Martin S. Favero Lectureship
Disinfection and Sterilization:
Successes and Failures

William A. Rutala, Ph.D., M.P.H.
University of North Carolina (UNC) Health Care and
UNC at Chapel Hill, NC
Disclosure: Clorox, Advanced Sterilization Products

Successes

- Effective cleaning procedures
- Effective and robust high-temperature and low-temperature sterilization technology
- Effective new technologies
  - Low-level disinfection
  - High-level disinfection
  - Prions
- Know how to kill emerging pathogens

Successes

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

Sterilization of "Critical Objects"

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Peracetic acid (0.2%)-chemical sterilization
Ozone
Vaporized hydrogen peroxide

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
Accelerated hydrogen peroxide	2.0%
Glut and phenol/phenate**	1.21%/1.93%

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

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
Accelerated hydrogen peroxide	0.5%

UD=Manufacturer's recommended use dilution

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)

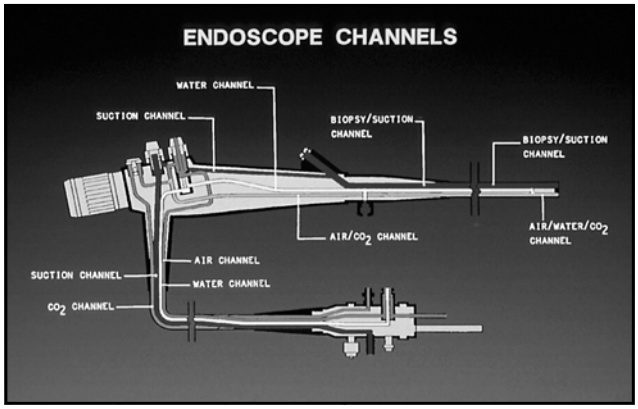
Disinfection and Sterilization of Emerging Pathogens

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

Failures

Failures

- Compliance
  - High level disinfection
  - Low level disinfection
    - Suboptimal surface cleaning/disinfection practices
    - Disconnect between science and registration process
- Flash Sterilization



Endoscope Reprocessing: Current Status of Cleaning and Disinfection

- Guidelines
  - Centers for Disease Control and Prevention, 2008
  - Multi-Society Guideline, 11 professional organizations, 2003
  - Society of Gastroenterology Nurses and Associates, 2000
  - European Society of Gastrointestinal Endoscopy, 2000
  - British Society of Gastroenterology Endoscopy, 1998
  - Gastroenterological Society of Australia, 1999
  - Gastroenterological Nurses Society of Australia, 1999
  - American Society for Gastrointestinal Endoscopy, 1996
  - Association for Professional in Infection Control and Epidemiology, 2000

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

Schembre DB. Gastroint Endoscopy 2000;10:215

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

TABLE 1. Reprocessing Failures of Semicritical or Critical Medical Instruments Resulting in Patient Notification

Location or institution, year	Instrument involved	No. of persons exposed
Sacramento, CA, 2002	Endoscope	750
Toronto, ON, 2003	Endoscope	146
Seattle, WA, 2004	Endoscope	600
Sacramento, CA, 2004	Endoscope	1,331
San Francisco, CA, 2004	Endoscope	2,000
Long Island, NY, 2004	Endoscope	177
Charleston, NC, 2004	Endoscope	1,383
Toronto, ON, 2003	Prostate biopsy probe	900
Pittsburgh, PA, 2005	Endoscope	200
Leesburg, VA 2005	Endoscope	144
San Diego, CA, 2006	Endoscope	300
Augusta, ME, 2006	Prostate biopsy needle	481
Dept Veterans Affairs, 2006	Prostate biopsy equipment	2,075
San Diego, CA, 2006	Surgical instrument	82

NOTE. Modified from a presentation by Douglas Nelson, MD, at the 33rd Annual Conference and International Meeting of the Association for Professionals in Infection Control and Epidemiology; Tampa, Florida, 2006.

