Disinfection, Sterilization and Antisepsis: An Overview

William A. Rutala, Ph.D., M.P.H.

Director, Statewide Program for Infection Control and Epidemiology, Research Professor of Medicine, University of North Carolina (UNC)

Former Director, Hospital Epidemiology, Occupational Health and Safety Program, UNC Health Care, Chapel Hill (1979-2017)

DISCLOSURES

2017-2018

- Consultations
  - ASP (Advanced Sterilization Products), PDI
- Honoraria
  - PDI, Kennall
- Scientific Advisory Board
  - Kinnos
- Grants
  - CDC, CMS

Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection, sterilization and antisepsis
  - Indications and methods for sterilization, high-level disinfection and low-level disinfection
  - Cleaning of patient-care devices
  - Sterilization
  - Disinfection (high-level and low-level disinfection)
  - Antisepsis

www.disinfectionandsterilization.org

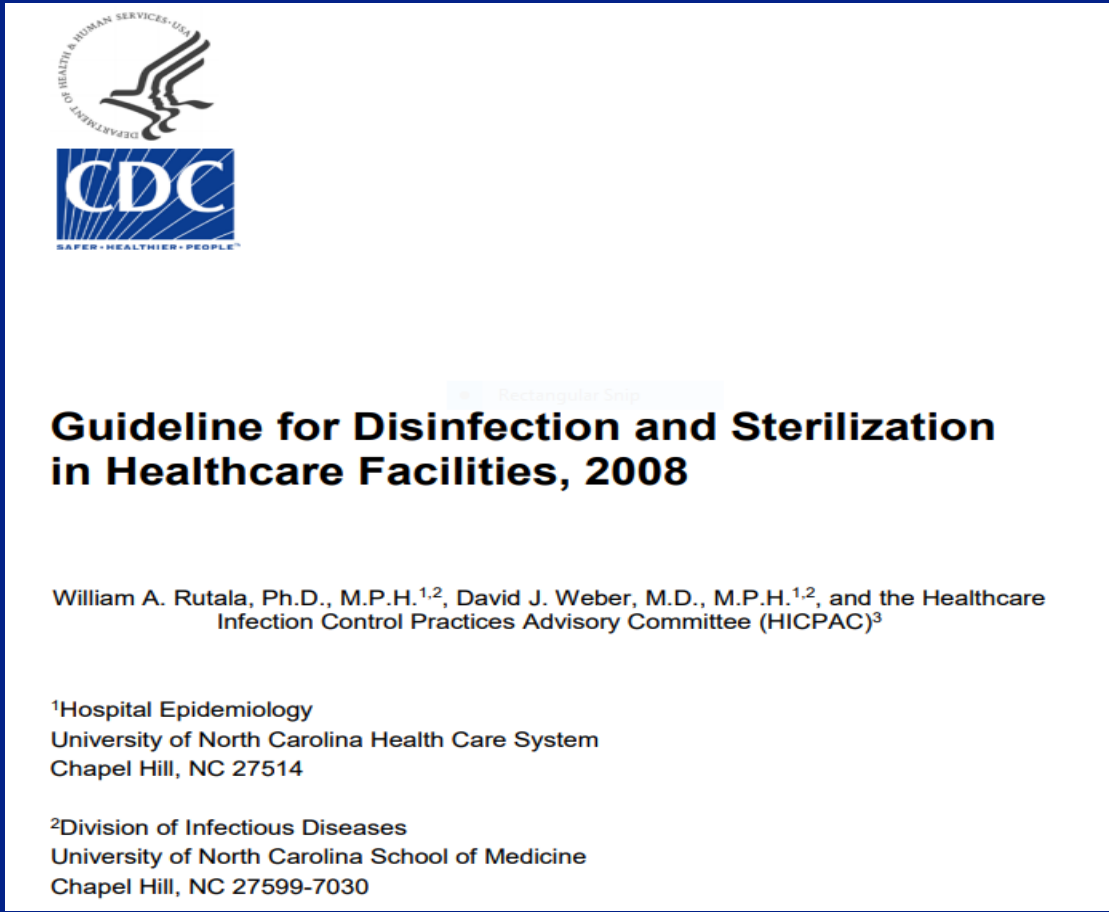
Sources of Healthcare-Associated Pathogens

