscopy	3	1130	6	689	9	1819
GI endoscopy, several*	0	0	3	4841	3	4841
<b>Total</b>	<b>28</b>	<b>10637</b>	<b>35</b>	<b>10831</b>	<b>63</b>	<b>21 468</b>

Seoane-Vazquez E, et al. Endoscopy 2007;39:742-778

TABLE 1. Outbreaks and Pseudo-Outbreaks Associated with Bronchoscopy, 2000–2012

Reference	Publication year	Microorganism	Outbreak or pseudo-outbreak?	Isolates	Infections	Deaths	Source of contamination
Cosgrove et al <sup>10</sup>	2012	<i>Pseudomonas</i> sp., <i>Stenotrophomonas</i>	Pseudo-outbreak	16	0	0	Irregularities in repair by third-party vendor, nonstandard part replacements
Rosengarten et al <sup>11</sup>	2010	<i>Burkholderia cepacia</i>	Pseudo-outbreak	3	0	0	Missing antibacterial filter on washer disinfectant
CDC <sup>12</sup>	2009	<i>Legionella pneumophila</i>	Pseudo-outbreak	4	0	0	Nonsterile ice used to cool saline filler syringes for bronchoalveolar lavage
Schuetz et al <sup>13</sup>	2009	<i>L. pneumophila</i>	Pseudo-outbreak	13	0	0	Immersion of uncapped saline-filled syringes in contaminated ice
Chroneou et al <sup>14</sup>	2009	<i>Mycobacterium chelonae</i>	Pseudo-outbreak	9	0	0	Contamination of an AER
DiazGranados et al <sup>15</sup>	2009	<i>Pseudomonas aeruginosa</i>	Both	12	2	0	Damaged bronchoscope
Schaffer et al <sup>16</sup>	2008	<i>Fusarium solani</i>	Pseudo-outbreak	4	0	0	Bronchoscope
Shimono et al <sup>17</sup>	2008	<i>P. aeruginosa</i>	Outbreak	7	7	0	Flaw in AER, failure to properly clean and disinfect bronchoscopes
Ahn et al <sup>18</sup>	2007	<i>Stenotrophomonas maltophilia</i>	Pseudo-outbreak	7	0	0	Failure to properly clean and disinfect bronchoscopes
Bou et al <sup>19</sup>	2006	<i>P. aeruginosa</i>	Outbreak	10	10	0	Failure to properly clean and disinfect bronchoscopes
Corne et al <sup>20</sup>	2005	<i>P. aeruginosa</i>	Both	16	4	0	Damaged internal channel caused by defective biopsy forceps
C�tre et al <sup>21</sup>	2005	Enteric GNR	Both	117	2	0	Bronchoscope: loose part of the biopsy channel
Larson et al <sup>22</sup>	2003	<i>Mycobacterium tuberculosis</i>	Pseudo-outbreak	3	1	0	Failure to properly clean bronchoscopes, use of an AER not approved for the type of bronchoscope
Singh et al <sup>23</sup>	2003	<i>Trichosporon mucoides</i>	Pseudo-outbreak	6	0	0	Defective bronchoscopes
Silva et al <sup>24</sup>	2003	<i>P. aeruginosa</i> , <i>Serratia marcescens</i>	Pseudo-outbreak	41	0	0	Failure to properly clean bronchoscopes
Srinivasan et al <sup>25</sup>	2003	<i>P. aeruginosa</i>	Outbreak	97	48	3?	Defective bronchoscopes: loosened biopsy port
Kirschke et al <sup>26</sup>	2003	<i>P. aeruginosa</i>	Both	20	1	0	Defective bronchoscopes: loosened biopsy port
Ramsey et al <sup>27</sup>	2002	<i>M. tuberculosis</i>	Pseudo-outbreak	10	4	0	Damaged bronchoscope; no leak testing; hole in bronchoscope sheath
Rossetti et al <sup>28</sup>	2002	<i>Mycobacterium gordonae</i>	Pseudo-outbreak	16	0	0	AER: failure to replace antibacterial filters, maintenance
Kressel and Kidd <sup>29</sup>	2001	<i>M. chelonae</i> , <i>Methylobacterium mesophilicum</i>	Pseudo-outbreak	20	0	0	AER contaminated with biofilm resistant to decontamination
Sorin et al <sup>30</sup>	2001	<i>P. aeruginosa</i>	Both	18	3	1	AER: inappropriate channel connectors
Kramer et al <sup>31</sup>	2001	<i>P. aeruginosa</i>					AER: disinfectant (0.04% glutaraldehyde) contaminated because of inadequate concentration (concentration mistakenly set too low)
Wilson et al <sup>32</sup>	2000	<i>Aureobasidium</i> sp.	Pseudo-outbreak	10	0	0	Reuse of single-use stopcocks
Gillespie et al <sup>33</sup>	2000	<i>M. chelonae</i>	Pseudo-outbreak	2	0	0	Contaminated water in AER
Schelenz and French <sup>34</sup>	2000	<i>P. aeruginosa</i>	Unknown	8	0	0	AER

