High-Level Disinfection, Sterilization and Antisepsis

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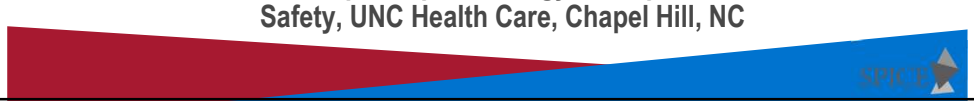

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Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection and sterilization principles
- Issues
  - Sterilization
  - High-level disinfection
  - Antisepsis

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CDC Guideline for Disinfection and Sterilization

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

Accessible version: https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Update: June 2024

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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

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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

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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**.

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DISINFECTION AND STERILIZATION

Rutala, Weber. AJIC 2023;51:A3-A12

- 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**

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Critical Medical/Surgical Devices

Rutala, Weber. AJIC 2023;51:A3-A12; 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
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores

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Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

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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

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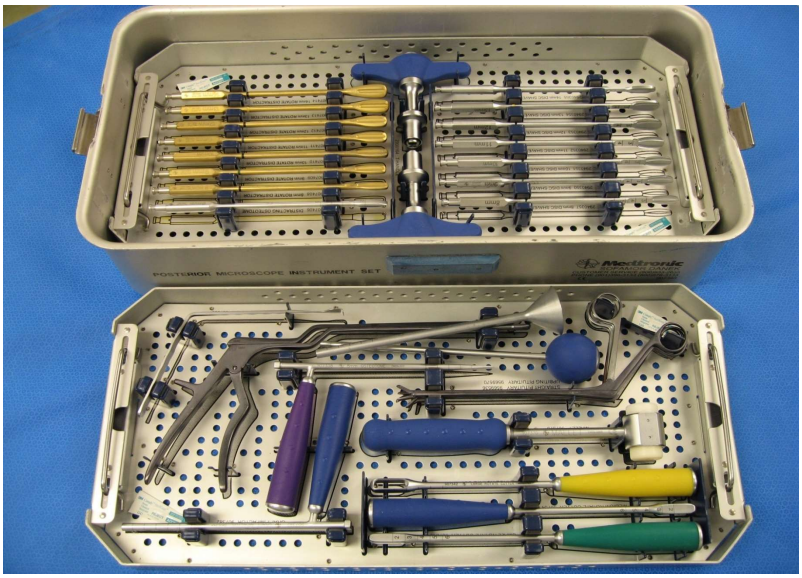

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Processing "Critical" Patient Care Objects

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, ethylene oxide, hydrogen peroxide plasma, ozone plus hydrogen peroxide, VHP or chemical sterilization.

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Sterilization of "Critical Objects"

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala, Weber. AJIC 2023;51:A3-A12

Heat resistant

- Steam sterilization

Heat sensitive

- Ethylene oxide
- Hydrogen peroxide gas plasma
- Vaporized hydrogen peroxide
- Ozone and hydrogen peroxide

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Chemical Sterilization of "Critical Objects"

Rutala, Weber. AJIC 2023;51:A3-A12

Glutaraldehyde (≥ 2.0%)
Hydrogen peroxide-HP (7.5%)
HP (1.0%) and PA (0.08%)
HP (7.5%) and PA (0.23%)
Glut (1.12%) and Phenol/phenate (1.93%)
Ortho-phthalaldehyde (0.55%)

Exposure time per manufacturers' recommendations

https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and Dec 2023

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Semicritical Medical Devices

Rutala, Weber. AJIC 2023;51:A3-A12; Rutala et al. AJIC 2016;44:e47

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >100 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

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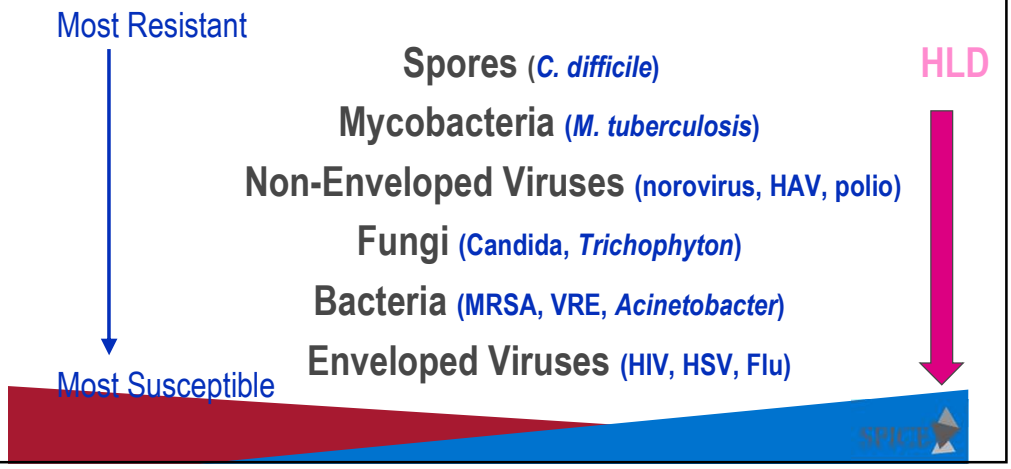
Microbiological Disinfectant Hierarchy

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



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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, thermometer, etc.
Method:	High-level disinfection

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Semicritical Items

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

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High-Level Disinfection of "Semicritical Objects"

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

https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and December 2023

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Environmental Contamination Leads to HAIs

Weber, Kanamori, Rutala. Curr Op Infect Dis .2016.

Evidence environment contributes

- Role-MRSA, VRE, *C. difficile*
- Surfaces are contaminated-~25%
- EIP survive days, weeks, months
- Contact with surfaces results in hand contamination; contaminated hands transmit EIP to patients
- Disinfection reduces contamination
- Disinfection (daily) reduces HAIs
- Rooms not adequately cleaned

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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

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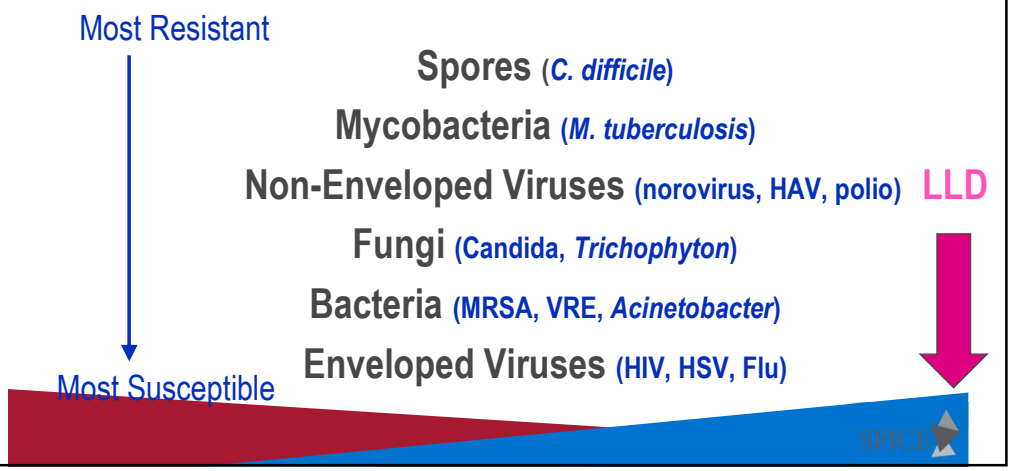
Microbiological Disinfectant Hierarchy

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



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LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

Rutala, Weber. AJIC 2023;51:A3-A12; Rutala, Weber. AJIC 2019;47:A3-A9

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%
PA with HP, 4% HP, chlorine (*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)

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Disinfection of Noncritical Surfaces Bundle

NL Havill AJIC 2013;41:S26-30; Rutala, Weber AJIC 2019

- Develop policies and procedures
- Select cleaning and disinfecting products
- Educate staff-environmental services and nursing
- Monitor compliance (thoroughness of cleaning, product use) and feedback
- Implement "no touch" room decontamination technology and monitor compliance

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Critical Medical/Surgical Devices

Rutala, Weber. AJIC 2023;51:A3-A12; 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**
    - **~85% of surgical instruments <100 microbes**
    - **Washer/disinfector removes or inactivates 10-100 million**
    - **Sterilization kills 1 trillion spores**

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Sterilization

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

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Methods in Sterilization

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Sterilization of "Critical Objects"

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala, Weber. AJIC 2023;51:A3-A12

Heat resistant

- Steam sterilization

Heat sensitive

- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

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“Ideal” Sterilization Method

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

Schneider PM. Tappi J. 1994;77:115-119

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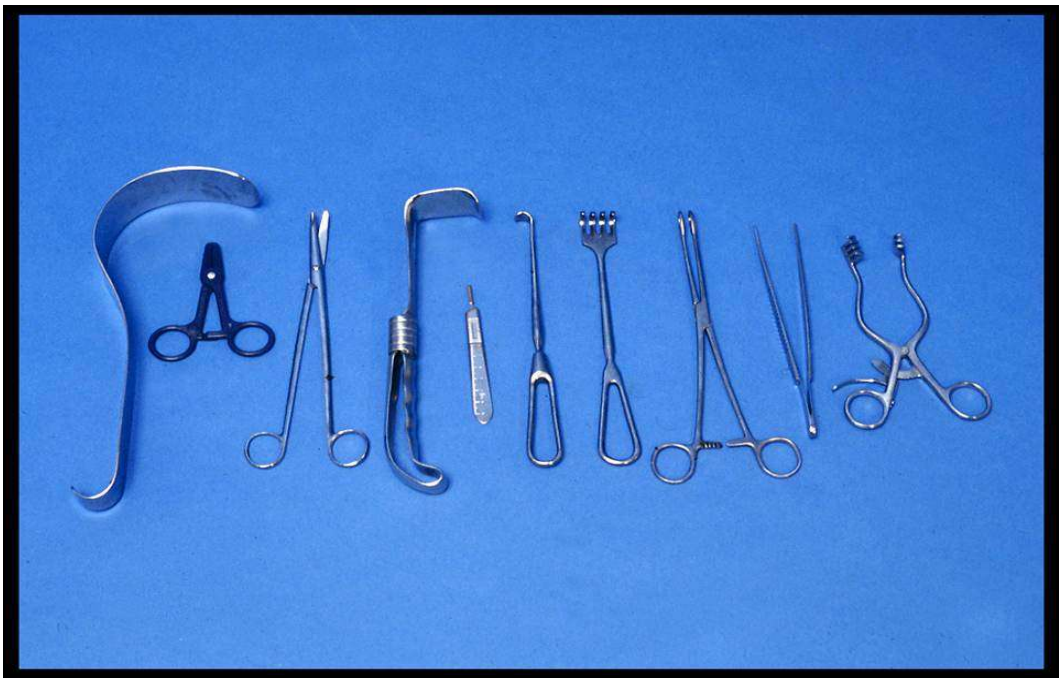

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Bioburden on Surgical Devices

Non-lumen Surgical Instruments Carry a Low Microbial Load (<100 CFU, 85%)

- Bioburden on instruments used in surgery (Nystrom, J Hosp Infect 1981)
  - 62% contaminated with $<10^1$
  - 82% contaminated with $<10^2$
  - 91% contaminated with $<10^3$
- Bioburden on surgical instruments (Rutala, Am J Infect Control 1997)
  - 72% contained $<10^1$
  - 86% contained $<10^2$
- Bioburden on surgical instruments (50) submitted to CP (Rutala, AJIC 2014)
  - 58% contained <10
  - 20% contained $\leq 10^2$
  - 16% contained $\leq 5x10^2$
  - 6% contained $<10^3$

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Inadequate Cleaning and Sterilization of Cataract Surgery

- May result in an adverse event after cataract surgery
  - TASS-Toxic Anterior Segment Syndrome
- Etiology may be multi-factorial with many potential causes:
  - Bacterial endotoxins; intraocular irrigating solutions with abnormal pH; intraocular medicals; topical ointments; inadequate sterilization; inadequate flushing of instruments between cases; preservatives; metallic precipitates; particulate contamination

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Pre-Cleaning

- Ideally, instruments should arrive in Central Processing free on visible contamination
- Wipe instruments clean and keep lumens flushed throughout surgery. Soiled instruments that will not be reused should be allowed to soak in a basin of sterile water for the remainder of the procedures
- Many hospitals spray instruments with an enzymatic solution
- Keep instruments moist (e.g., damp towel) as it prevents hardening

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Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners (single use) 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.