Weinstein RA. Am J Med 1991:91 (suppl 3B):179S

- Endogenous flora (SSI, UTI, CLABSI): 40-60%
- Exogenous: 20-40% (e.g., cross-infection via contaminated hands [staff, visitors])
- Other (environment): 20%
  - Medical devices
  - Contact with environmental surfaces (direct and indirect contact)

CDC Guideline for Disinfection and Sterilization

Rutala, Weber, HICPAC. November 2008. www.cdc.gov



Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

William A. Rutala, Ph.D., M.P.H.[1,2], David J. Weber, M.D., M.P.H.[1,2], and the Healthcare Infection Control Practices Advisory Committee (HICPAC)[3]

[1]Hospital Epidemiology
University of North Carolina Health Care System
Chapel Hill, NC 27514

[2]Division of Infectious Diseases
University of North Carolina School of Medicine
Chapel Hill, NC 27599-7030

Medical/Surgical Devices

WA Rutala, DJ Weber, and HICPAC, www.cdc.gov

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (developed 1968).

CRITICAL-medical/surgical devices which enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

SEMICRITICAL-medical devices 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-medical devices that touch only intact skin require low-level disinfection.

Critical Medical/Surgical Devices

Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2016;44:e47

- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments
    - Enormous margin of safety, rare outbreaks (2 in 60 years)
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores

Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

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

Penicylinders Sterilized by Various Low-Temperature Sterilization Methods

Alfa et al. Infect Cont Hosp Epidemiol 1996;17:92-100

Challenge:	12/88	100%ETO	HCFC-ETO	HP Plasma
10% Serum, 0.65% Salt (7 organisms, N=63)	97%	60.3%	95.2%	37%
No Serum or Salt, (3 organisms, N=27)	100%	100%	96%	100%

The three organisms included: *E. faecalis*, *M. chelonei, B. subtilis* spores. The seven organisms included: *E. faecalis*, *P. aeruginosa, E.coli*, *M. chelonei, B. subtilis* spores, *B. stearothermophilus* spores, *B. circulans* spores

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 disinfector
- Manual

Washer/Disinfector

Removal/Inactivation of Inoculum (Exposed) on Instruments

Rutala WA, Gergen MF, Weber DJ. ICHE 2014;35:883-885

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


DON'T YOU EVER WASH YOUR WEAPONS BEFORE YOU USE THEM?
NO, WHY?
DIK BROWNE 9-5
YOU COULD GIVE SOMEONE AN INFECTION

IS THERE A STANDARD TO DEFINE WHEN A DEVICE IS CLEAN?

- There is currently no universal standard to define when a device is "clean", cleanliness controlled by visual
- Potential methods: level of detectable bacteria; protein (6µg/cm^2); endotoxin; ATP; lipid; hemoglobin; carbohydrate; bilirubin; total organic carbon; cleaning indicators for washer disinfectors; boroscope
- This is due in part to the fact that no universally accepted test soils to evaluate cleaning efficiency and no standard procedure for measuring cleaning efficiency
- At a minimum, a cleaning process should: reduce the natural bioburden; remove organic/inorganic contaminants; provide devices that when sterilized have a SAL 10^{-6}

Methods in Sterilization

Sterilization of “Critical Objects”

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Ozone and hydrogen peroxide

Vaporized hydrogen peroxide

Sterilization
Enormous Margin of Safety!