NOTE. AER, automated endoscope reprocessor; GNR, gram-negative rods.

# DISINFECTION OF ENDOSCOPES

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JUNE 2011, VOL. 32, NO. 6

ASGE-SHEA GUIDELINE

## Multisociety Guideline on Reprocessing Flexible GI Endoscopes: 2011

Bret T. Petersen, MD, FASGE; Jennifer Chennat, MD; Jonathan Cohen, MD, FASGE; Peter B. Cotton, MD, FASGE;  
David A. Greenwald, MD, FASGE; Thomas E. Kowalski, MD; Mary L. Krinsky, DO; Walter G. Park, MD;  
Irving M. Pike, MD, FASGE; Joseph Romagnuolo, MD, FASGE;  
for the ASGE Quality Assurance in Endoscopy Committee; and William A. Rutala, PhD, MPH;  
for the Society for Healthcare Epidemiology of America



# Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

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- Since 2003, changes in
  - High-level disinfectants
  - Automated endoscope reprocessors
  - Endoscopes
  - Endoscopic accessories
- However, efficacy of decontamination and high-level disinfection is unchanged and the principles guiding both remain valid
- Additional outbreaks of infection related to suboptimal infection prevention practices during endoscopy or lapses in endoscope reprocessing (unfamiliarity with endoscope channels, accessories, attachments; gaps in infection prevention at ASC)

# Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

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- Transmission categorized as:
  - Non-endoscopic and related to care of intravenous lines and administration of anesthesia or other medications
    - ◆ Multidose vials
    - ◆ Reuse of needles and syringes
    - ◆ Intravenous sedation tubing
  - Endoscopic and related to endoscope and accessories
    - ◆ Failure to sterilize biopsy forceps between patients
    - ◆ Lapses in reprocessing tubing used in channel irrigation

# Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

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## ■ Unresolved Issues

- Interval of storage after which endoscopes should be reprocessed before use
  - ◆ Data suggest that contamination during storage for intervals of 7-14 days is negligible, unassociated with duration, occurs on exterior of instruments and involves only common skin organisms
  - ◆ Data are insufficient to proffer a maximal outer duration for use of appropriately cleaned, reprocessed, dried and stored endoscopes
- Microbiologic surveillance testing after reprocessing
  - ◆ Detection of non-environmental pathogens indicator of faulty reprocessing equipment, inadequate solution, or failed human process

# Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

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## ■ Unresolved Issues

- Optimal frequencies for replacement of: clean water bottles and tubing for insufflation of air and lens wash water, and waste vacuum canisters and suction tubing
  - ◆ Concern related to potential for backflow from a soiled endoscope against the direction of forced fluid and air passage into clean air/water source or from tubing/canister against a vacuum into clean instruments
- Microbiologic surveillance testing after reprocessing
  - ◆ Detection of non-environmental pathogens indicator of faulty reprocessing equipment, inadequate solution, or failed human process

# 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

# CLEANING OF ENDOSCOPES

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- 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