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Ultrasonic Cleaners

- Use sound waves to create bubbles that disrupt small particles that may exist in hard-to-clean places on instruments (fine cleaning)
- Used after initial cleaning that removes all visible and accessible soiling is carried out and before 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**

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Washer/Disinfector

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

- Five Chambers
  - Pre-wash: water/enzymatic is circulated over the load for 1 min
  - Wash: detergent wash solution (150°F) is sprayed over the 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 the 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

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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

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

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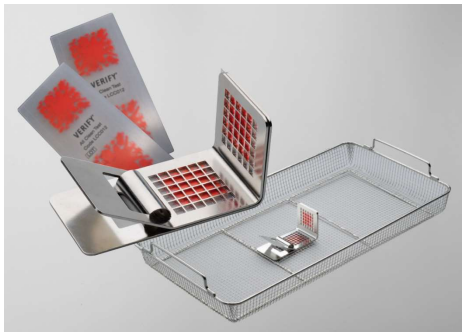
Cleaning Indicators for Washer Disinfector

- Monitor the automated washer and instrument cleaning chemistry functionality; AAMI recommends weekly (preferably daily)
- Washer indicators have been used in Europe and Canada and some US hospitals
- Indicator includes proteins, lipids, and polysaccharides to mimic common challenging test soils
- Washer indicators are chemical indicators imprinted with a dried test soil formula and a dye



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Mechanical Cleaning Equipment in CP

- When tested to verify adequate cleaning
  - Should be carried out weekly
  - Upon installation of the equipment
  - After major repairs

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

- There is currently no 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
- 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}

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Methods in Sterilization

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Sterilization of "Critical Objects"

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

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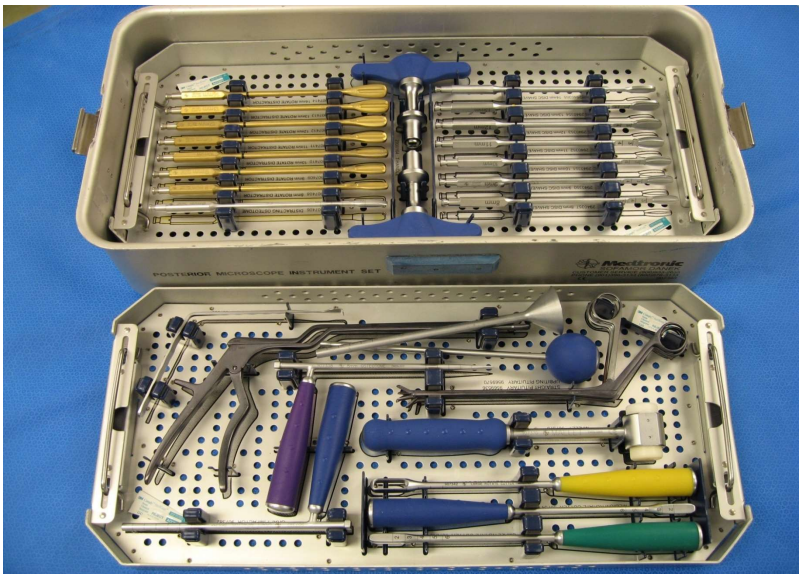

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Steam Sterilization

Rutala, Weber AJIC 2019;47:A3-A9

- 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

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Minimum Steam Sterilization Times

Time at 132°C in Prevacuum Sterilizer

Item	Minimum exposure	Minimum drying time
Wrapped instruments	4 min	30 min
Textile packs	4 min	5 min

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Immediate Use Steam Sterilization

- "Flash" originally defined as sterilization of an unwrapped object at 132°C for 3 min at 27-28 lbs pressure in gravity
- "Flash" used for items that must be used immediately and cannot be packaged, sterilized and stored before use
- "Flash" used to be suboptimal time/temp, minimal cleaning, no BI, not covered
- "Flash" is an antiquated term and replaced by "immediate use steam sterilization
- The same critical reprocessing steps (such as cleaning, decontaminating, and transporting) must be followed

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Immediate Use Steam Sterilization

- "Immediate Use" is defined as the shortest possible time between a sterilized item's removal from sterilizer and aseptic transfer to sterile field
- A sterilized item intended for immediate use is not stored for future use.
- Sterilization process monitoring is essential
- Instruments inventories should be adequate to meet surgical volumes and permit the time to complete all critical elements of reprocessing

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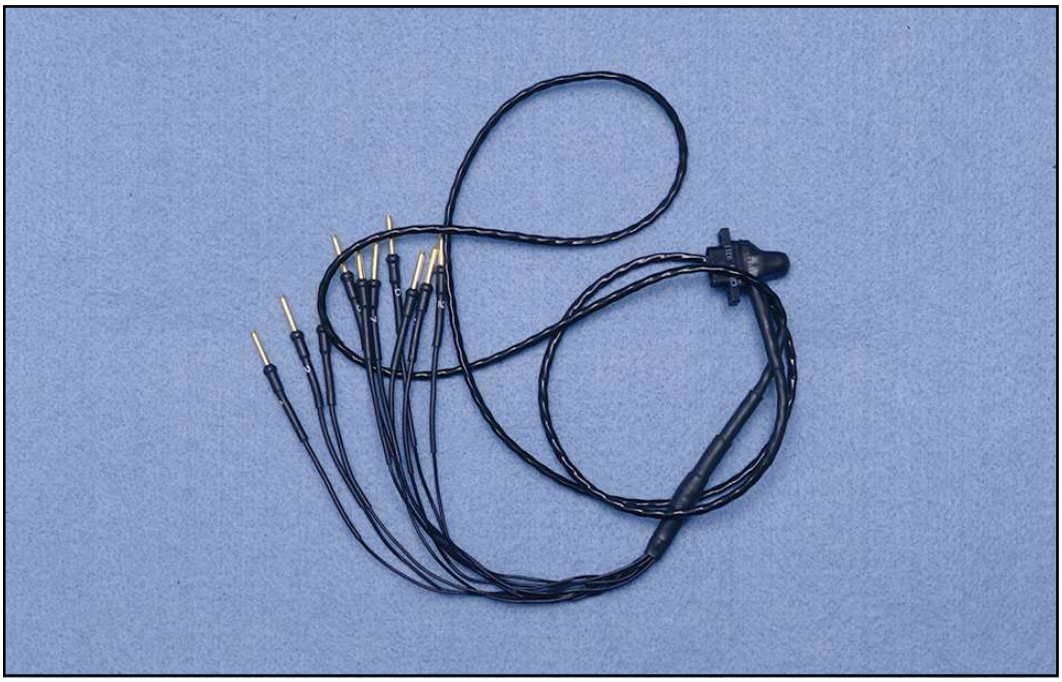

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Sterilization of "Critical Objects"

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2019;47:A3-A9

Heat resistant

- Steam sterilization

Heat sensitive

- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

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Ethylene Oxide (ETO)

Rutala, Weber. AJIC 2023;51:A3-A12

- 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 require ETO emission reduction of 90-99.9%
  - Potential hazard to patients and staff
  - Lengthy cycle/aeration time

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Hydrogen Peroxide Gas Plasma Sterilization

Rutala, Weber. AJIC 2023;51:A3-A12; Rutala, Weber AJIC 2019;47:A3-A9

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

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Hydrogen Peroxide Gas Plasma Sterilization

Rutala, Weber. AJIC 2023;51:A3-A12; Rutala, Weber AJIC 2019;47:A3-A9

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

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Ozone and Hydrogen Peroxide

- Sterizone VP4, 510(k) FDA clearance,TSO_3 Canada
- Sterilizer has a 4.4ft^3 chamber
- Low temperature (41^oC); uses VHP and ozone in multiple phases
- Can sterilize multi-channeled flexible endoscopes (max 4) having internal lumens ≥1.45 mm in inner diameter and ≤3,500 mm and ≥1.2 mm in inner diameter and ≤ 1,955 mm in overall length (commonly found in video colonoscopies and gastroscopes)
- Advantages/Disadvantages-limited information in peer-review literature

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Vaporized Hydrogen Peroxide

Rutala, Weber. AJIC 2023;51:A3-A12; Rutala, Weber AJIC 2019;47:A3-A9

- 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

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Sterilization of "Critical Objects"

Rutala, Weber. AJIC 2023;51:A3-A12

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

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STERILIZATION

Factors affecting the efficacy of sterilization

- Bioburden
- Cleaning
- Pathogen type
- Protein and salt
- Biofilm accumulation
- Lumen length and diameter
- Restricted flow

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Evaluation of Microbicidal Activities of Sterilization Technologies in Salt and Serum

Rutala et al. Infect Control Hosp Epidemiol 2020 **doi:10.1017/ice.2020.2**

Organism	Mean Inoculating Suspension/mL	Mean Carrier Quantitation (Day of Run)	Mean Carrier Quantitation (24 h ETO)	% Failure (Carriers Positive/Carriers Tested) Steam	ETO	HPGP	VHP
Vegetative cells							
Pseudomonas aeruginosa	8.1×10^8	2.0×10^6	3.5×10^4	0 (0/30)	0 (0/50)	0 (0/40)	13 (5/40)
Escherichia coli	1.1×10^9	3.4×10^6	5.1×10^5	0 (0/30)	4 (2/50)[b]	3 (1/40)[b]	75 (30/40)
Vanomycin-resistant enterococci	5.9×10^8	2.8×10^6	2.8×10^6	0 (0/30)	8 (4/50)[b]	10 (4/40)[b]	93 (37/40)
Staphylococcus aureus	4.8×10^8	2.3×10^6	2.5×10^6	0 (0/30)	0 (0/40)	0 (0/30)	93 (28/30)
Mycobacterium terrae	1.4×10^9	5.2×10^4	3.2×10^5	0 (0/20)	0 (0/30)	0 (0/30)	97 (29/30)
Vegetative cells, total				0 (0/140)	3 (6/220)	3 (5/180)	72 (129/180)
Bacillus atropheaus spores	1.5×10^7	1.2×10^5	1.3×10^5	0 (0/30)	0 (0/30)	0 (0/30)	83 (25/30)
Geobacillus stearothermophilus spores	5.4×10^6	5.1×10^4	6.0×10^4	0 (0/30)	0 (0/30)	0 (0/30)	73 (22/30)
Clostridiodes difficile spores	1.3×10^7	4.4×10^4	4.2×10^4	0 (0/20)	0 (0/30)	0 (0/30)	100 (30/30)
Spore total				0 (0/80)	0 (0/90)	0 (0/90)	86 (77/90)
Overall total				0 (0/220)	2 (6/310)	2 (5/270)	76 (206/270)

Note. ETO, ethylene oxide; HPGP, hydrogen peroxide gas plasma; FCS, fetal calf serum; ND, not done.
[a]To simulate inadequate cleaning, the inoculum for the vegetative bacteria contained 10% FCS and 0.65% salt but 10% FCS and 0.29% salt for the spores *B. atropheaus* and *G. stearothermophilus*; and 10% FCS and 0.52% salt *C. difficile* spores
[b]Runs with ETO and HPGP failure of vegetative bacteria had higher carrier quantitation (day of run) than the mean carrier quantitation for the other runs and that organism (ie, 4.07×10^6 vs 2.54×10^6 for VRE; 8.30×10^6 vs 2.40×10^6 for *E. coli*).

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Comparative Evaluation of the Microbicidal Activities of Sterilization Technologies in the Presence of Salt and Serum

Study conditions not representative of practice or manufacturer's recommendations
Rutala et al. 2019

Organism	Steam	ETO	HPGP	VHP
Vegetative Cells-Pa, Ec, VRE, Sa, Mt	0% (0/140)	3% (6/220)	3% (5/180)	72% (129/180)
Spores-Ba, Gs, Cd	0% (0/80)	0% (0/90)	0% (0/90)	86% (77/90)
Overall Total	0% (0/220)	2% (6/310)	2% (5/270)	76% (206/270)

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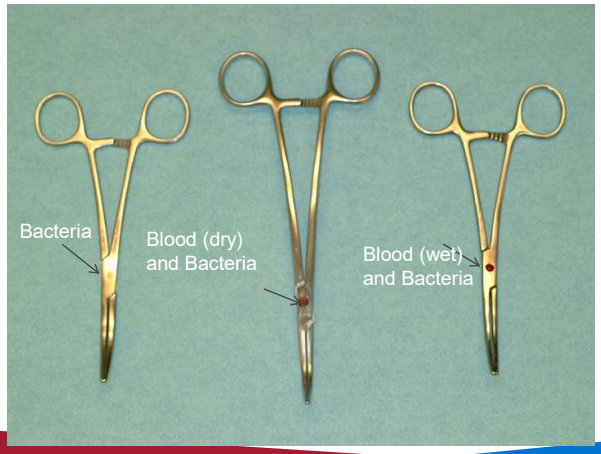
"Dirty" (non-cleaned) Instruments



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Effectiveness of the microbicidal activity of sterilization technologies in the presence of blood on "dirty" (noncleaned) instruments*

Test organism	Method of sterilization	Instruments "dirty" (noncleaned) with or without blood†	Instrument quantitation (Mean)	No. of positives/no. of runs (% Positive)
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	$\sim 1.56\times10^5$	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich†)	$\sim 1.99\times10^5$	0/12 (0)
	ETO	Dirty	$\sim 1.53\times10^5$	0/10 (0)
		Dirty with blood	$\sim 2.35\times10^5$	0/11 (0)
	HPGP	Dirty	$\sim 1.58\times10^5$	5/10 (50)
		Dirty with blood	$\sim 2.35\times10^5$	9/15 (60)
Mycobacterium terrae	Steam Sterilization	Dirty	$\sim 4.25\times10^6$	0/10 (0)
P aeruginosa	HPGP	Dirty	$\sim 1.81\times106$	3/15 (20%)
Bacillus atrophaeus (spores)	ETO	Dirty	$\sim 2.30\times10^7$	6/10 (60)
		Dirty with blood	$\sim 4.08\times10^7$	9/10 (90)
MRSA	ETO	Dirty	$\sim 2.62\times10^6$	0/10 (0)
		Dirty with blood	$\sim 1.72\times10^6$	0/10 (0)
	HPGP	Dirty	$\sim 1.10\times10^6$	4/10 (40)
		Dirty with blood	$\sim 1.27\times10^6$	4/10 (40)
VRE	ETO	Dirty	$\sim 2.27\times10^6$	0/10 (0)
		Dirty with blood	$\sim 3.59\times10^6$	0/10 (0)
	HPGP	Dirty	$\sim 2.63\times10^6$	3/10 (30)
		Dirty with blood	$\sim 2.34\times10^6$	9/10 (90)
Vegetative cells, total	Steam Sterilization			0/10 (0)
	ETO			0/40 (0)
	HPGP			23/55 (42)
Spore total	Steam Sterilization			0/22 (0)
	ETO			15/41 (37)
	HPGP			14/25 (56)
Overall total	Steam Sterilization			0/32 (0)
	ETO			15/81 (19)
	HPGP			37/80 (46)

Abbreviations: ETO, ethylene oxide; HPGP, hydrogen peroxide gas plasma; MRSA, methicillin-resistant *Staphylococcus aureus*; VRE, vancomycin-resistant *Enterococcus*.