100 quadrillion (10^{17}) margin of safety

Sterilization kills 1 trillion spores, washer/disinfector removes or inactivates 10-100 million; ~100 microbes on surgical instruments

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

Rutala, Weber, CDC Guideline 2008. www.cdc.gov

Sterilization monitored routinely by combination of mechanical, chemical, and biological parameters

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters present
- Biological - *Bacillus* spores that directly measure sterilization

Sterilility Indicators Table

	Before Exposure (Do not use)	After Exposure (Sterile) (Ok if package is intact)
Steam Autoclave		
Tape		
Strip		
Peel Pack		
Ethylene Oxide (ETO. gas)		
Tape		
Strip		
Peel Pack		
Tape		
Strip		
Strip		

6/23/97

Super Rapid Readout Biological Indicators

Commercially available

BI (blue cap)

- Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
- 30 minute result (from 1hour)

BI (brown cap)

- Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
- 1 hour result (from 3 hours)

Semicritical Medical Devices

Rutala et al. AJIC 2016;44:e47

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >130 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
      - Microbial load, 10^7-10^{10}
      - Complexity
      - Biofilm
  - Other semicritical devices, rare outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex

Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Laryngoscopes

High-Level Disinfection
No Margin of Safety

0 margin of safety

Microbial contamination 10^7-10^{10}: compliant with reprocessing guidelines 10,000 microbes after reprocessing:

maximum contamination, minimal cleaning (10^2)/HLD (10^4)

High-Level Disinfection of "Semicritical Objects"

Rutala, Weber, HICPAC. www.cdc.gov

Exposure Time ≥ 8m-45m (US), 20°C

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde	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%
Peracetic acid	0.2%
Glut and isopropanol	3.4%/26%
Glut and phenol/phenate**	1.21%/1.93%

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

Transmission of Infection by Endoscopy

Kovaleva et al. Clin Microbiol Rev 2013. 26:231-254

Scope	Outbreaks	Micro (primary)	Pts Contaminated	Pts Infected	Cause (primary)
Upper GI	19	Pa, *H. pylori*, *Salmonella*	169	56	Cleaning/Dis-infection (C/D)
Sigmoid/Colon oscopy	5	*Salmonella*, HCV	14	6	Cleaning/Dis-infection
ERCP	23	*P. aeruginosa* (Pa)	152	89	C/D, water bottle, AER
Bronchoscopy	51	Pa, Mtb, Mycobacteria	778	98	C/D, AER, water
Totals	98		1113	249	

Based on outbreak data, if eliminated deficiencies associated with cleaning, disinfection, AER, contaminated water and drying would eliminate about 85% of the outbreaks.

Reason for Endoscope-Related Outbreaks

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain 10^{7-10}
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: $4\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-unclear if contribute to failure of endoscope reprocessing

Noncritical Medical Devices

Rutala et al. AJIC 2016;44:e1; Rutala, Weber. Env Issues NI, Farber 1987

- Noncritical medical devices
- Transmission: secondary transmission by contaminating hands/gloves via contact with the environment and transfer to patient
- Control measures: hand hygiene and low-level disinfection
- Noncritical devices (stethoscopes, blood pressure cuffs, wound vacuum), rare outbreaks