TABLE 2. Steps in the Disinfection Process and Mechanisms of Failure

Disinfection step	Reason for disinfection step	Mechanism for failure
Cleaning	Remove bioburden Remove substances that might interfere with disinfection: blood, salt, protein	Inadequate policies; Inadequate training or supervision; failure to clean immediately (ie, allowing body fluids to dry); failure to brush all channels; damaged internal channel(s); poorly mated internal components
Appropriate disinfectant	Inactivation of contaminating microbes	Ineffective disinfectant (eg, iodides); inadequate concentration; inadequate duration; inadequate temperature
Contact between disinfectant and contaminating microbes	Requirement for killing	AER: failure to use channel connectors; AER: wrong channel connectors; occluded lumen; torn or damaged lumen
Rinse	Remove potentially toxic chemicals (eg, glutaraldehyde, hydrogen peroxide)	Mucous membrane damage to subsequent patient (eg, colitis); contaminated rinse water
Prevention of recontamination	Prevent contamination with environmental microbes	Tap water rinse without subsequent alcohol rinse; failure to air-dry endoscope; contaminated AER; reassembly of valves before storage; placement of endoscope in contaminated container; storage in coiled position (rather than hanging straight)

# Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

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- Relatively new technologies for HLD
  - EvoTech
  - OER-Pro
- Endoscope durability and longevity
  - No published data regarding materials durability and potential for reduced function or reduced ability to attain HLD



# EVOTECH w/Cleaning Claim



- Integrated double-bay AER
- **Eliminates manual cleaning**
- Uses New High-Level Disinfectant (HLD) with IP protection
- Single-shot HLD
- Automated testing of endoscope channels and minimum effective concentration of HLD
- Incorporates additional features (LAN, LCD display)
- **Eliminates soil and microbes equivalent to optimal manual cleaning. BMC ID 2010; 10:200**



# 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

# 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
Accelerated hydrogen peroxide	0.5%

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UD=Manufacturer's recommended use dilution

# NOVEL METHODS OF ROOM DISINFECTION

- No touch methods
  - Ultraviolet light
  - Hydrogen peroxide (HP)
    - ◆ Sterinis: Fine mist by aerosolizing solution of 5% HP, <50 ppm silver
    - ◆ Steris: Vaporized HP from 35% HP
    - ◆ Bioquell: HP vapor from 35% HP
- Self disinfecting surfaces
  - Copper
  - Silver or silver ion impregnated
  - Sharklet pattern
  - Light activated antimicrobial coatings
- Accelerated hydrogen peroxide

# Novel Methods of Room Disinfection



# COMPARISON OF ROOM DECONTAMINATION SYSTEMS THAT USE UV IRRADIATION AND HYDROGEN PEROXIDE (HP)

	Sterinis	Steris	Bioquell	Tru-D
Abbreviation	DMHP (dry mist HP)	VHP (vaporized HP)	HPV (HP vapor)	UV-C
Active agent	Stenusil (5% HP, <50 ppm silver cations)	Vaprox (35% HP)	35% HP	UV-C irradiation at 254 nm
Application	Aerosol of active solution	Vapor, noncondensing	Vapor, condensing	UV irradiation, direct and reflected
Aeration (removal of active agent from enclosure)	Passive decomposition	Active catalytic conversion	Active catalytic conversion	Not necessary
Sporicidal efficacy	Single cycle does not inactivate <i>Bacillus atrophaeus</i> BIs; ~4-log <sub>10</sub> reduction in <i>Clostridium difficile</i> <sup>a</sup> and incomplete inactivation in situ	Inactivation of <i>Geobacillus stearothermophilus</i> BIs	Inactivation of <i>G. stearothermophilus</i> BIs; >6-log <sub>10</sub> reduction in <i>C. difficile</i> <sup>a</sup> in vitro and complete inactivation in situ	1.7–4-log <sub>10</sub> reduction in <i>C. difficile</i> <sup>a</sup> in situ
Evidence of clinical impact	None published	None published	Significant reduction in the incidence of <i>C. difficile</i>	None published

# UV ROOM DECONTAMINATION: ADVANTAGES AND DISADVANTAGES

## ■ Advantages

- Reliable biocidal activity against a wide range of pathogens
- Surfaces and equipment decontaminated
- Room decontamination is rapid (~15 min) for vegetative bacteria
- HVAC system does not need to be disabled and room does not need to be sealed
- UV is residual free and does not give rise to health and safety concerns
- No consumable products so operating costs are low (key cost = acquisition)