*Rutala WA et al. Does blood on "dirty" instruments interfere with the effectiveness of sterilization technologies. Infection Control Hospital Epidemiology (2021), 1–3 doi:10.1017/ice.2021.202. Study conditions not representative of practice or manufacturer's recommendations.

†Sandwich consists of "dirty" or noncleaned instrument, then an inoculum of spores or vegetative bacteria, and lastly overlaid with blood after inoculum dry. One *G. stearothermophilus* experiment was done with the spores mixed with the inoculum and then placed on the dirty instrument.

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Effectiveness of the Microbicidal Activity of Steam Sterilization in the Presence of Blood on "Dirty" Instruments

Rutala et al. Infect Cont Hosp Epidemiol 2021 https://doi.org/10.1017/ice.2021.202

Test Organism	Method of Sterilization	Instruments "dirty" (non-cleaned) with or without blood2	Instrument Quantitation (Mean)	% Positive
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	~ 1.56x105	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich2)	~ 1.99x105	0/12 (0)
Mycobacterium terrae	Steam Sterilization	Dirty	~ 4.25x106	0/10 (0)

[1]Study conditions not representative of practice or manufacturer's recommendations.
[2]Sandwich consists of "dirty" or non-cleaned instrument, then an inoculum of spores or vegetative bacteria, and lastly overlaid with blood after inoculum dry. One *G. stearothermophilus* experiment was done with the spores mixed with the inoculum and then placed on the dirty instrument.

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Comparative Evaluation of the Microbicidal Activity of Low-Temperature Sterilization Technologies to Steam Sterilization

Conclusions

- All LTST technologies have limitations
- LTST (ETO, HP gas plasma) demonstrate a significant number of failures in presence of serum or salt
- Salt and serum provide protection for spores and bacteria
- Steam sterilization is the most effective and had the largest margin of safety, followed by ETO and HPGP and lastly, VHP

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Recommendations
Methods of Sterilization

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

- Steam is preferred for critical items not damaged by heat (most robust-kills in presence of organic matter)
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)

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Conclusions

- 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

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Sterilization Practices

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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

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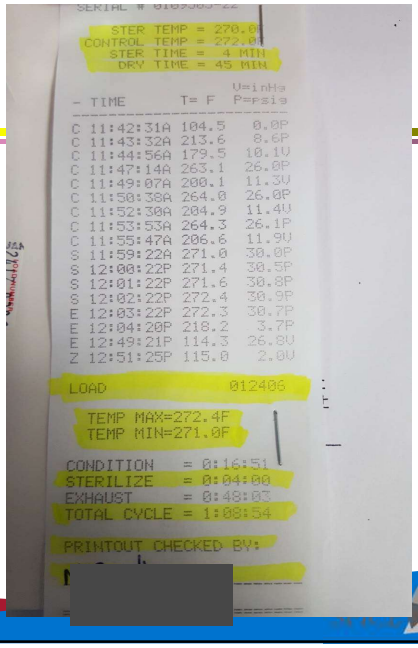
Objectives of Monitoring the Sterilization Process

- 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

85

Sterilizer Receipt



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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

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Six Classes of Indicators Are Recognized by International Organization of Standards (ISO)

Table 2. Chemical Indicator Classifications

Class I Process indicators	Process indicators are attached to or printed on the outside of all packs to discern which packages have been processed from those that have not been processed in a sterilizer.
Class 2 Bowie-Dick test	The Bowie-Dick test is used to reveal the pass/fail rate in dynamic air removal steam sterilizers. This Class 2 chemical indicator should be used in an empty chamber daily, preferably before any loads are processed at the beginning of the day.
Class 3 Single parameter indicator	The single parameter chemical indicator is placed inside each package and provides data on time or temperature, revealing if one of these sterilization parameters has been met during a cycle.
Class 4 Multi-parameter indicators	Multiparameter indicators react to two or more sterilization parameters, such as time and temperature or time and pressure.
Class 5 Integrating indicators	React to all critical parameters of sterilization cycle over a range of temperatures; performance must equal that of the biological indicators.
Class 6 Emulating indicators	Cycle specific; react to all critical parameters for a specified sterilization level; used at the pack/tray level.

Fundamentals of Dental Hygiene, March 2009

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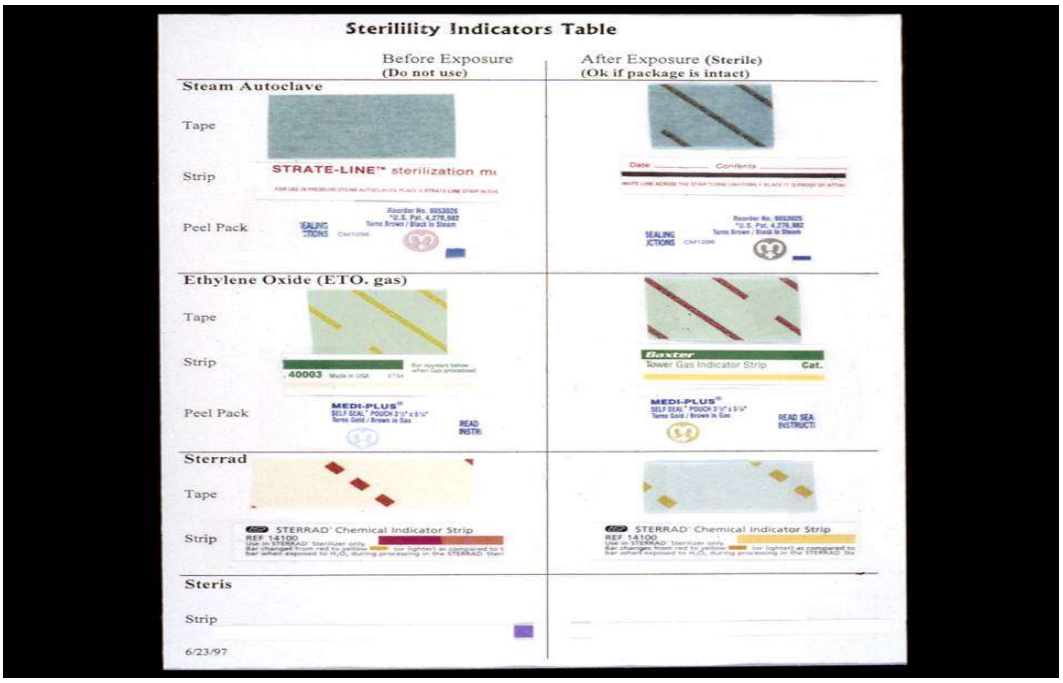

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Biological Indicators

- **Select BIs that contain spores of *Bacillus atrophaeus***
  - Rationale: BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process

Bacillus atrophaeus

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Biological Monitors

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

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

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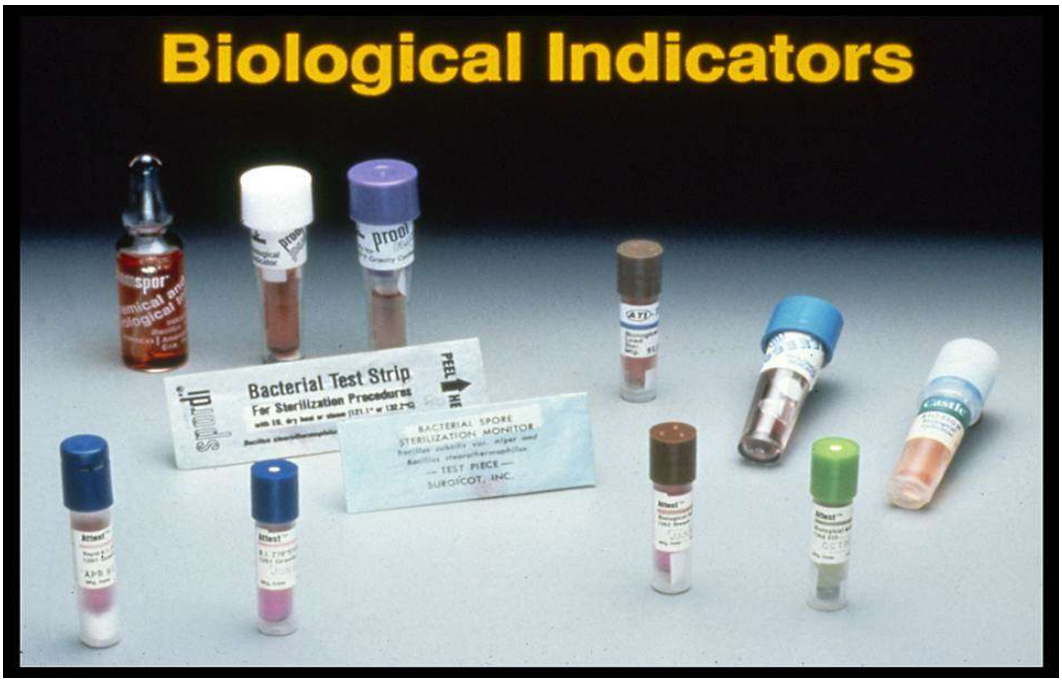

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Rapid Readout BIs for Steam Now Require a 1-3h Readout Compared to 24-48h

Rutala, Jones, Weber ICHE 1996. 17:423

Vol. 17 No. 7 INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY 423

COMPARISON OF A RAPID READOUT BIOLOGICAL INDICATOR FOR STEAM STERILIZATION WITH FOUR CONVENTIONAL BIOLOGICAL INDICATORS AND FIVE CHEMICAL INDICATORS

William A. Rutala, PhD, MPH; Suzanne M. Jones, MPH; David J. Weber, MD, MPH

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Super Rapid Readout Biological Indicators

Commercially available

1491 BI (blue cap)
- Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
- 24-minute result

1492V BI (brown cap)
- Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
- 24-minute result

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Rapid Readout Biological Indicator for Steam (24m), ETO (4hr) and HP Sterilizers (variable)

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30m, 24m, 15m Biological Indicator for HP Sterilizers

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Vaporized Hydrogen Peroxide (VHP) Biological Indicator Options (*all G. stearothermophilus*)

Refer to BI manufacturer's IFU for cycles the BI is cleared for

VHP read out time	Number of cleared biological indicators
24 hours	2
2 hours	1
30 minutes	1
24 minutes	1
20 minutes	1
15 minutes	1

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Recommendations
Monitoring of Sterilizers

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

- Monitor each load with physical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items

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Recommendations
Monitoring of Sterilizers

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

- Following a single positive biological indicator used with a method other than steam, treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator.
- Following a positive biological indicator with steam sterilization, objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or procedure is defective or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the suspect load.

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Recommendations
Methods of Sterilization

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

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)

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Recommendations
Storage of Sterile Items
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- 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)

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Recommendations
Storage of Sterile Items
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- 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.