Effective Surface Decontamination

Product and Practice

LOW-LEVEL DISINFECTION FOR NONCRITICAL MEDICAL DEVICES AND SURFACES

Rutala, Weber. Infect Control Hosp Epidemiol. 2014;35:855-865

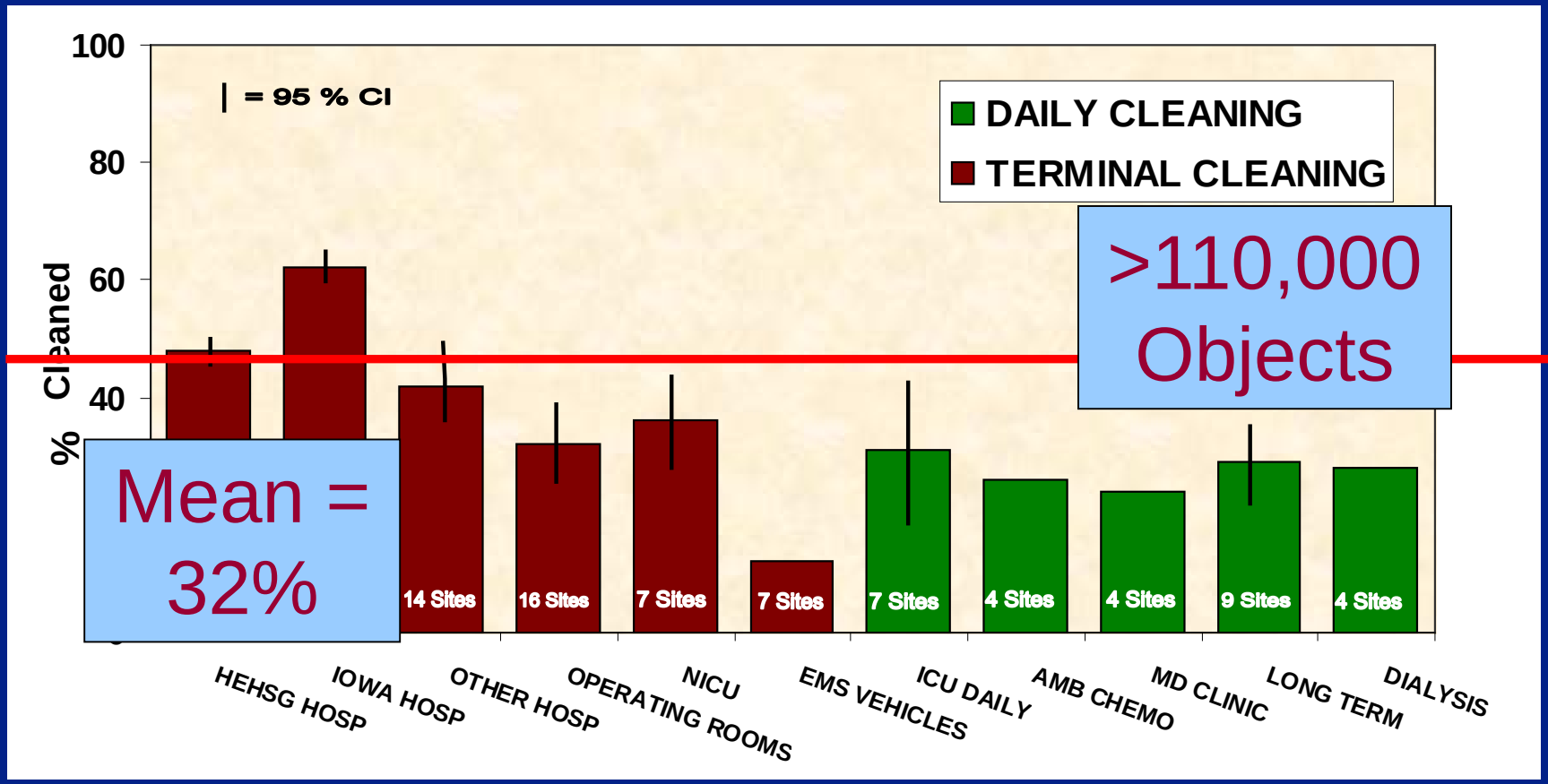
Exposure time ≥ 1 min

Germicide	Use Concentration
Ethyl or isopropyl alcohol	70-90%
Chlorine	100ppm (1:500 dilution)
Phenolic	UD
Iodophor	UD
Quaternary ammonium (QUAT)	UD
QUAT with alcohol	RTU
Improved hydrogen peroxide (HP)	0.5%, 1.4%
Peracetic acid with HP (*C. difficile*)	UD

UD=Manufacturer's recommended use dilution; others in development/testing-electrolyzed water; polymeric guanidine; cold-air atmospheric pressure plasma (Boyce Antimicrob Res IC 2016. 5:10)

Thoroughness of Environmental Cleaning

Carling P. AJIC 2013;41:S20-S25



How Will We Prevent Infections Associated with the Environment?