## ■ Disadvantages

- No studies evaluating whether use reduces HAIs
- Can only be done for terminal disinfection (i.e., not daily cleaning)
- All patients and staff must be removed from room
- Substantial capital equipment costs
- Does not remove dust and stains which are important to patients/visitors
- Sensitive use parameters (e.g., UV dose delivered)

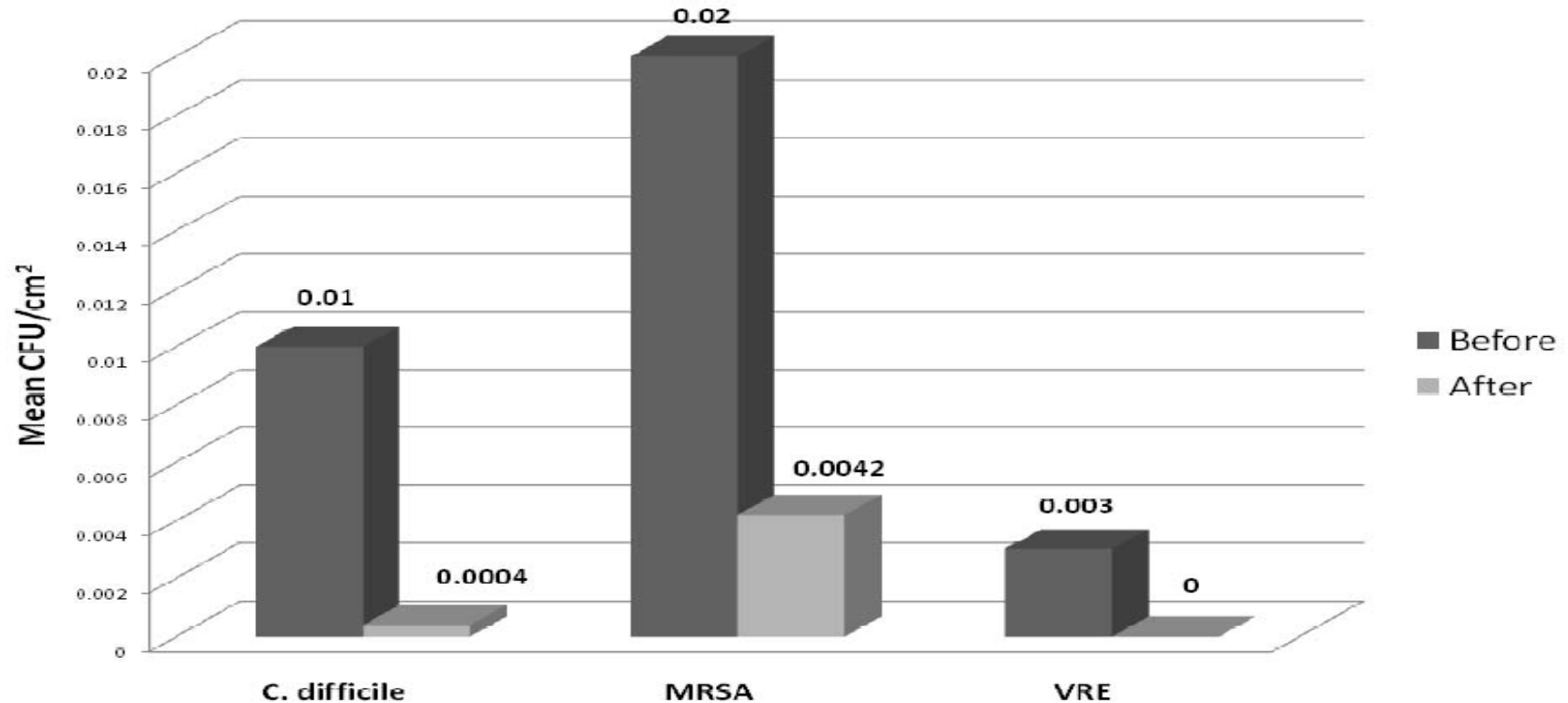


# EFFECTIVENESS OF UV ROOM DECONTAMINATION

TABLE 1. UV-C Decontamination of Formica Surfaces in Patient Rooms Experimentally Contaminated with Methicillin-Resistant *Staphylococcus aureus* (MRSA), Vancomycin-Resistant *Enterococcus* (VRE), Multidrug-Resistant (MDR) *Acinetobacter baumannii*, and *Clostridium difficile* Spores