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Proper Storage of Sterile, Reprocessed Items

- Items stored (guidance)
  - At least 18 inches below the ceiling
  - 8 inches above the floor
  - 2 inches from the wall
  - If rack used, it should be solid bottom to avoid contamination of items from dust on the floor
  - Room should be positive pressure, <75F and RH <70% (30-60%)

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Sterile, Reprocessed Item

- Prior to opening a sterile package, the end user should inspect the package for
  - Signs of contamination such as moisture, tears, or discoloration in addition to the expiration date

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High-Level Disinfection

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High-Level Disinfection of "Semicritical Objects"

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

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Glutaraldehyde

Rutala, Weber. AJIC 2016:44:e1-e6

- Advantages
  - Numerous use studies published
  - Relatively inexpensive
  - Excellent materials compatibility
- Disadvantages
  - Respiratory irritation from vapor
  - Pungent and irritating odor
  - Relatively slow mycobactericidal activity
  - Coagulate blood and fix tissues to surfaces
  - Allergic contact dermatitis

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Ortho-phthalaldehyde

Rutala, Weber. AJIC 2016:44:e1-e6

Advantages

- Fast acting HLD
- No activation
- Excellent materials compatibility
- Not a known irritant to eyes and nasal passages
- Weak odor

Disadvantages

- Stains protein gray
- Cost ($30/gal);but lower reprocessing costs-soak time, devices per gal)
- Slow sporicidal activity
- Eye irritation with contact
- Exposure may result in hypersensitivity

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Comparison of Glutaraldehyde and OPA

Rutala, Weber. AJIC 2016:44:e1-e6

>2.0% Glutaraldehyde

- HLD: 45 min at 25°C
- Needs activator
- 14 day use life
- 2 year shelf life
- ACGIH ceiling limit, 0.05ppm
- Strong odor
- MEC, 1.5%
- Cost - $10/gallon

0.55% Ortho-phthalaldehyde

- HLD: 12 min at 20°C
- No activator needed
- 14-day use life
- 2-year shelf life
- No ACGIH or OSHA limit
- Weak odor
- MEC, 0.3%
- Cost - $30/gallon

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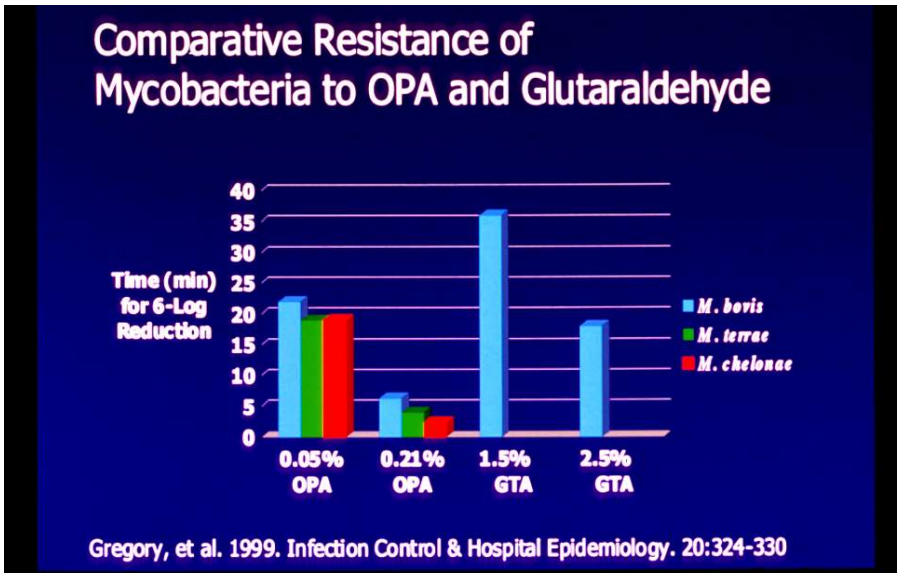

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Ortho-phthalaldehyde (OPA)

Contraindications for OPA

- Repeated exposure to OPA, following manual reprocessing of urological instruments, may have resulted in hypersensitivity in some patients with a history of bladder cancer undergoing repeated cystoscopy.
- Out of approximately 1 million urological procedures, there have been reports of 24 patients who have experience 'anaphylaxis-like' reactions after repeated cystoscopy (typically after 4-9 treatments).
- Risk control measures: residues of OPA minimized; and contraindicated for reprocessing of urological instruments used on patients with history of bladder cancer.

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Hydrogen Peroxide

Rutala, Weber. AJIC 2016:44:e1-e6

- Advantages
  - No activation required
  - Enhanced removal of organisms
  - No disposal issues
  - No odor or irritation issues
  - Does not coagulate blood or fix tissues to surfaces
  - Use studies published
- Disadvantages
  - Material compatibility concerns for brass, zinc, copper, and nickel/silver plating (cosmetic and functional damage)
  - Eye damage with contact

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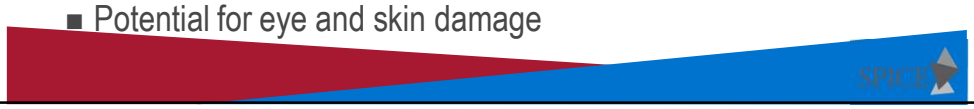
Peracetic Acid/Hydrogen Peroxide

Rutala, Weber. AJIC 2016:44:e1-e6

- Advantages
  - No activation required
  - No odor or irritation issues
  - Effective in the presence of organic matter
- Disadvantages
  - Material compatibility issues for lead, brass, copper, zinc (cosmetic and functional damage)
  - Limited clinical use
  - Potential for eye and skin damage



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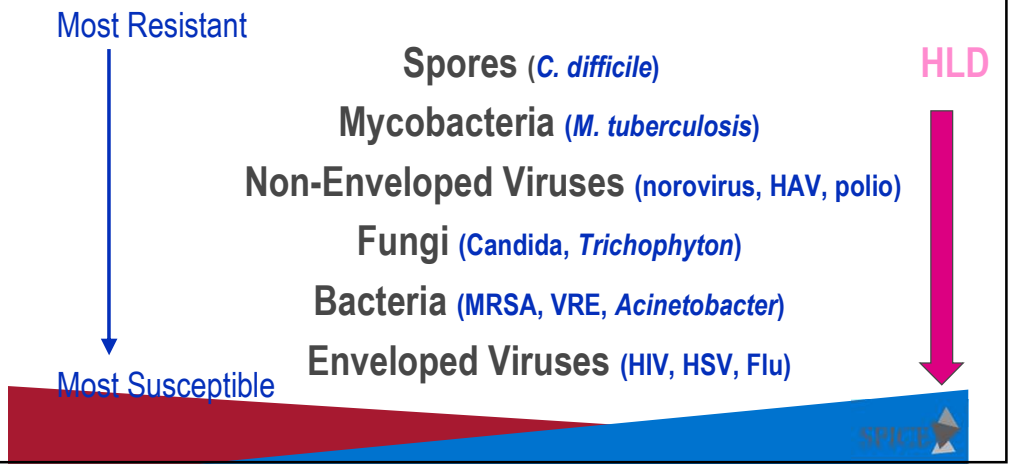
Microbiological Disinfectant Hierarchy

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



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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**

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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

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Infections/Outbreaks Associated with Semicritical Medical Devices

SES1

Rutala, Weber. Am J Infect Control. Rutala WA, Weber DJ. Am J Infect Control. 2019 Jun;47S:A79-A89.

- HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare (3)
- No articles related to possible transmission of HIV via medical device
- Greatest evidence of transmission associated with GI endoscopes/bronchoscopes(~130 outbreaks) likely due to microbial load and complexity.
- Several other semicritical medical devices are associated with infections related to inadequate reprocessing

Table 2
Infections and outbreaks associated with semicritical medical devices*

Instruments	# Outbreaks/ Infections	# Outbreaks/ Infections with bloodborne pathogens
Vaginal probes	0**	0
Nasal endoscopes	0	0
Hysteroscopes	0	0
Laryngoscopes	2[43-45]	0
Urologic instrumentation (eg, cystoscopes, ureteroscopes)	8[46-53]	0
Transrectal-ultrasound guided prostate probes	1[40]	0
Transesophageal echocardiogram	5[31,54-57]	0
Applanation tonometers	2[41,42]	
GI endoscopes/bronchoscopes	~130[7,8]	3 HBV[34]; HCV[35,36]

GI, gastrointestinal; *HBV*, hepatitis B virus; *HCV*, hepatitis C virus.
*These infections/outbreaks were found in the peer-review literature through PubMed and Google.
**Does not include outbreaks associated with contaminated ultrasound gel used with vaginal probes or transmission via health care personnel.

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Slide 118

SES1 please confirm correct cite- it was listed as "in press"
Shenoy, Erica Seiguer,M.D.,Ph.D., 8/27/2021

Reprocessing Medical Devices:
The Good, The Bad and The Ugly

119

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/Colonoscopy	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.

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Duodenoscope-Related Outbreaks of CRE and Other MDROs Without Reprocessing Breaches

Rutala et al. AJIC 2019;47:A62-A66

MDRO	Resistance gene	No. of patients (infected)	Propagated outbreak	Positive scope(s)	Molecular link	Reference
Klebsiella pneumoniae	*mcr-1*	2	No	No	Yes-WGS	Shenoy et al, 2018[21]
K pneumoniae	$bla_{oxa-232}$	15 (8)	No	No	Yes-PCR	Kim et al, 2016[19]
Escherichia coli (AmpC)	bla_{CMY-2}	35	No	Yes (2)	Yes-PCR, PFGE	Wendorf et al, 2015[16]
K pneumoniae	bla_{oxa-48}	12	Yes	No	Yes-PCR, PFGE	Kola et al, 2015[23]
K pneumoniae	bla_{KPC}	34?	No	Yes (3)	Yes-PCR, PFGE, MLST, WGS	Marsh et al, 2015[22]
E coli	bla_{NDM}	39	Yes	Yes (1)	Yes-PCR, PFGE	Epstein et al, 2014[17]
Pseudomonas aeruginosa	bla_{VIM-2}	22	Yes	Yes (1)	Yes-PCR*, PFGE, repetitive-sequence-based PCR typing	Verfaillie et al, 2015[24]
E coli	bla_{NDM-1}	3 (3)	No	No	Unknown	Smith et al, 2015[20]
K pneumoniae	bla_{KPC-2}, bla_{SHV-12}	13	Yes	Yes (2)	Yes-PCR, PFGE, MLST	Carbonne et al, 2010[18]

CRE, carbapenem-resistant *Enterobacteriaceae*; *MDRO*, multidrug-resistant organism; *MLST*, multilocus sequence typing; *PCR*, polymerase chain reaction; *PFGE*, pulsed-field gel electrophoresis; *WGS*, whole-genome sequencing.

*PCR for resistance gene.

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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-could contribute to failure of endoscope reprocessing

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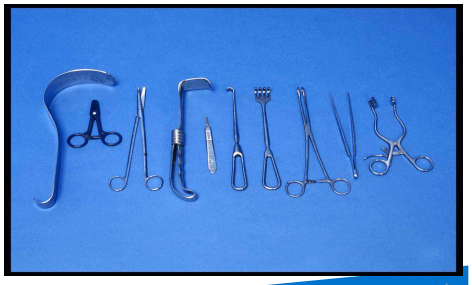
ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel]-10^{7-10} bacteria/endoscope

Surgical instruments-$<10^{2}$ bacteria



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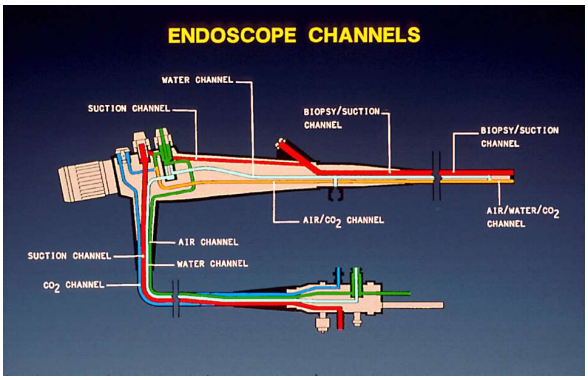
FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

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

- Heat labile
- Long, narrow lumens (3.5ft, 1-3mm)
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, 10^{7-10}
- Cleaning (2-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction) essential for patient safe instrument



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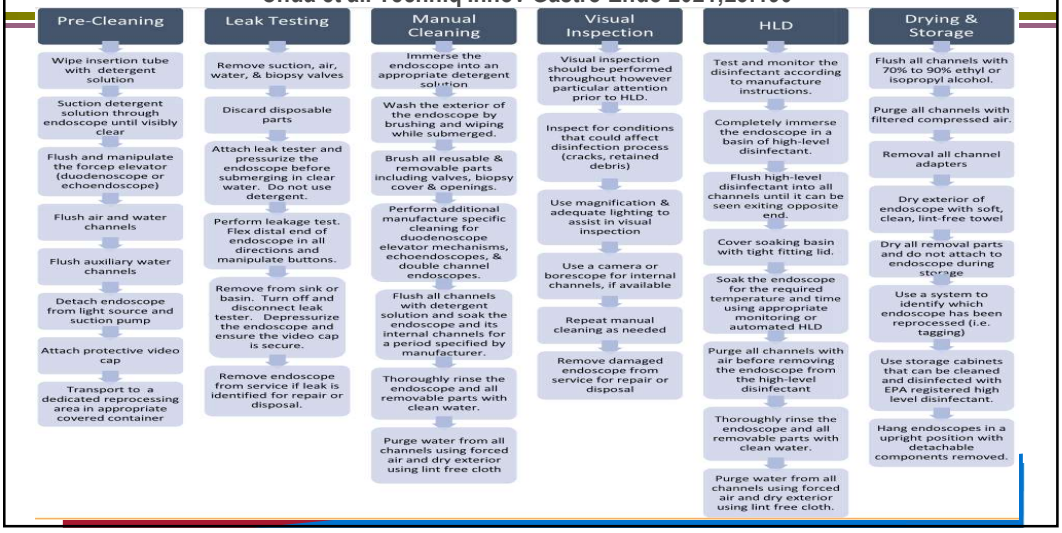
Complexity of Endoscope Reprocessing

