Best Practices for Cleaning, Disinfection, and Sterilization in Healthcare
Prof. William Rutala, University of North Carolina
Sponsored by WHO First Patient Safety Challenge, Clean Care is Safer Care

Best Practices for Cleaning, Disinfection and Sterilization in Healthcare

William A. Rutala, Ph.D., M.P.H.
University of North Carolina (UNC) Health Care System and UNC at Chapel Hill, NC

Hosted by Benedetta Allegranzi
WHO Technical Lead
Clean Care is Safer Care

Sponsored by
WHO Patient Safety Challenge
Clean Care is Safer Care

Disinfection and Sterilization

- Provide overview of disinfection and sterilization recommendations
  - Indications and methods for sterilization, high-level disinfection and low-level disinfection
  - Cleaning of patient-care devices
  - Sterilization practices
  - Disinfection practices

disinfectionandsterilization.org

Disinfection and Sterilization in Healthcare Facilities

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

- Overview
  - Last Centers for Disease Control and Prevention guideline in 1985
  - 158 pages (>82 pages preamble, 34 pages recommendations, glossary of terms, tables/figures, >1000 references)
  - Evidence-based guideline
  - Cleared by HICPAC February 2003; delayed by FDA
  - Published in November 2008

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 (or non-germicidal detergent).

Efficacy of Disinfection/Sterilization
Influencing Factors

Cleaning of the object

Organic and inorganic load present

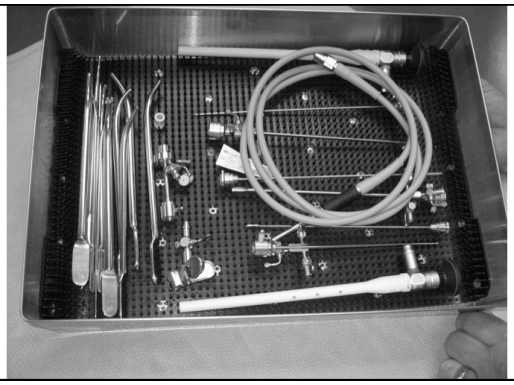
Type and level of microbial contamination

Concentration of and exposure time to disinfectant/sterilant

Nature of the object

Temperature and relative humidity

Hosted by Benedetta Allegranzi, World Health Organisation
A Webber Training Teleclass
www.webbertraining.com



Processing "Critical" Patient Care Objects

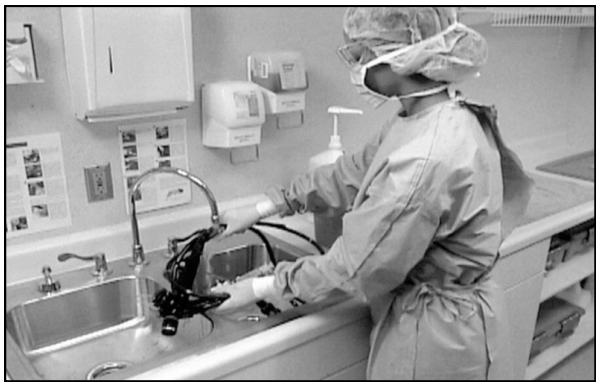
Classification:	Critical objects enter normally sterile tissue or vascular system, or through which blood flows.
Object:	Sterility.
Level germicidal action:	Kill all microorganisms, including bacterial spores.
Examples:	Surgical instruments and devices; cardiac catheters; implants; etc.
Method:	Steam, ETO, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, ozone or chemical sterilization.

Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

Sterilization of "Critical Objects"

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Ozone
Vaporized hydrogen peroxide



Processing "Semicritical" Patient Care Objects

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:	Respiratory therapy and anesthesia equipment, GI endoscopes, endocavitary probes, etc.
Method:	High-level disinfection

Semicritical Items

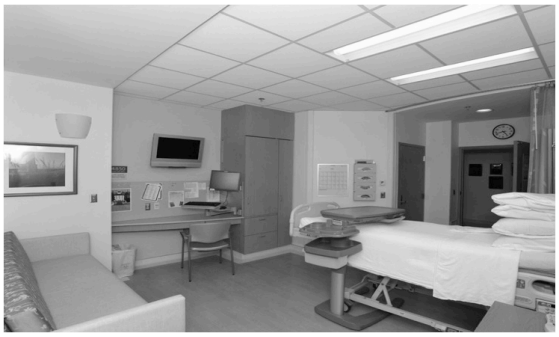
- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Diaphragm fitting rings

High-Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 8m-45m (US), 20ºC

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%
Glut and isopropanol	3.4%/26%
Glut and phenol/phenate**	1.21%/1.93%