Disinfection and Sterilization New Systems and Technologies

- New technology that eliminates risk (AERs) or improved compliance
- Elimination of high-level disinfection
  - Improve low-temperature sterilization process so all semicritical items can be sterilized (no restrictions, simple and inexpensive)
  - Develop semicritical items that can be steam sterilized
  - Develop disposable semicritical items (e.g., endoscopes)

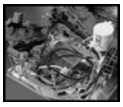
EVOTECH w/Cleaning Claim

- Product Definition:
  - 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)

Reliance™ EPS
Endoscope Processing System


Reliance™ DG


Klenzyme®, CIP® 200


Endoscope Processing Support


Reliance™ PI

Disinfection and Sterilization
New Systems and Technologies

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Risk of Acquiring MRSA, VRE, and *C. difficile* from Prior Room Occupants

- Admission to a room previously occupied by an MRSA-positive patient or VRE-positive patient significantly increased the odds of acquisition for MRSA and VRE (although this route is a minor contributor to overall transmission). Arch Intern Med 2006;166:1945.
- Prior environmental contamination, whether measured via environmental cultures or prior room occupancy by VRE-colonized patients, increases the risk of acquisition of VRE. Clin Infect Dis 2008;46:678.
- Prior room occupant with CDAD is a significant risk for CDAD acquisition. ICACC (K-4194) 2008. Shaughnessy et al.

Role of the Environment in Transmission

Pathogens implicated in transmission via contaminated noncritical surfaces (survival in the environment and recovered from the environment)

- **Bacteria**
  - **Oxacillin-resistant** *Staphylococcus aureus*
  - **Vancomycin-resistant** *Enterococcus spp.*
  - *Clostridium difficile*
  - *Acinetobacter* **and** *P. aeruginosa*
- **Viruses**
  - **Rotavirus**
  - **Norovirus**
  - **SARS coronavirus**

Environmental Contamination MRSA

- 27% of 350 surfaces sampled in the rooms of affected patients were contaminated with MRSA. When patients had MRSA in a wound or urine, 36% of surfaces were contaminated. Boyce et al. ICHE 1997;18:622.
- 74% of 359 swabs taken before cleaning yielded MRSA. French et al. J Hosp Infect 2004;57:31

C. difficile Environmental Contamination

- Frequency of sites found contaminated~10->50% from 13 studies-stethoscopes, bed frames/rails, call buttons, sinks, hospital charts, toys, floors, windowsills, commodes, toilets, bedsheets, scales, blood pressure cuffs, phones, door handles, electronic thermometers, flow-control devices for IV catheter, feeding tube equipment, bedpan hoppers
- *C. difficile* spore load is low; 7 studies assessed the spore load and most found <10 colonies on surfaces found to be contaminated. Two studies reported >100; one reported a range of "1->200" and one study sampled several sites with a sponge and found 1,300 colonies *C. difficile*.

Practice or Product

Practice* NOT Product

*surfaces not wiped

Patient Area Cleaning/Disinfecting

PC Carling et al, ICHE 2008;29:1 and ICHE 2008;29:1035

- Monitor cleaning performance using an invisible fluorescent targeting method. Rooms (14 high-touch objects) were marked and evaluated after terminal cleaning.
- Results: 1,605 rooms and 20,646 objects were evaluated in 36 hospitals. Mean proportion of objects cleaned was 48%. Following education and process improvement feedback, cleaning improved to 77%
- Conclusion: Substantial opportunity for improving terminal cleaning/disinfecting activities.

TABLE. Rates of Cleaning for 14 Types of High-Risk Objects

Object	Percentage cleaned		95% CI
	Mean ± SD	Range	
Sink	82 ± 12	57-97	77-88
Toilet seat	76 ± 18	40-98	68-84
Tray table	77 ± 15	53-100	71-84
Bedside table	64 ± 22	23-100	54-73
Toilet handle	60 ± 22	23-89	50-69
Side rail	60 ± 21	25-96	51-69
Call box	50 ± 19	9-90	42-58
Telephone	49 ± 16	18-86	42-56
Chair	48 ± 28	11-100	35-61
Toilet door knobs	28 ± 22	0-82	18-37
Toilet hand hold	28 ± 23	0-90	18-38
Bedpan cleaner	25 ± 18	0-79	17-33
Room door knobs	23 ± 19	2-73	15-31
Bathroom light switch	20 ± 21	0-81	11-30

NOTE. CI, confidence interval.