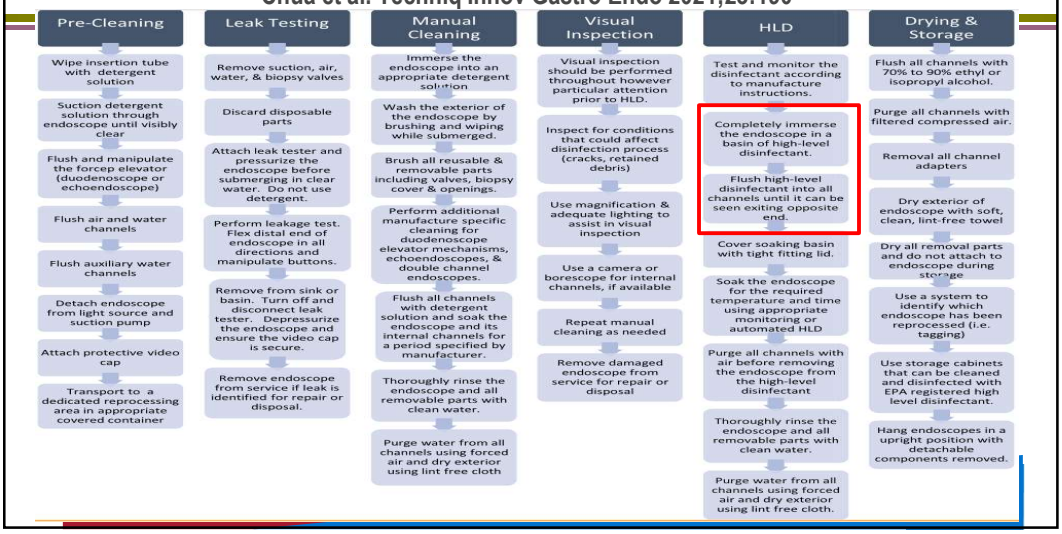
Chua et al. Techniq Innov Gastro Endo 2021;23:190



125

Complexity of Endoscope Reprocessing

Chua et al. Techniq Innov Gastro Endo 2021;23:190



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Reprocessing Channeled Endoscopes

Cystoscope- "completely immerse" in HLD (J Urology 2008.180:588)

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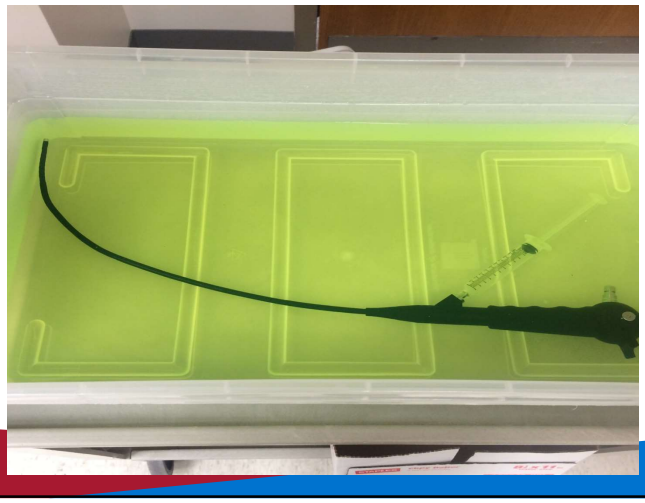
Reprocessing Channeled Endoscopes Manually

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe and lumen filled with HLD)



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Reprocessing Channeled Endoscopes

Rutala, Gergen, Bringhurst, Weber. ICHE. 2016;37:228-231

Exposure Method	CRE (*K. pneumoniae*) Inoculum before HLD (glutaraldehyde)	CRE (K. pneumoniae) Contamination after HLD
Passive HLD (immersed, not perfused)	$3.2x10^8$ $1.9x10^9$ $4.1x10^8$	$3.1x10^8$ $4.6x10^8$ $1.0x10^8$
Active HLD (perfused HLD into channel with syringe)	$3.0x10^8$ $9.2x10^8$ $8.4x10^8$	0 0 0

- Pathogens must have exposure to HLD for inactivation
- Immerse channeled flexible scope into HLD will not inactivate channel pathogens
- Completely immerse the endoscope in HLD and **ensure all channels (e.g., hysteroscopes, cystoscopes) are perfused**
- Air pressure in channel stronger than fluid pressure at fluid-air interface

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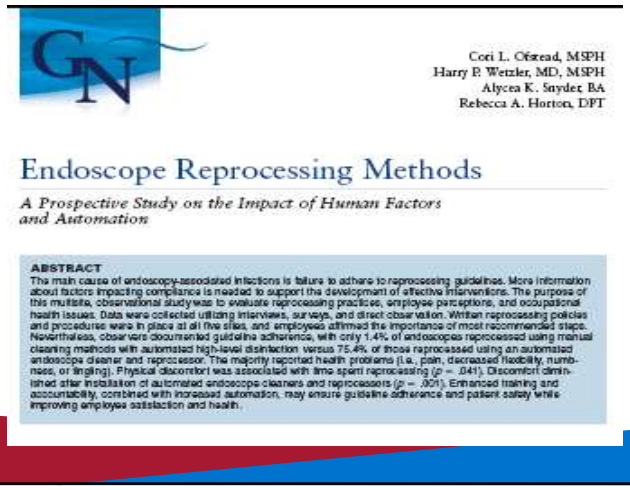
Endoscope Reprocessing Methods

Ofstead , Wetzler, Snyder, Horton, Gastro Nursing 2010; 33:204



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Endoscope Reprocessing Methods

A Prospective Study on the Impact of Human Factors and Automation

ABSTRACT

The main cause of endoscopy-associated infections is failure to adhere to reprocessing guidelines. More information about factors impacting compliance is needed to support the development of effective interventions. The purpose of this multisite, observational study was to evaluate reprocessing practices, employee perceptions, and occupational health issues. Data were collected utilizing interviews, surveys, and direct observation. Written reprocessing policies and procedures were in place at all five sites, and employees affirmed the importance of most recommended steps. Nevertheless, observers documented guideline adherence, with only 1.4% of endoscopes reprocessed using manual cleaning methods with automated high-level disinfection versus 75.4% of those reprocessed using an automated endoscope cleaner and reprocessor. The majority reported health problems (i.e., pain, decreased flexibility, numbness, or tingling). Physical discomfort was associated with time spent reprocessing ($p = .041$). Discomfort diminished after installation of automated endoscope cleaners and reprocessors ($p = .001$). Enhanced training and accountability, combined with increased automation, may ensure guideline adherence and patient safety while improving employee satisfaction and health.

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Endoscope Reprocessing Methods

Ofstead , Wetzler, Snyder, Horton, Gastro Nursing 2010; 33:204

Performed all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed using AER

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

Observed Activity	Steps Completed (%) (n = 69)
Leak test performed in clear water	77
Disassemble endoscope completely	100
Brush all endoscope channels and components	43
Immerse endoscope completely in detergent	99
Immerse components completely in detergent	99
Flush endoscope with detergent	99
Rinse endoscope with water	96
Purge endoscope with air	84
Load and complete automated cycle for high-level disinfection	100
Flush endoscope with alcohol	86
Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

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Automated Endoscope Reprocessors

AERs automate and standardize endoscope reprocessing steps

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Microbial Surveillance of GI Endoscopes

Saliou et al. Endoscopy. 2016

Characteristics of Sample	Action Level (TCU>100/scope) or EIP
Gastroscope	26.6%
Colonoscope	33.7%
Duodenoscope	34.7%
Echo-endoscope	31.9%
AER	27.2%
Manual	39.3%
Age of endoscope <2 years	18.9%
Age of endoscope >2 years	38.8%

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Visual Inspection of GI Endoscopes and Bronchoscopes

GI Endoscopes, Ofstead et al. Am J Infect Control. 2017. 45:e26-e33

- All endoscopes (n=20) had visible irregularities (e.g., scratches)
- Researchers observed fluid (95%), discoloration, and debris in channels
- 60% scopes with microbial contamination

Bronchoscopes, Ofstead et al. Chest. 2018

- Visible irregularities were observed in 100% (e.g., retained fluid, scratches, damaged insertion tubes)
- Microbial contamination in 58%
- Reprocessing practices deficient at 2 of 3 sites

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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)

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Evidence-Based Recommendation for Sterilization of Endoscopes

(FDA Panel Recommendation for Duodenoscopes, May 2015; more peer-reviewed publications (>150) for the need for shifting from disinfection to sterilization than any other recommendation of AAMI, CDC [HICPAC], SHEA, APIC, SGNA, ASGE)

>130 plus endoscope-related outbreaks

GI endoscope contamination rates of 20-40% after HLD

Scope commonly have disruptive/irregular surfaces

>50,000 patient exposures involving HLD

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What Should We Do Now?

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GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406

EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.[1] Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.[1]

In this issue of *JAMA*, Epstein and colleagues[2] report findings from their investigation of a cluster of New Delhi metallo-β-lactamase (NDM)-producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

Related article page 1447

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.[3,4] High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.[3] However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care-associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.[3,5] However, until now,

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What Is the Public Health Benefit?
No ERCP-Related Infections

Margin of Safety-currently nonexistent; sterilization will provide a safety margin (~6 $\log_{10}$). To prevent infections, all duodenoscopes should be devoid of microbial contamination.

HLD (≥6 $\log_{10}$ reduction)

vs

Sterilization (12 $\log_{10}$ reduction=SAL 10^{-6})

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Disinfection and Sterilization

Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

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

CRITICAL - objects which **directly or indirectly/secondarily (i.e., via a mucous membrane such as duodenoscope, cystoscope, bronchoscope)** 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).

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Duodenoscope-Related Outbreaks of CRE and Other MDROs Without Reprocessing Breaches

Rutala et al. AJIC 2019;47:A62-A66

MDRO	Resistance gene	No. of patients (infected)	Propagated outbreak	Positive scope(s)	Molecular link	Reference
Klebsiella pneumoniae	*mcr-1*	2	No	No	Yes-WGS	Shenoy et al, 2018[21]
K pneumoniae	$bla_{oxa-232}$	15 (8)	No	No	Yes-PCR	Kim et al, 2016[19]
Escherichia coli (AmpC)	bla_{CMY-2}	35	No	Yes (2)	Yes-PCR, PFGE	Wendorf et al, 2015[16]
K pneumoniae	bla_{oxa-48}	12	Yes	No	Yes-PCR, PFGE	Kola et al, 2015[23]
K pneumoniae	bla_{KPC}	34?	No	Yes (3)	Yes-PCR, PFGE, MLST, WGS	Marsh et al, 2015[22]
E coli	bla_{NDM}	39	Yes	Yes (1)	Yes-PCR, PFGE	Epstein et al, 2014[17]
Pseudomonas aeruginosa	bla_{VIM-2}	22	Yes	Yes (1)	Yes-PCR*, PFGE, repetitive-sequence-based PCR typing	Verfaillie et al, 2015[24]
E coli	bla_{NDM-1}	3 (3)	No	No	Unknown	Smith et al, 2015[20]
K pneumoniae	bla_{KPC-2}, bla_{SHV-12}	13	Yes	Yes (2)	Yes-PCR, PFGE, MLST	Carbonne et al, 2010[18]

CRE, carbapenem-resistant *Enterobacteriaceae*; *MDRO*, multidrug-resistant organism; *MLST*, multilocus sequence typing; *PCR*, polymerase chain reaction; *PFGE*, pulsed-field gel electrophoresis; *WGS*, whole-genome sequencing.

*PCR for resistance gene.

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Supplemental Measures to Reduce Infection Risk

Rutala WA, Weber DJ. ICHE 2015;36:643-648; Rutala et al. AJIC 2019:47:A62

Hospitals performing ERCPs should do one of the following; FDA adopted these recommendations

- Ethylene oxide sterilization after high level disinfection with periodic microbiologic surveillance
- **Double high-level disinfection** with periodic microbiologic surveillance
- High-level disinfection with scope quarantine until negative culture
- **Liquid chemical sterilant** processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance
- High-level disinfection with periodic microbiologic surveillance

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Did supplemental measures work?

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Randomized Trial of Single versus Double HLD of Duodenoscopes

Bartles et al Gastro Endos 2018;88:306

Double HLD demonstrated no benefit over single HLD; no significant differences observed

TABLE 2. Summary of culture positivity rates in the 2 study arms

	Double HLD	Single HLD	*P* value*
	All cultures		
Specimen-based			
No. of specimens	3052	2798	
Any growth	127 (4.2)	108 (3.9)	.60 (.64)
Growth of high-concern pathogens	3 (.1)	5 (.2)	.49 (.43)
Encounter-based			
No. of encounters	1526	1399	
Any growth	122 (8.0)	102 (7.3)	.52 (.54)
Growth of high-concern pathogens	3 (.2)	5 (.4)	.49 (.43)

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Randomized Trial of Single versus Double HLD of Duodenoscopes

Bartles et al Gastro Endos 2018;88:306

All 8 high-concern pathogen cultures were recovered from elevator mechanism samples

TABLE 1. Details of 8 cultures positive for high-concern pathogens, cultured from 5 different duodenoscopes and linear echoendoscopes

Facility	Culture date	Duodenoscope and linear echoendoscope identification	High-level disinfection method	High-concern pathogen(s) detected
A	2/26/2016	1	Single	*Enterococcus* spp
A	4/8/2016	2	Double	*Enterococcus* spp
A	4/29/2016	2	Single	*Enterobacter cloacae*
A	5/6/2016	3	Double	*Aeromonas* spp
A	8/8/2016	4	Double	*Escherichia coli* (ESBL+), *Enterococcus* spp
B	7/15/2016	5	Single	*E coli* (ESBL−) and *Enterococcus faecalis*
B	7/29/2016	5	Single	*E coli* (ESBL+) and *Enterococcus faecalis*
B	8/1/2016	5	Single	*Enterococcus faecium*

ESBL+, extended spectrum β-lactamase; +, positive; −, negative.