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



Processing "Noncritical" Patient Care Objects

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 (or detergent for housekeeping surfaces)

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 (e.g., 1:64)

Methods in Sterilization

Sterilization of "Critical Objects"

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Ozone
Vaporized hydrogen peroxide

Cleaning

- Critical and semicritical 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

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 (150ºF) 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 (180ºF) 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 180F

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

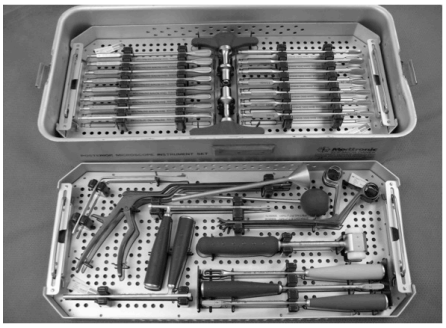
Washer/disinfectors are very effective in removing/inactivating microorganisms from instruments

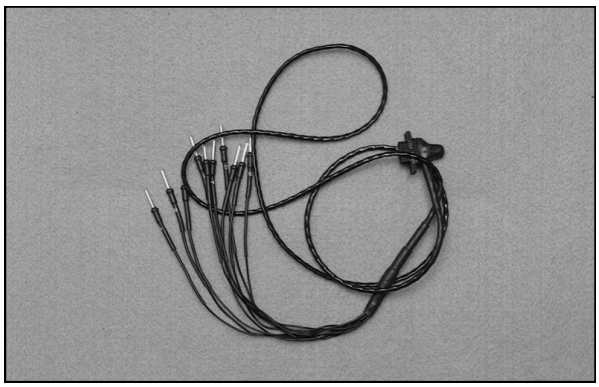
Sterilization

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

Steam Sterilization

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Least affected by organic/inorganic soils
  - Rapid cycle time
  - Penetrates medical packing, device lumens
- Disadvantages
  - Deleterious for heat labile instruments
  - Potential for burns





Newer Trends in Sterilization of Patient Equipment

- Alternatives to ETO-CFC
  ETO-CO_2, ETO-HCFC, 100% ETO
- Newer Low Temperature Sterilization Technology
  Hydrogen Peroxide Gas Plasma
  Vaporized hydrogen peroxide
  Ozone

Ethylene Oxide (ETO)

- 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

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

Hydrogen Peroxide Gas Plasma Sterilization

Disadvantages

- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about 3.5ft^3 to 7.3ft^3
- Endoscopes or medical devices restrictions based on lumen internal diameter and length (see manufacturer's recommendations); expanded claims with NX
- Requires synthetic packaging (polypropylene) and special container tray

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 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

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

Recommendations
Methods of Sterilization

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer (times, temperatures, gas conc)
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Aerate surgical and medical items that have been sterilized in the ETO sterilizer

Recommendations
Methods of Sterilization

- Dry heat sterilization (e.g., 340F for 60 minutes) can be used to sterilize items (e.g., powders, oils) that can sustain high temperatures

Immediate Use Steam Sterilization
Multi-Society from AAMI, AORN, APIC, IAHCSMM-March, 2011

- "Flash Sterilization" an antiquated term that does not describe current cycles used for items not intended to be stored for later use
- Item is not stored or held for a future case or used from one case to another; used for procedure which it sterilized
- Cleaning, decontamination and reprocessing are critical and must be followed
- Should not be used for implants unless no other option
- Cycle parameters determined by the design of the instrument, the characteristics of the load, the sterilizer capability and the packaging (if used)

Sterilization Practices

Packaging

- Once items are cleaned, dried, and inspected, items are wrapped or placed in a rigid container
- Arranged in tray/basket according to guidelines
  - Hinged instruments opened
  - Items with removable parts should be disassembled
  - Heavy items positioned not to damage delicate items
- Several choices to maintain sterility of instruments: rigid containers, peel pouched; sterilization wraps

Packaging
Sterilization Wraps

- An effective sterilization wrap would:
  - Allow penetration of the sterilant
  - Provide an effective barrier to microbial penetration
  - Maintain the sterility of the processed item after sterilization
  - Puncture resistant and flexible
  - Drapeable and easy to use
- Multiple layers are still common practice due to the rigors of handling

Recommendations
Storage of Sterile Items

- Sterile storage area should be well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.
- Sterile items should be stored so that packaging is not compromised
- Sterilized items should be labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and the expiration date (if applicable)