Organism	Inoculum	UV-C line of sight						P
		Total		Direct		Indirect		
		No. of samples	Decontamination, log <sub>10</sub> reduction, mean (95% CI)	No. of samples	Decontamination, log <sub>10</sub> reduction, mean (95% CI)	No. of samples	Decontamination, log <sub>10</sub> reduction, mean (95% CI)	
MRSA	4.88 log <sub>10</sub>	50	3.94 (2.54–5.34)	10	4.31 (3.13–5.50)	40	3.85 (2.44–5.25)	.06
VRE	4.40 log <sub>10</sub>	47	3.46 (2.16–4.81)	15	3.90 (2.99–4.81)	32	3.25 (1.97–4.62)	.003
MDR <i>A. baumannii</i>	4.64 log <sub>10</sub>	47	3.88 (2.59–5.16)	10	4.21 (3.27–5.15)	37	3.79 (2.47–5.10)	.07
<i>C. difficile</i> spores	4.12 log <sub>10</sub>	45	2.79 (1.20–4.37)	10	4.04 (3.71–4.37)	35	2.43 (1.46–3.40)	<.001

# EFFECTIVENESS OF UV ROOM DECONTAMINATION



**Figure 4** Mean number of colony-forming units (CFU) of *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and vancomycin-resistant *Enterococcus* (VRE) recovered from contaminated surfaces in hospital rooms before and after disinfection with the Tru-D device. Two-hundred sixty-one total surfaces from 66 rooms were cultured, including call lights, bedside tables, telephones, and bed rails.