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Comparison of High-Level Disinfection and Sterilization Procedures

Synder et al. Gastroenterology 2017;153:1018

Table 1. Frequency of the Primary Outcome (≥1 Multidrug-resistant Organism), or Secondary Outcomes of any Growth > 0 CFU and Growth of ≥10 CFU on any Duodenoscope Culture

		Growth, Elevator Mechanism or Working Channel (%)		
Trial Arm	(N)	≥1 MDRO	>0 CFU[a]	≥10 CFU[b]
sHLD	174	0	28 (16.1)	4 (2.3)
dHLD	169	0	27 (16.0)	7 (4.1)
HLD/ETO	173	0	39 (22.5)	9 (4.2)
Total	516	0	94 (18.3)	20 (3.9)

[a] $P = .21$.
[b] $P = .36$ by Fisher's exact test.

- Found no significant differences between groups (sHLD, dHLD and HLD/ETO)
- Enhanced disinfection methods did not provide additional protection against contamination
- However
  - Sterilizer used not FDA cleared with SAL10^{-6} for duodenoscopes
  - AER was not indicated for reprocessing duodenoscopes
  - Storage in non-ventilated cabinet per AORN, AAMI/ANSI ST91; SGNA

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Multisociety Guideline on Reprocessing Flexible GI Endoscopes

Day et al. Gastro Endosc 2021;93:11-35

- In a nonoutbreak setting, repeat HLD has no additional benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes

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Supplemental Measures to Reduce Infection Risk

Rutala WA, Weber DJ. ICHE 2015;36:643-648; Rutala et al. AJIC 2019:47:A62

Hospitals performing ERCPs should do one of the following; FDA adopted these recommendations

- Ethylene oxide sterilization after high level disinfection with periodic microbiologic surveillance
- Double high-level disinfection with periodic microbiologic surveillance
- High-level disinfection with scope quarantine until negative culture
- **Liquid chemical sterilant processing system using peracetic acid** (rinsed with extensively treated potable water) with periodic microbiologic surveillance
- High-level disinfection with periodic microbiologic surveillance

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Double HLD versus Liquid Chemical Sterilization for Reprocessing Duodenoscopes

Gromski et al. Gastro Endosc 2021;93:927

No significant difference of positive cultures when comparing double HLD (8) with duodenoscopes undergoing liquid chemical sterilant (9). Most isolates low-concern organisms.

TABLE 2. Organisms detected in positive cultures from all duodenoscope reprocessing surveillance cultures

Organism	Double high-level disinfection (8 positive cultures)*	Liquid chemical sterilization (9 positive cultures)†
Coagulase-negative *Staphylococcus* spp.	5	5
Micrococcus spp.		2
Bacillus spp.	2	3
Streptococcus viridans		1
***Enterococcus* spp.**		1
Klebsiella pneumoniae	1	
Enterobacter cloacae	1	

Organisms in bold type are considered high-concern organisms.
*One culture in the double high-level disinfection group had more than 1 organism grow in a positive culture.
†Three cultures in the liquid chemical sterilization group had more than 1 organism grow in a positive culture.

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Supplemental Measures for Endoscope Reprocessing

Day et al. Gastro Endosc 2021;93:11-35; Gromski et al. Gastro Endosc 2021;93:927; Synder et al. Gastroenterology 2017;153:1018; Bartles et al Gastro Endos 2018;88:306

- In a nonoutbreak setting, repeat HLD has no significant benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes (16.1% v 9.2%)
- In nonoutbreak setting, limited data suggest that ETO sterilization does not reduce bacterial contamination rates in duodenoscopes compared with single HLD
- No significant difference of positive cultures when comparing double HLD (8) with duodenoscopes undergoing liquid chemical sterilant (9).
- The use of ETO sterilization on duodenoscopes during infectious outbreaks has been associated with terminating these outbreaks and such a modality should be considered in selected settings and patient populations
- However, many barriers to widespread use of ETO including cost, only 20% hospital use ETO (availability), possible damage to scopes, exposure of staff to ETO, exposure/turnaround time

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Where are we?

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Why Shift from HLD to Sterilization

Rutala, Weber. AJIC 2023;51:A96-A106

- National/international guidelines recommend sterilization for lumened endoscopic devices (AORN; AAMI)
- FDA has recommended sterilization for bronchoscopes rather than HLD when feasible (FDA, 2021)
- FDA has recommended sterilization for duodenoscopes (FDA Panel, 2015)
- FDA has precluded use of HLD for certain urologic endoscopes due to HLD failure…FDA recommends sterilization (FDA, 2022)
- FDA has promoted innovation to enhance safety (e.g., use of fully disposable, sterile duodenoscopes) (FDA, 2022)

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Future/Novel Approaches to Endoscope Reprocessing to Improve Patient Safety

Rutala et al. AJIC 2019:47:A62; Chua et al. Techniq Innov Gastro Endo 2021;23:190

- Antimicrobial detergents-reduce microbial contamination
- Automated Endoscope Reprocessing-HLD should be provided in an approved AER (manual-1.4% compliance vs 75.4% using AER)
- Endoscope sterilization-materials compatibility, throughput
- Disposable endoscopes (device innovations)
  - Partially-does it decrease bacterial contamination after HLD
  - Fully-GI and bronchoscopes; cost, scope performance
- Use of non-endoscopic methods to diagnose or treat disease
- Assessment tool that is predictive of microbial contamination or infection risks

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Characteristics of Disposable Duodenoscopes

Chua et al. Techniq Innov Gastro Endo 2021;23:190

Table 2. Characteristics of disposable duodenoscopes.

	EvisExera III TJF-Q190V (Olympus)	ED34-i10T (Pentax)	ED34-i10T2 (Pentax)	ED-580XT (Fujifilm)	EXALT Model D (Boston Scientific)	aScopeDuodeno (Ambu)
Disposable component	Endcap	Endcap	Endcap	Endcap	Entire endoscope	Entire endoscope
Field of view (degrees)	100	100	100	100	108	130
Depth of view (mm)	5-60	4-60	4-60	4-60	5-60	Not available
Working length (mm)	1240	1250	1250	1250	1240	1240
Instrument channel (mm)	4.2	4.2	4.2	4.2	4.2	4.2
Insertion tube diameter (mm)	11.3	11.6	11.6	11.3	11.3	11.3
Distal end diameter (mm)	13.5	13	13	13.1	15.1	13.7
Distal end with endcap (mm)	13.5	13.8	13.4	14.9	15.1	13.7

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Duodenoscope Lever Position

Alfa et al. AJIC 2018;46:73-75

- Bacteria will survive if the elevator lever was improperly positioned (in horizontal position instead of 45°) in AER
- *E. faecalis* (7 log inoculum, 2-6 log recovered) and *E. coli* (0-3 log) survived disinfection of sealed and unsealed elevator wire channel duodenoscopes in 2 different AERs
- Ensure proper lever position when placed in AERs with PA

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Multisociety Guideline on Reprocessing Flexible GI Endoscopes

Day et al. Gastro Endosc 2021;93:11-35

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ENDOSCOPE REPROCESSING

Rutala, Weber, CDC Guideline 2008. www.cdc.gov; Multi-Society Guideline on Endoscope Reprocessing, 2021; AORN 2024; AAMI 2021

- PRECLEAN- point-of-use (bedside) remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels; leak testing
- 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 20°C). 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

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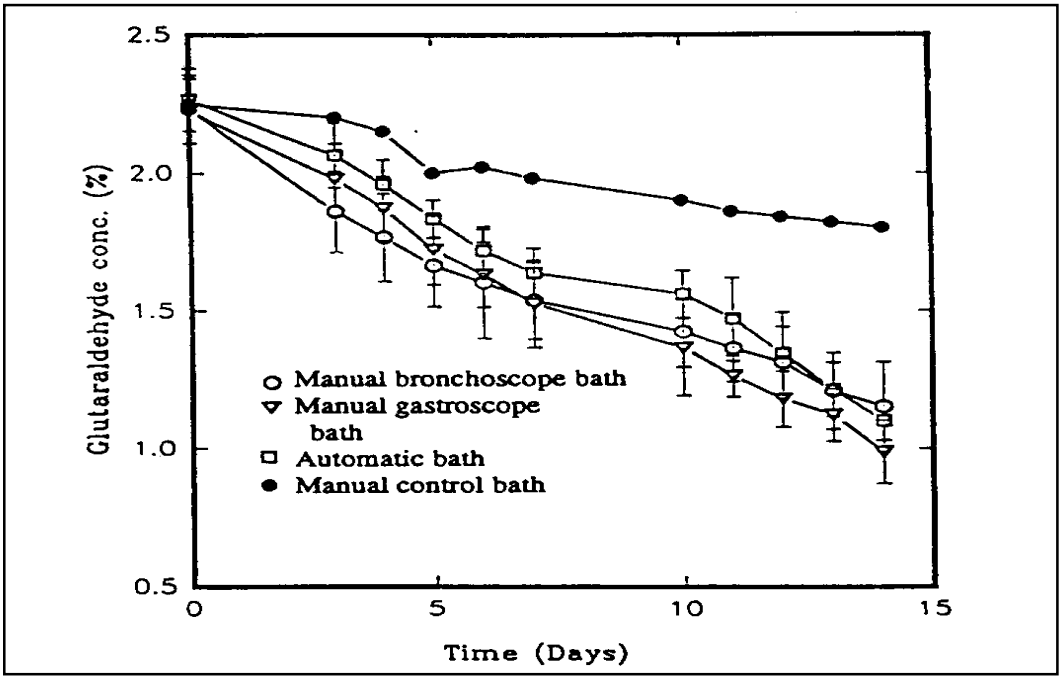
2.5
2.0
1.5
1.0
0.5
Glutaraldehyde conc. (%)
0
5
10
15
Time (Days)
Manual bronchoscope bath
Manual gastroscope bath
Automatic bath
Manual control bath

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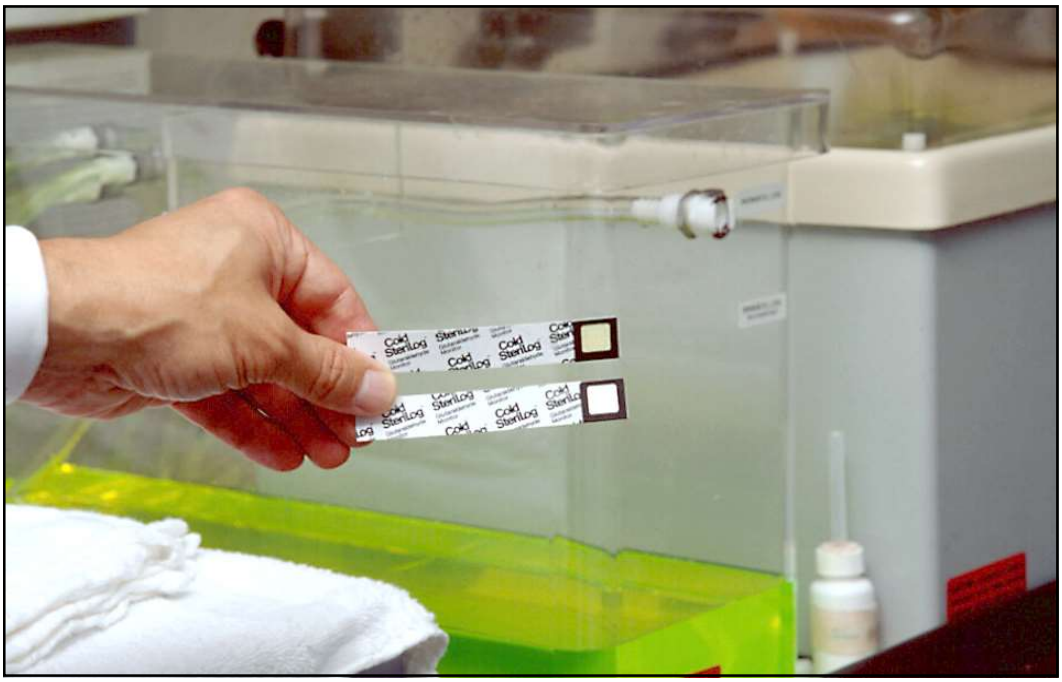

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Minimum Effective Concentration Chemical Sterilant

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

- Dilution of chemical sterilant occurs during use
- Test strips are available for monitoring MEC
- Quality control test strips
- Test strips for glutaraldehyde monitor 1.5%
- Test strip not used to extend the use-life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used (used daily, test at least daily). Follow the disinfectant and test strips MIFU.
- Record results

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Documented Evidence of Quality Processes

- Test date
- HLD temperature (e.g., minimum of 68°F or 77°F [warmer})
- Test strip lot number
- Date test strips expire (comply with strip use directions…completely submerge strip into solution for 3 seconds and remove; remove excess by standing upright on towel; read results in 75 seconds; read color)
- Test strip quality control pass or fail
- Date disinfectant expires
- Disinfectant MEC (minimum effective concentration); test every use HLD
- Records kept for set number of years (depends on local/state regulations)

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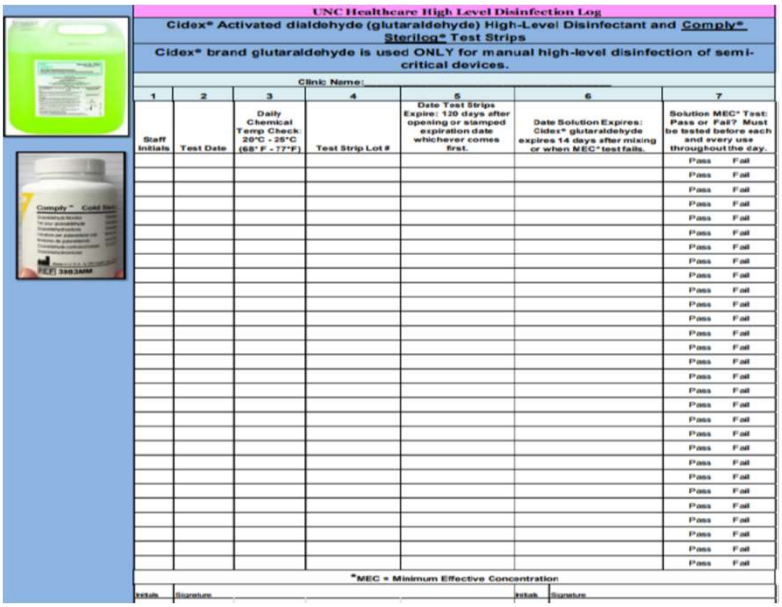

UNC Healthcare High Level Disinfection Log

Cidex® Activated dialdehyde (glutaraldehyde) High-Level Disinfectant and Comply® Steritest® Test Strips

Cidex® brand glutaraldehyde is used ONLY for manual high-level disinfection of semi-critical devices.