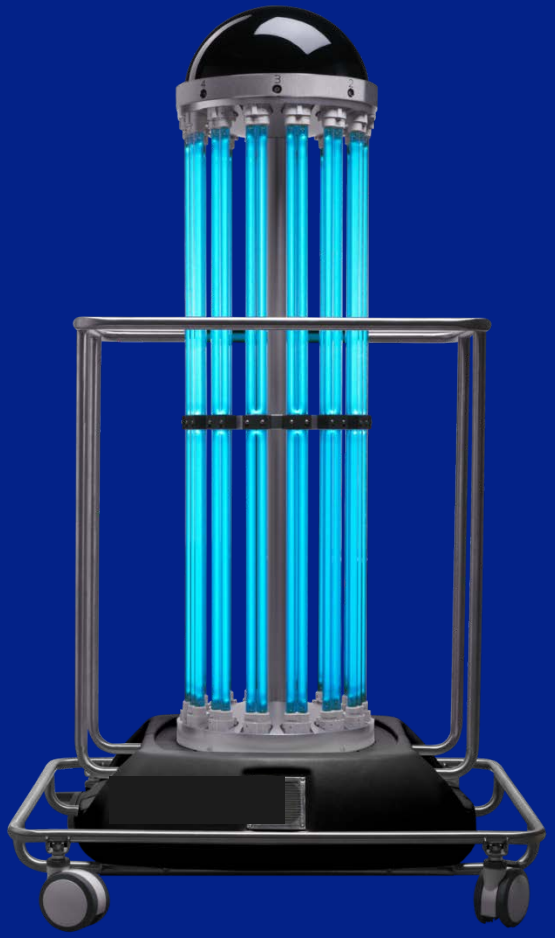
Weber, Rutala et al. AJIC;2016:44:e77-e84; Anderson et al. Lancet 2017;389:805-14; Anderson et al. Lancet Infect Dis 2018;June 2018.

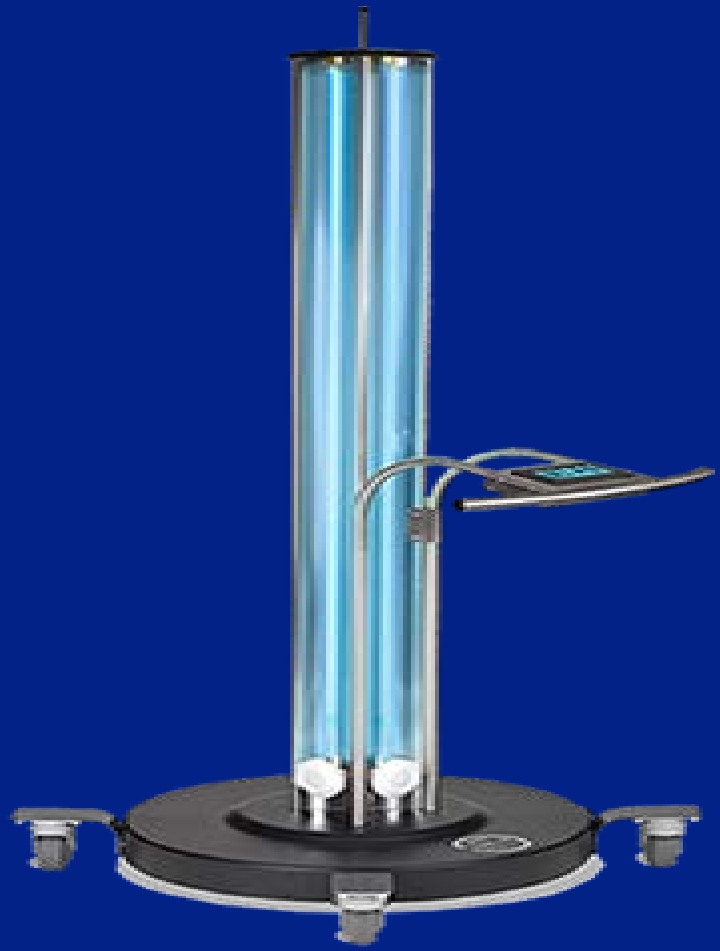
- Implement evidence-based practices for surface disinfection
  - Ensure use of safe and effective (against emerging pathogens such as *C. auris* and CRE) low-level disinfectants
  - Ensure thoroughness of cleaning (new thoroughness technology)
- Use “no touch” room decontamination technology proven to reduce microbial contamination on surfaces and reduction of HAIs at terminal/discharge cleaning
- Use new continuous room decontamination technology that continuously reduces microbial contamination