# HP ROOM DECONTAMINATION: ADVANTAGES AND DISADVANTAGES

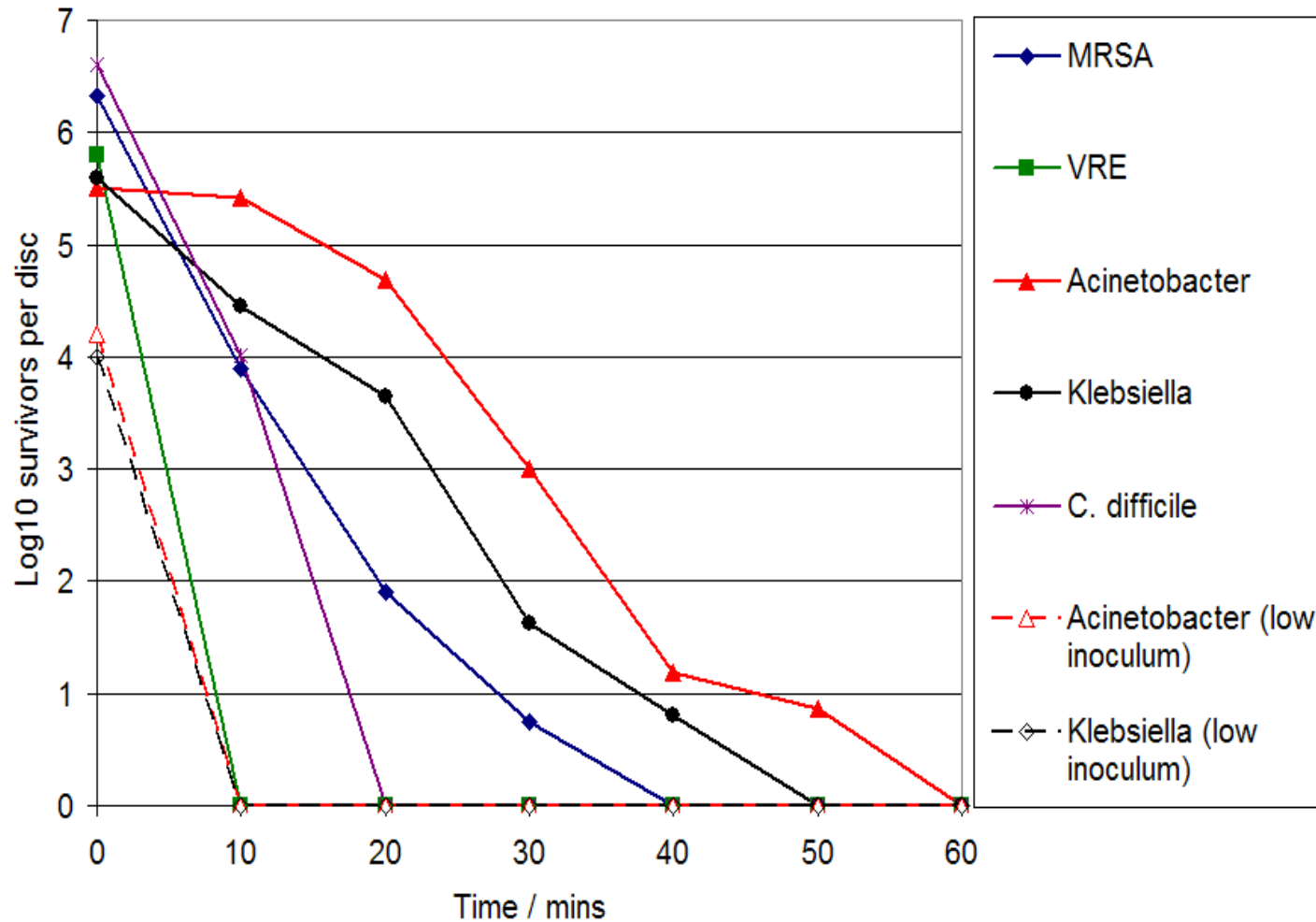
## ■ Advantages

- Reliable biocidal activity against a wide range of pathogens
- Surfaces and equipment decontaminated
- Demonstrated to decrease disease incidence (*C. difficile*)
- Residual free and does not give rise to health and safety concerns (aeration units convert HPV into oxygen and water)
- Useful for disinfecting complex equipment and furniture

## ■ Disadvantages

- Can only be done for terminal disinfection (i.e., not daily cleaning)
- All patients and staff must be removed from room
- Decontamination takes approximately 3-5 hours
- HVAC system must be disabled and the room sealed with tape
- Substantial capital equipment costs
- Does not remove dust and stains which are important to patients/visitors
- Sensitive use parameters (e.g., HP concentration 280 ppm)

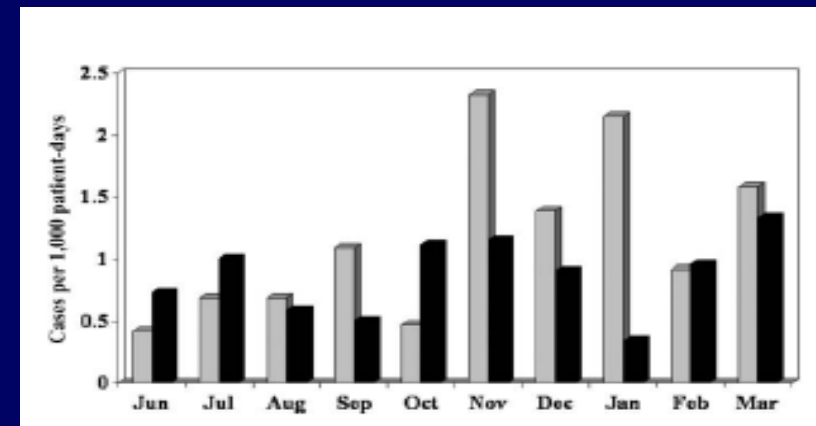
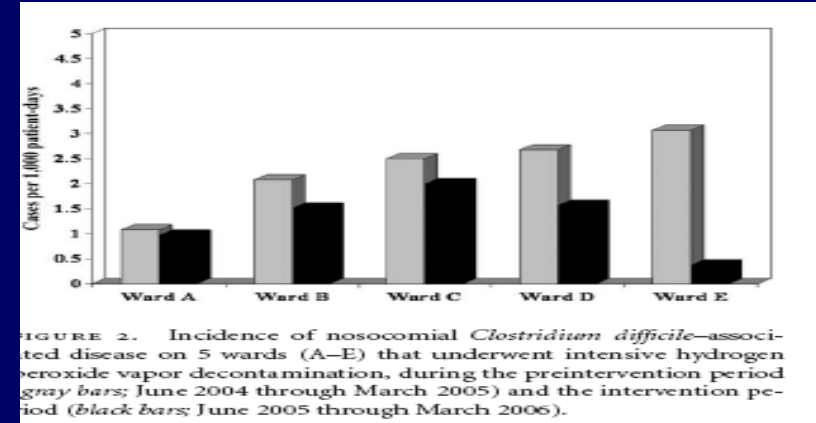
# HPV *in vitro* Efficacy