Clinic Name: _____

1	2	3	4	5	6	7
Staff Initials	Test Date	Daily Chemical Temp Check: 20°C - 25°C (68° F - 77°F)	Test Strip Lot #	Date Test Strips Expire: 120 days after opening or stamped expiration date whichever comes first.	Date Solution Expires: Cidex® glutaraldehyde expires 14 days after mixing or when MEC* test fails.	Solution MEC* Test: Pass or Fail? Must be tested before each and every use throughout the day.
						Pass Fail

*MEC = Minimum Effective Concentration

Initials | Signature | Initials | Signature

Courtesy UNCH, Pam Miller

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Disposable vs Reusable Laryngoscopes

- Many hospitals transitioning to disposable laryngoscopes
- Saves time
- Virtually eliminates risk of cross contamination
- Reduces likelihood on non-performing equipment
- Possibly cost-effective when considering reprocessing costs

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Reprocessing of Rigid Laryngoscopes

JHI 2008, 68:101; ICHE 2007, 28:504; AJIC 2007, 35: 536; AJIC 2023;51:A96-A106

- Limited guidelines for reprocessing laryngoscope's blades and handles
- For years, 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 microbes/blood/OPIM suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCH-blades and handles sterilized).

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Contamination of Laryngoscope Handles

Rutala, Weber AJIC 2016;44:e1-e6

J Hosp Infect 2010;74:123

- 55/64 (86%) of the handles deemed "ready for patient use" positive for HA pathogens (*S. aureus*, enterococci, *Klebsiella*, *Acinetobacter*)

Anesth Analg 2009;109:479

- 30/40 (75%) samples from handles positive (CONS, *Bacillus*, *Streptococcus*, *S. aureus*, *Enterococcus*) after cleaning

AANA J 1997;65:241

- 26/65 (40%) of the handles and 13/65 (20%) of the blades were positive for occult blood. These blades and handles were identified as ready for patient use.

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Storage of Semicritical Items

TJC. 2023

- In the absence of specific directions from the manufacturer, items that have been HLD must be stored in “a manner that will protect from contamination”
- TJC does not require items that have been HLD to be placed in a cabinet, pouch, bag or other container to “protect if from contamination” during storage unless recommended by the manufacturer.
- Organizations should also ensure that the medical device is dry, as residual moisture could lead to proliferation of microorganisms if the device is still wet

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Endocavitary Probes

Rutala, Weber, HIPAC. www.cdc.gov 2008; Rutala, Weber. AJIC 2016.44:e53-e62

- 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

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Endocavitary Probe Covers

Rutala, Weber. AJIC 2013. 41:S60-S66; Rutala, Weber. AJIC 2016.44:e53-e62; AJIC 2023;51:A96-A106

- 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%)
- Condoms superior to probe covers for ultrasound probe (1.7% condom, 8.3% leakage for probe covers)

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Reprocessing Reusable Medical/Surgical Devices

- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- Reprocessing laryngoscopes
- Endocavitary probes
- Ultrasound probe reprocessing

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Do ultrasound transducers used for placing peripheral or central venous access devices require HLD/sterilization?

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Transducer Disinfection for Insertion of Peripheral and Central Catheters

Association of Vascular Access Guideline. June 2018; AIUM 2017

- "All transducers/probes used for peripheral VAD insertion will undergo, at a minimum, low-level disinfection…." Clean (step 1) the probe prior to disinfection (step 2).
- "During assessment, consider using a single-use condom or commercially manufactured transducer sheath (excluded: transparent dressing, gloves) during all use where there is the possibility of contact with blood/body fluids or non-intact skin"
- "Perform ALL ultrasound guided vascular access device insertions (PIV, Midline, PICC, CVC, arterial line) with the use of a sterile sheath and single-use sterile gel".
  - After the procedure, the used sheath should be inspected for tears and the transducer inspected for potential compromise
  - Once inspected, the probe should be cleaned and then disinfected.

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Transducer Disinfection for Insertion of Peripheral and Central Catheters

Association of Vascular Access (AVA) Guideline. June 2018; AIUM 2017

- All clinicians involved in ultrasound guidance should undergo comprehensive training on disinfection of the ultrasound transducers
- The AVA recommendations are similar to guidelines from the American Institute for Ultrasound in Medicine (AIUM): that is, internal probes-HLD; "interventional percutaneous procedure probes that are used for percutaneous needle or catheter placement…should be cleaned using LLD and be used in conjunction with a single-use sterile probe cover", if probe cover compromised HLD the probe.
- Some publications have interpreted CDC and AIUM recommendations differently (AJIC 2018:46:913-920): ultrasound guided CVC insertion (critical-sterilize or HLD with sterile sheath and sterile gel); scan across unhealthy skin (semicritical-HLD and use with clean sheath and clean gel)

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Transducer Disinfection for Insertion of Peripheral and Central Catheters

Comments

- Blood contamination of probe is infrequent
- Sheath plus cleaning plus LLD should eliminate HBV, HCV, HIV
- Likelihood of transmission, even if probe still contaminated, very remote – would require contaminating virus gaining entry via contact with the actual injection site
- Transmission of HIV, HBV, HCV via a probe using on external body surface never demonstrated
- Only semicritical medical device to transmit HBV or HCV is GI endoscope (HIV not transmitted)
- If all devices that could contact non-intact skin or be blood contaminated require HLD prior to reuse that would include linen/mattresses (Burn Center), stethoscopes, BP cuffs, xray cassettes, etc

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Reuse of Single Use Devices

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FDA Developments

- August 2000, FDA issued final SUD Enforcement Guidance. Hospitals and TPR regulated the same as original equipment manufacturer (OEM).
- A device labeled for single-use only that is reprocessed is considered as a new device. **Hospital is considered the manufacturer.**
- **As a new device, all federal controls regarding the manufacture and marketing of the device apply.**

179

Hospital's Options: USA

- Option 1-Comply with enforcement guidance (August 14, 2000) and continue to reprocess SUDs
- Option 2-Use Third Party Reprocessor (premarket requirements new for TPR as they have been using non-premarket requirements)
- Option 3-avoid reuse of SUDs

180

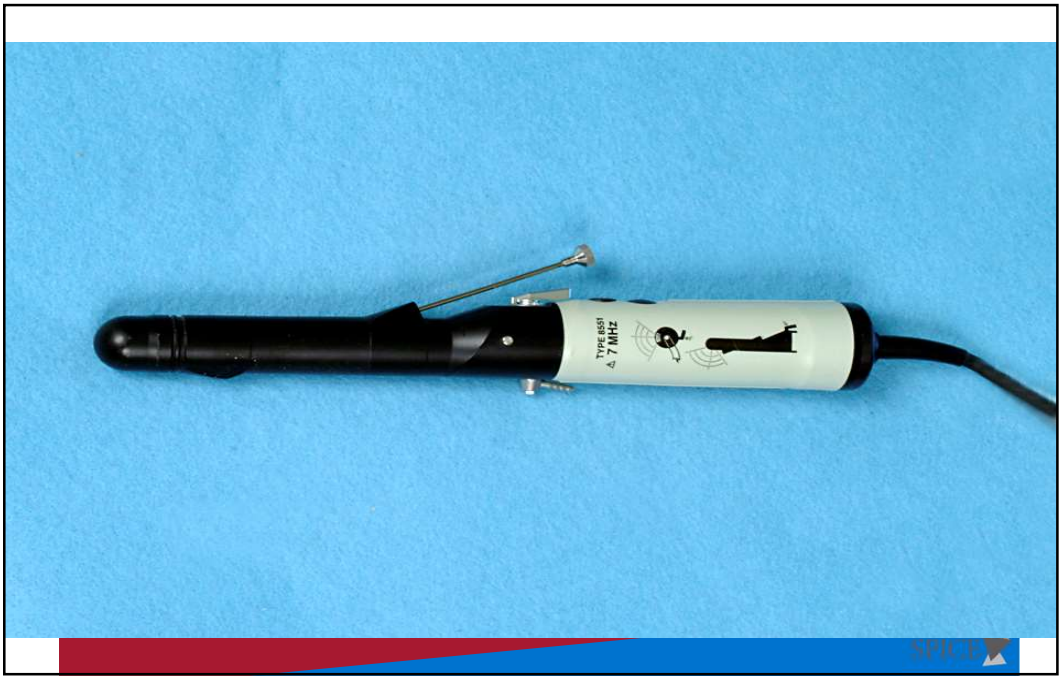
Do Not Reuse Single-Use Devices

- Federal judge convicted a urologist who reused needle guides meant for single use during prostate procedures (Sept 2014)
- Third party reprocessor OK
- **Criminal prosecution** (based on conspiracy to commit adulteration)

181

Special Instrument Reprocessing Issues

182



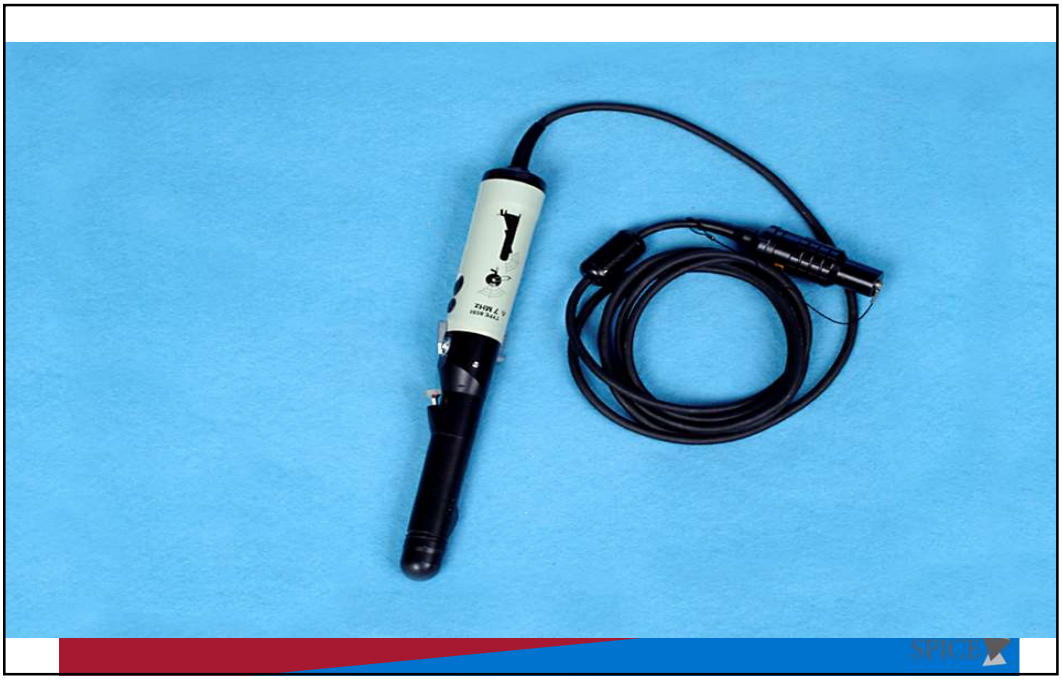
183

Prostate Biopsy Probe

Rutala et al. ICHE 2007;28:916-919

- Evaluated effectiveness of HLD when assembled (needle biopsy holder in probe) and unassembled.
- Inoculated (10^6-10^7 *P. aeruginosa*): internal lumen/outside surface of needle biopsy holder; internal lumen of probe with and without needle biopsy holder in place
- Conclusion: HLD achieved when unassembled but not when assembled

184



185

Adenovirus 8

A Common Cause of Epidemic Keratoconjunctivitis

186

187

Adenovirus 8

- Adenovirus is extremely hardy when deposited on environmental surfaces and may be recovered from plastic and metal surfaces for more than 30 days
- Elimination of adenovirus from inanimate surfaces and ophthalmic instruments is essential in preventing outbreaks of epidemic keratoconjunctivitis
- Unfortunately, no reports that validate CDC recommendations for disinfecting tonometer tips. CDC. MMWR 1985; 34:533.