Mean proportion of surfaces disinfected at terminal cleaning is ~50%

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Quality Improvement

Monitoring the Effectiveness of Cleaning

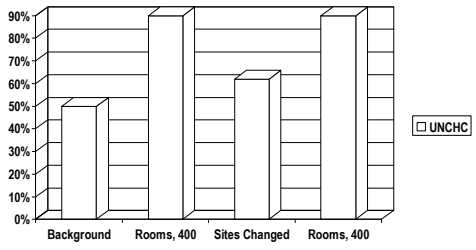
Cooper et al. AJIC 2007;35:338

- Visual assessment-not a reliable indicator of surface cleanliness
- ATP bioluminescence-measures organic debris (each unit has own reading scale)
- Microbiological methods-<2.5CFUs/cm^2-pass; can be costly and pathogen specific
- Fluorescent marker

Fluorescent Marker

- A mixture of several glues, soaps, and a target dye (Carling, 2009)
  - Dries rapidly
  - Simple
  - Easily removed by wetted cloth
  - Environmentally stable
  - Rapid
  - Unfortunately, not readily available (Carling and Sodexho)

Rates of Cleaning for High-Risk Objects



Room Decontamination Units

MRSA, VRE, ***C. difficile***

- Hydrogen peroxide vapor
- Hydrogen peroxide gas
- UV

Hydrogen Peroxide Vapor Decontamination

- **Bartels MD et al. J Hosp Infect 2008;70:35. MRSA/Sterinis**
- **Boyce JM et al. ICHE 2008;29:723.** *C. difficile*/**Bioquell**
- **Shapey S et al. J Hosp Infect 2008 (in press).** *C. difficile*/**Sterinis**
- **Hardy KJ et al. J Hosp Infect 2007;66:360. MRSA/Bioquell**
- **Hall L et al. J Clin Microbiol 2007;45: 810.** *M. tuberculosis*/**Bioquell**
- **Bates CJ, Pearse R. J Hosp Infect 2005;61:364.** *S. marcescens*/**Bioquell**
- **Johnston MD et al. J Microbiol Methods 2005;60:403.** *C. botulinum*/**Bioquell**
- **French GL et al. J Hosp Infect 2004;57:31. MRSA/Bioquell**
- **Heckert RA et al. Appl Environ Microbiol 1997;63:3916. Viruses/Steris VHP**
- **Klapes NA et al. Appl Environ Microbiol 1990;56;503.** *Bacillus* **spores/Prototype HPV generator**

UV Room Decontamination

- Fully automated, self calibrates, activated by hand-held remote
- Room ventilation does not need to be modified
- Uses UV-C (254 nm range) to decontaminate surfaces
- Measures UV reflected from walls, ceilings, floors or other treated areas and calculates the operation time to deliver the programmed lethal dose for pathogens.
- UV sensors determines and targets highly-shadowed areas to deliver measured dose of UV energy
- After UV dose delivered, will power-down and audibly notify the operator
- Reduces colony counts of pathogens by >99.9% within 20 minutes

Room Decontamination with UV

(Rutala, Gergen, Weber, 2009, Unpublished Results)

Organism	Dose Reading (time)	Log_{10} Reduction (10 sites, 5 replicates)
MRSA	~470 mj/cm^2 (~15m)	3.91
VRE	~660 mj/cm^2 (~15m)	3.36
Acinetobacter	~630 mj/cm^2 (~14m)	3.77
C. difficile	~2120 mj/cm^2 (~50m)	2.67

Failures

- Compliance
  - High level disinfection
  - Low level disinfection
    - Suboptimal surface cleaning/disinfection practices
    - Disconnect between science and registration process
- Flash Sterilization

Contact Time for Surface Disinfection

- CDC guidelines recommends a 1 minute contact time for noncritical surfaces/items. If user selects exposure conditions that differ from label, the user assumes liability and subject to FIFRA.
- Labels on most products registered by EPA specifies a contact time of 10 minutes (some have times of 1-3 minutes)
- Such a long contact time is impractical because dry time 1-3 minutes
- Multiple investigators demonstrated the effectiveness of these disinfectants against bacteria, yeasts, viruses-remedy disconnect

Flash Sterilization

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 250ºF for instruments when there is an "extreme emergency".
- In 1969, Perkins redefined flash sterilization to the current definition of an unwrapped item at 270ºF 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.

Successes

- Effective cleaning procedures
- Effective and robust high-temperature and low-temperature sterilization technology
- Effective new technologies
  - Low-level disinfection
  - High-level disinfection
  - Prions
- Know how to kill emerging pathogens

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Thank you

Martin S. Favero Lectureship, 2009