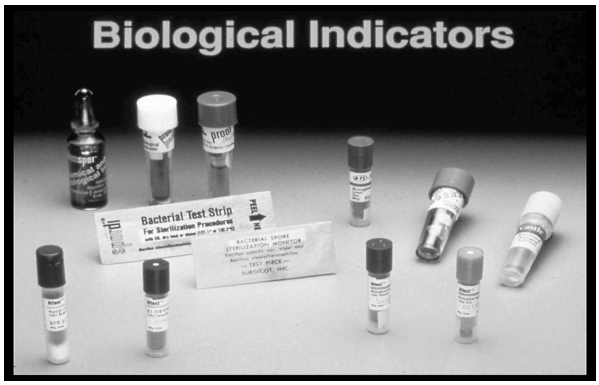
Objectives of Monitoring the Sterilization Process

- 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

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

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters present (Class 1-6)
- Biological - *Bacillus* spores that directly measure sterilization



Biological Monitors

- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus (formerly B. subtilis)*
- ETO - *B. atrophaeus*
- New low temperature sterilization technologies
  HP gas plasma (Sterrad) - *G. stearothermophilus*
  Ozone-*G. stearothermophilus*

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 CI not a substitute for BI).
- Use biological indicators for every load containing implantable items and quarantine items, whenever possible, until the biological indicator is negative.

Recommendations
Storage of Sterile Items

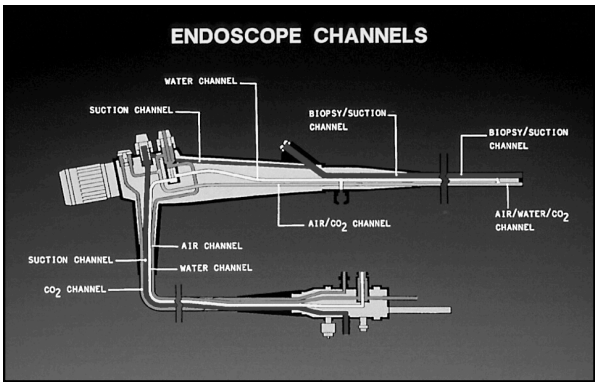
- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g., tear, wetness). Packages should be evaluated before use for lose of integrity.
- Time-related shelf life (less common) considers items remain sterile for varying periods depending on the type of material used to wrap the item/tray. Once the expiration date is exceeded the pack should be reprocessed.

Disinfection Practices

Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Diaphragm fitting rings

Endoscopes/AERS



ENDOSCOPE REPROCESSING

Multi-Society Guideline on Endoscope Reprocessing, 2011

- PRECLEAN-point-of-use remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels
- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for exposure time (>2% glut at 20m at 20ºC). If AER used, review model-specific reprocessing protocols from both the endoscope and AER manufacturer
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water. Flush channels with alcohol and dry
- DRY-use forced air to dry insertion tube and channels
- STORE-hang in vertical position to facilitate drying; stored in a manner to protect from contamination

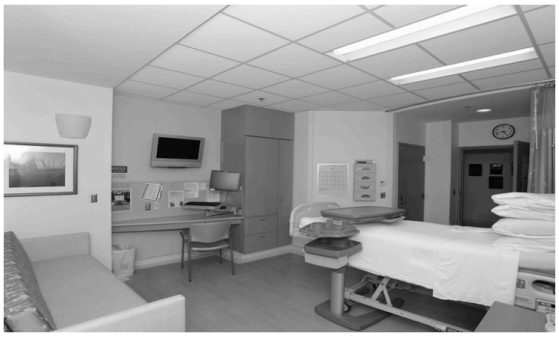
High-Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 8m-45m (US), 20ºC

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%
Glut and isopropanol	3.4%/26%
Glut and phenol/phenate**	1.21%/1.93%

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

Noncritical Items



Surface Disinfection

Noncritical Patient Care-CDC, 2008

- Disinfecting Noncritical Patient-Care Items
  - Process noncritical patient-care equipment with a EPA-registered disinfectant at the proper use dilution and a contact time of at least 1 min. *Category IB*
  - Ensure that the frequency for disinfecting noncritical patient-care surfaces be done minimally when visibly soiled and on a regular basis (such as after each patient use or once daily or once weekly). *Category IB*

Surface Disinfection

Environmental Surfaces-CDC, 2008

- Disinfecting Environmental Surfaces in HCF
  - Disinfect (or clean) housekeeping surfaces (e.g., floors, tabletops) on a regular basis (e.g., daily, three times per week), when spills occur, and when these surfaces are visibly soiled. *Category IB*
  - Use disinfectant for housekeeping purposes where: uncertainty exists as to the nature of the soil on the surfaces (blood vs dirt); or where uncertainty exists regarding the presence of multi-drug resistant organisms on such surfaces. *Category II*