“NO TOUCH” APPROACHES TO ROOM DECONTAMINATION

(UV/VHP~20 microbicidal studies, 12 HAI reduction studies; will not discuss technology with limited data)

Weber, Kanamori, Rutala. Curr Op Infect Dis 2016;29:424-431; Weber, Rutala et al. AJIC; 2016:44: e77-e84; Anderson et al. Lancet 2017;389:805-14; Anderson et al. Lancet Infect Dis 2018;June 2018.





Enhanced Disinfection Leading to Reduction of Microbial Contamination and a Decrease in Patient Col/Infection

Anderson et al. Lancet 2017;389:805-814; Rutala et al. ICHE In press.

	Standard Method	Enhanced method		
	Quat	Quat/UV	Bleach	Bleach/UV
EIP (mean CFU per room)[a]	60.8	3.4	11.7	6.3
Reduction (%)		94	81	90
Colonization/Infection (rate)[a]	2.3	1.5	1.9	2.2
Reduction (%)		35	17	4

All enhanced disinfection technologies were significantly superior to Quat alone in reducing EIPs. Comparing the best strategy with the worst strategy (i.e., Quat vs Quat/UV) revealed that a reduction of 94% in EIP (60.8 vs 3.4) led to a 35% decrease in colonization/infection (2.3% vs 1.5%). Our data demonstrated that a decrease in room contamination was associated with a decrease in patient colonization/infection. First study which quantitatively described the entire pathway whereby improved disinfection decreases microbial contamination which in-turn reduced patient colonization/infection.

Antisepsis

Antiseptic Agents

(used alone or in combination)

Boyce , Pittet. https://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

- Alcohols, 60-95%
- Chlorhexidine, 2% and 4% aqueous
- Iodophors
- PCMX
- Triclosan

Antiseptics

- Hand Hygiene-improvement and compliance monitoring
- Preoperative showers
- Preoperative skin preparation
- Surgical hand scrub
- Skin preparation prior to insertion of catheters
- Routine daily bathing of patients

Summary of Best Antiseptics

JM Boyce, 2007 Disinfection, Sterilization, Antisepsis, Rutala WA ed. 237-248

- **Preoperative showers**-CHG is preferred; significant impact on SSIs not proven
- **Preoperative skin preparation**-alcohol-containing products (with CHG or iodophor)
- **Surgical hand scrub**-alcohol-containing products reduce bacteria on hands best
- **Vascular access site preparation**-alcohol preparation containing >0.5% CHG
- **Routine daily bathing of patients**-CHG appear to be more effective than standard soap and water

Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection, sterilization and antisepsis
  - Indications and methods for sterilization, high-level disinfection and low-level disinfection
  - Cleaning of patient-care devices
  - Sterilization
  - Disinfection (high-level and low-level disinfection)
  - Antisepsis

Summary

- D/S evidenced-based recommendations must be followed to prevent exposure to pathogens that may lead to infection
- Antiseptics must be used optimally to prevent infections that originate from the skin and patient contact

THANK YOU!

www.disinfectionandsterilization.org