# Room Decontamination With HPV

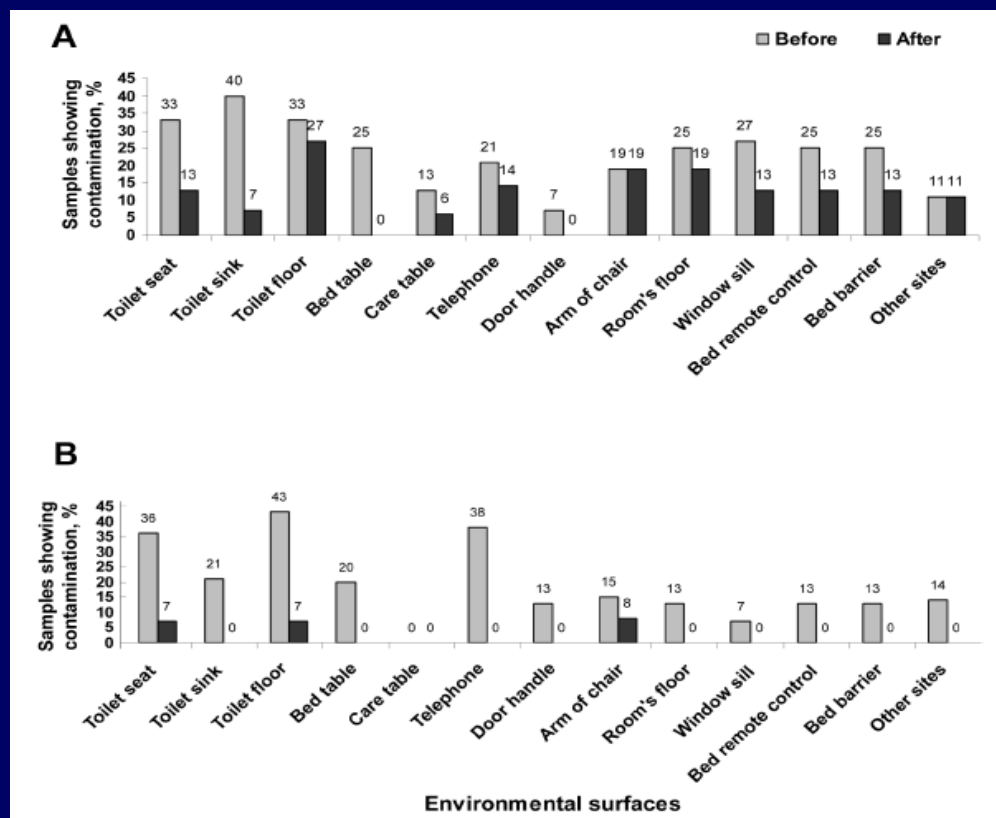
- Study design
  - Before and after study of HPV
- Outcome
  - *C. difficile* incidence
- Results
  - HPV decreased environmental contamination with *C. difficile* ( $p < 0.001$ ), rates on high incidence floors from 2.28 to 1.28 cases per 1,000 pt-days ( $p = 0.047$ ), and throughout the hospital from 1.36 to 0.84 cases per 1,000 pt days ( $p = 0.26$ )