Effective Surface Decontamination

Practice and Product

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

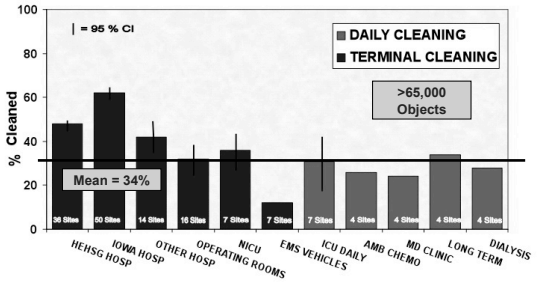
TABLE 2
DISINFECTANT ACTIVITY AGAINST ANTIBIOTIC-SUSCEPTIBLE AND ANTIBIOTIC-RESISTANT BACTERIA

	Log_{10} Reductions							
	VSE		VRE		MSSA		MRSA	
Product	0.5 min	5 min	0.5 min	5 min	0.5 min	5 min	0.5 min	5 min
Vesphene IIse	>4.3	>4.3	>4.8	>4.8	>5.1	>5.1	>4.6	>4.6
Clorox	>5.4	>5.4	>4.9	>4.9	>5.0	>5.0	>4.6	>4.6
Lysol Disinfectant	>4.3	>4.3	>4.8	>4.8	>5.1	>5.1	>4.6	>4.6
Lysol Antibacterial	>5.5	>5.5	>5.5	>5.5	>5.1	>5.1	>4.6	>4.6
Vinegar	0.1	5.3	1.0	3.7	+1.1	+0.9	+0.6	2.3

Abbreviations: MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-susceptible *S aureus*; VRE, vancomycin-resistant *Enterococcus*; VSE, vancomycin-susceptible *Enterococcus*.
Data represent mean of two trials (n=2). Values preceded by ">" represent the limit of detection of the assay. Assays were conducted at a temperature of 20°C and a relative humidity of 45%. Results were calculated as the log of N0/Nt, where N0 is the titer of bacteria surviving after exposure and Nt is the titer of the control.

Rutala WA, Barbee SL, Aguiar NC, Sobsey MD, Weber DJ. Antimicrobial Activity of Home Disinfectants and Natural Products Against Potential Human Pathogens. *Infection Control and Hospital Epidemiology* 2000;21:33-38.

Thoroughness of Environmental Cleaning
Carling and coworkers, SHEA 2010



Practice* NOT Product

*surfaces not wiped

Role of the Environment in Transmission

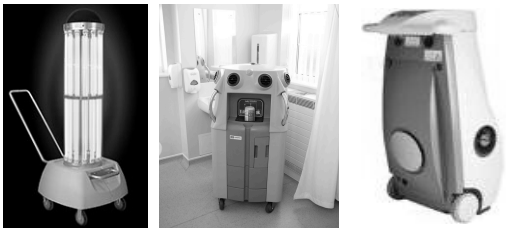
Pathogens implicated in transmission via contaminated noncritical surfaces (survival in the environment and recovered from the environment)

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

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). Huang et al. 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. Drees et al. Clin Infect Dis 2008;46:678.
- Prior room occupant with CDAD is a significant risk for CDAD acquisition. Shaughnessy et al. ICHE 2011:32:201

New Approaches to Room Decontamination



Summary

UV and HP decontamination units have been demonstrated to be effective against various pathogens (including *C. difficile* spores) and offer an option for room decontamination

Disinfection and Sterilization

- Provide overview of disinfection and sterilization recommendations
  - Indications and methods for sterilization, high-level disinfection and low-level disinfection
  - Cleaning of patient-care devices
  - Sterilization practices
  - Disinfection practices

Summary

- Critical and semicritical items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Disinfection and sterilization guidelines must be followed to prevent patient exposure to pathogens that may lead to infection
- Contaminated surfaces contribute to pathogen transmission and health care facilities may need to introduce control measures to ensure all surfaces are completely cleaned daily and terminally

Thank you

Best Practices for Cleaning, Disinfection, and Sterilization in Healthcare
Prof. William Rutala, University of North Carolina
Sponsored by WHO First Patient Safety Challenge, Clean Care is Safer Care

References

- 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. November 2008. www.cdc.gov
- Rutala WA. APIC guideline for selection and use of disinfectants. Am J Infect Control 1996;24:313

Hosted by Benedetta Allegranzi, World Health Organisation
A Webber Training Teleclass
www.webbertraining.com