Boyce JM, et al. ICHE 2008;29:723-729



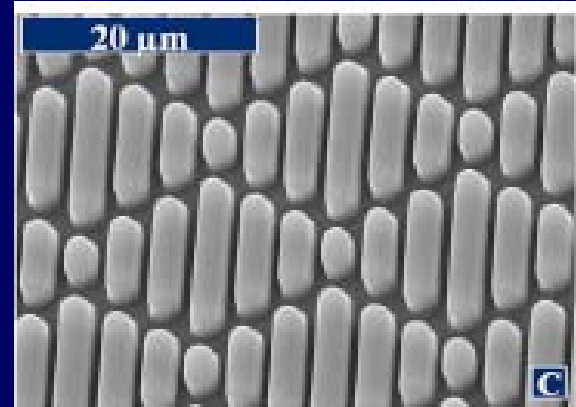
# EFFICACY OF HYPOCHLORITE VS HYDROGEN PEROXIDE DRY MIST

- Study design: Prospective randomized before-after study, 2007
- Setting: 2 French hospitals
- Methods: Disinfection: A=0.5% hypochlorite; B=HP-Ag cation dry-mist (Sterusil)
- Results
  - After disinfection 12% of samples from hypochlorite rooms and 2% from HP showed contamination ( $p < 0.005$ )
- No measurement of cleaning thoroughness



# SELF DISINFECTING SURFACES

Copper coated  
overbed table



Sharklet Pattern

Antimicrobial  
effects of silver



Triclosan pen

# SELF DISINFECTING SURFACES

- Copper (Surfaces contaminated on copper objects)<sup>1</sup>
  - VRE (1.8% → 0.2%)\*; MSSA (4.6% → 1.3%)\*; MRSA (3.7% → 2.3%), Coliforms (8.1% → 3.4%)\*; *C. difficile* (0.4% → 1.4%) {\* p<0.05}
  - Decrease (when significant, 1-2-log<sub>10</sub>)
- Silver<sup>2</sup>
  - Silver (surfacine) active against *S. aureus*, VRE, *E. coli*, *Klebsiella*
  - Reduction 3-5-log<sub>10</sub>
- Sharklet pattern<sup>3</sup>
  - Sharklet pattern effective in decreasing growth of *S. aureus* on surfaces
- Light activated antimicrobial coating (methylene blue, gold nanoparticles)<sup>4</sup>
  - Coating able to reduce MRSA 99.33% to 99.99%

<sup>1</sup>Karpanen T, et al. ICHE (In press); <sup>2</sup>Brady MJ, et al. Am J Infect Control 2003;31:208-214; <sup>3</sup>Chung KK, et al. Biointerphases 2007;2:89-94; <sup>4</sup>Ismail S, et al. ICHE 2011;32:1130-1132



# Disinfection and Sterilization of Emerging Pathogens

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- Hepatitis C virus
- Norovirus
- Novel H1N1 influenza
- SARS Coronavirus
- *Helicobacter pylori*
- *E.coli* 0157:H7
- Bioterrorism agents (anthrax, plague, smallpox)
- Antibiotic-resistant microbes (MDR-TB, VRE, MRSA)
- *Clostridium difficile*
- *Cryptosporidium*

# 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 with the exception of prions

# Failure to Follow Disinfection and Sterilization Principles

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- 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

1. Confirm disinfection or sterilization reprocessing failure
2. Impound any improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, automated endoscope reprocessor) until proper functioning can be assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether disinfection/sterilization failure increases patient risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of state and federal authorities
12. Consider patient notification
13. Develop long-term follow-up plan
14. Perform after-action report

FIGURE 1. Protocol for exposure investigation after a failure of disinfection and sterilization procedures

# CONCLUSIONS

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- Rigorous adherence to disinfection/sterilization guideline necessary to prevent healthcare associated outbreaks
  - Cleaning must precede disinfection/sterilization
  - Must pay special attention to disinfection of endoscopes (associated with more outbreaks than any other medical device)
- Contaminated hospital surfaces important in transmission of several organisms: MRSA, VRE, *C. difficile*, *Acinetobacter*, norovirus
- Novel “no touch” methods may be useful in reducing surface contamination
- In the event of a possible disinfection/sterilization failure an organized method for evaluating risk may aid in assessing patient risk