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CDC, 1985

- Applanation tonometers-Soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine (~1:10 household bleach)
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol

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Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- Ineffective <2 $\log_{10}$ reduction
  - Bactoshield (4% CHG)
  - Vesphene (phenolic)
  - 70% isopropyl alcohol
  - 3% hydrogen peroxide
  - TBQ (0.06% QUAT)
  - Novaplus (10% povidone iodine)
  - Soft 'N Sure (0.5% triclosan)
  - Acute-Kare (1% chloroxylenol)
  - Sterilox (218 and 695 ppm chlorine)
  - Dettol (4.8% chloroxylenol)
  - Accel TB (0.5% accelerated hydrogen peroxide)
  - Microcyn (~80 ppm chlorine)

190

Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- ~4 $\log_{10}$ reduction
  - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50)
  - Clorox Clean-up, ~1,910 ppm chlorine
  - Clorox disinfecting spray (65% ethanol, 0.6% Quat)
  - Steris 20 sterilant, 0.35% peracetic acid
  - Ethanol, 70%
  - Lysol disinfecting spray (79.6% ethanol, 0.1% Quat)
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde

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CDC Guidelines

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

- CDC, 1985. Applanation tonometers-soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol
- CDC, 2008. Wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5000 ppm chlorine or 70% ethyl alcohol. Category II.
- These results emphasize the proper selection of disinfectants for use in disinfecting semicritical items (e.g., applanation tonometers)

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Failure to Follow Disinfection and Sterilization Principles

What Do You Do?

Scenario:

Hospital A discovered that for the past 3 days all surgical instruments were exposed to steam sterilization at 132°C for 0 minutes rather than the intended 4 minutes. A central processing technician turned the timer to 0 minutes in error.

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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY FEBRUARY 2007, VOL. 28, NO. 2

ORIGINAL ARTICLE

How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

BACKGROUND. Disinfection and sterilization are critical components of infection control. Unfortunately, breaches of disinfection and sterilization guidelines are not uncommon.

OBJECTIVE. To describe a method for evaluating a potential breach of guidelines for high-level disinfection and sterilization of medical devices.

METHODS. The appropriate scientific literature was reviewed to determine the frequency of failures of compliance. A risk assessment model was constructed.

RESULTS. A 14-step protocol was constructed to aid infection control professionals in the evaluation of potential disinfection and sterilization failures. In addition, a model is presented for aiding in determining how patients should be notified of the potential adverse event. Sample statements and letters are provided for communicating with the public and individual patients.

CONCLUSION. Use of a protocol can guide an institution in managing potential disinfection and sterilization failures.

Infect Control Hosp Epidemiol 2007; 28:146-155

In the United States in 1996, there were approximately 46,500,000 surgical procedures and a much larger number of

infection failure on record involved the distribution of an inactive lot of glutaraldehyde disinfectant solution that had

194

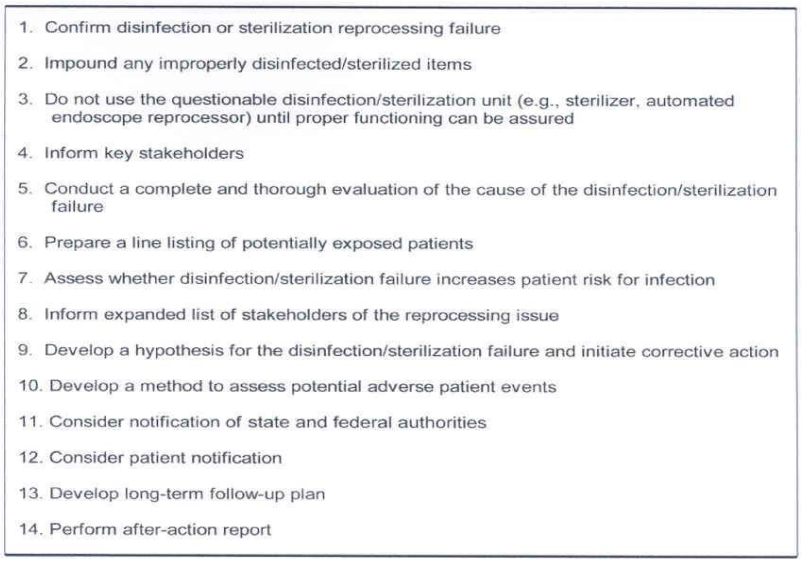

FIGURE 1. Protocol for exposure investigation after a failure of disinfection and sterilization procedures

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Failure to Follow Disinfection and Sterilization Principles

Rutala, Weber. ICHE 2007;28:146-155

- What do you do?
  - Follow the 14 steps at website disinfectionandsterilization.org (confirm failure, embargo improperly D/S items, investigate the cause, etc)
  - The steps provide a general outline, but each event is unique and you must be flexible and adaptable
  - Communication among key stakeholders is very important
  - Ethical to notify patients if there is a risk-should be upfront and factual
  - Train staff and access processes/practices to minimize recurrence
  - These are stressful events (patients and staff) but the goal is to assess failure and protect patients rather than assessing blame

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Recommendations
Quality Control

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency, staff should:
  - hands-on training
  - all work supervised until competency is documented
  - competency testing should be conducted at commencement of employment and regularly
  - review written reprocessing instructions to ensure compliance

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Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection and sterilization principles
- **Issues**
  - **Sterilization**
  - **High-level disinfection**
  - **Low-level disinfection**
  - **Antisepsis**

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Antisepsis

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Antiseptic Agents

(used alone or in combination)

Boyce , Pittet. https://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf; Rutala, Boyce, Weber. AJIC 2023;51:A3-A12

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

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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

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Hand Hygiene

- No discussion of preoperative bathing
- No discussion of surgical site preparation
- No discussion of skin antisepsis before IV
- No preferential selection of antiseptics

202

Summary of Best Antiseptics

JM Boyce. AJIC 2019.47:A17-A22; Boyce AJIC 2023;51:A58-A63

- **Preoperative showers**-CHG is preferred; significant impact on SSIs not proven
- **Preoperative skin preparation**-alcohol-containing products (with CHG or iodophor-SHEA 2014)
- **Surgical hand antisepsis**-alcohol-containing products reduce bacteria on hands best
- **Vascular access site preparation**-alcohol preparation containing >0.5% CHG (SHEA/IDSA 2014)
- **Routine daily bathing/skin treatment of patients**-CHG appear to be more effective than standard soap and water

203

Guideline for Hand Hygiene in Healthcare Settings

JM Boyce, D Pittet, HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

ttps://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm

204

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)

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Hand Hygiene

- Hand Hygiene-a general term that applies to either handwashing, antiseptic handwash, antiseptic handrub, or surgical hand antisepsis
- Main Results: alcohol-based handrubs reduce bacterial bacterial counts on hands more effectively than plain soaps, and in a majority of studies more effectively than antimicrobial soaps.

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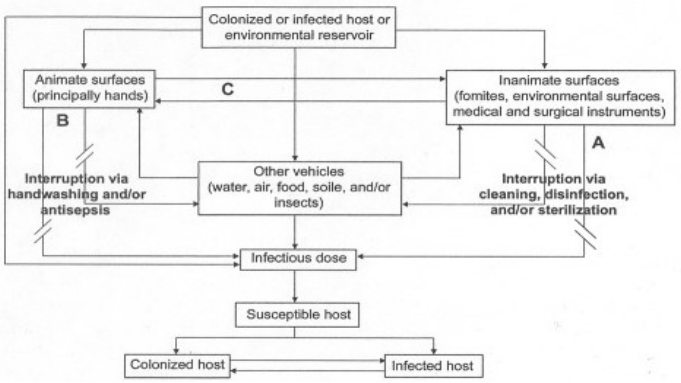
Evidence of Transmission of Pathogens on Hands

- Transmission from patient to patient via HCW hands requires four elements
  - Organisms on HCWs hands (via patient or environment)
  - Organisms must survive for several minutes on hands
  - Hand hygiene must be inadequate or agent inappropriate
  - Contaminated hands of HCW must come in contact with another patient (or an inanimate object that will contact patient)

209

TRANSMISSION MECHANISMS INVOLVING THE SURFACE ENVIRONMENT



Rutala WA, Weber DJ. In:"SHEA Practical Healthcare Epidemiology" (Lautenbach E, Woeltje KF, Malani PN, eds), 3rd ed, 2010

210

Hand-borne Microorganisms

- Presence – bacterial counts on hands range from 10^4 to 10^6
  - resident microorganisms-attached to deeper layers of the skin and are more resistant to removal; less likely to be associated with HAIs.
  - transient microorganisms-colonize the superficial layers of skin and amenable to removable; acquired by direct contact with patients or contaminated environment surfaces; frequently associated with HAIs.

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Hand Hygiene Practices in Healthcare

- Hand hygiene has been reported to average 40% (34 studies)
  - Inaccessibility of hand hygiene supplies
  - Skin irritation from hand hygiene agents
  - Inadequate time for hand hygiene
  - Interference with patient care
  - Lack of knowledge of the guidelines
  - Lack of information on the importance of hand hygiene

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Hand Hygiene Practices in Healthcare

- Observational studies revealed that duration averages from 6.6 to 21 sec, and in 10/14 studies HW <15 sec, and in 8/14 studies HW $\leq$ 10 sec
- HCWs also fail to wash all surfaces of their hands and fingers effectively

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Hand Hygiene History

- Guidelines:
  - U.S. Public Health Service (1961)-soap and water, 1-2 min before and after patient contact
  - CDC (1975 and 1985)-non-antimicrobial handwashing between patient contacts, antimicrobial before invasive procedures
  - APIC (1988 and 1995)-similar to CDC, more discussion of alcohol-based handrubs
  - HICPAC (1996)-either antimicrobial soap or a waterless antiseptic agent be used for cleaning hands upon leaving MRSA/VRE patient rooms

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Hand Hygiene

- Recommendations
  - IA-strongly recommended for implementation and strongly supported by experimental, clinical or epidemiological studies
  - IB- strongly recommended for implementation and supported by some experimental, clinical or epidemiological studies
  - IC-required for implementation, as mandated by federal and/or state regulation
  - II-suggested for implementation and supported by suggestive clinical or epidemiological studies or a theoretical rationale

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Indications for Handwashing and Hand Antisepsis

- Hands are visibly dirty or soiled, wash with non-antimicrobial soap and water or antimicrobial soap and water. Category IA
- If hands are not visibly soiled, use an alcohol-based handrub for routinely decontaminating hands in all other clinical situations. IA. Alternatively, wash hands with antimicrobial soap and water. IB
  - Before having direct contact with patients. IB
  - Before donning sterile gloves when inserting a central intravascular catheter. IB

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Indications for Handwashing and Hand Antisepsis

- Decontaminate hands not visibly soiled with handrub/antimicrobial (continued)
  - Before inserting urinary catheter, peripheral vascular catheter, or other invasive device. IB
  - After contact with a patient's intact skin. IB
  - After contact with body fluids, mucous membrane, non-intact skin or wound dressings, as long as hands are not soiled. IA
  - If moving from a contaminated body site to clean site. II
  - After contact with inanimate objects in vicinity of patient. II
  - After removing gloves. IB

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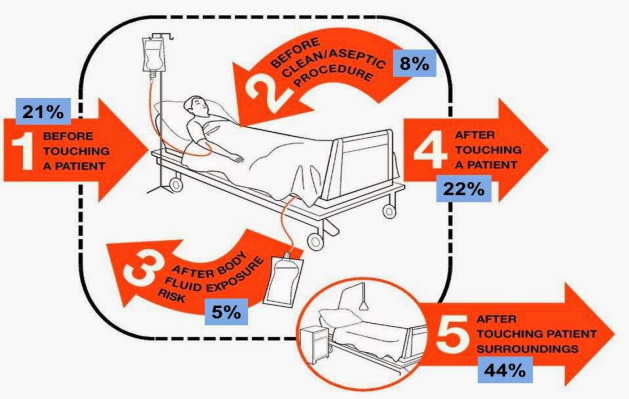
Simplify the Message: Clean In, Clean Out



Diller T, AJIC 2014 June

219

Indications for Handwashing and Hand Antisepsis

- Use non-antimicrobial/antimicrobial before eating and after using a restroom. IB
- Antimicrobial towelettes may be an alternative to washing hands with non-antimicrobial soap and water. IB
- No recommendation on routine use of non-alcohol-based handrubs. Unresolved issue

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Alcohol-Based Handrubs

- Minimize factors adversely affecting adherence to hand hygiene protocols
  - Reduce bacterial counts more effectively than washing hands with non-antimicrobial and antimicrobial soaps
  - Can be made much more accessible
  - Require less time to use
  - Produce less skin irritation and dryness
  - Improved adherence to hand hygiene policies and reduce NI rates

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Hand Hygiene and "Clean Procedures"

- Personnel contaminate hands by performing "clean procedures"
- Nurses contaminate hands with 100-1000 CFU during such "clean" activities as lifting patients, taking the patient's pulse, blood pressure, or oral temperature, or touching the patient's hand, shoulder, or groin.

223

Studies Comparing Relative Efficacy of Plain Soap or Antimicrobial Soap vs Alcohol-Based Antiseptics in Reducing Counts on Hands

- Alcohol more effective than plain soap (17 studies)
- In all but two trials (15/17), alcohol-based solutions reduced bacterial counts on hands to a greater extent than washing with soaps or detergents containing povidone-iodine, 4% CHG, or triclosan

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Hand Hygiene Technique

- Apply alcohol-based handrub to one hand and rub hands together, covering all surfaces. Follow manufacturer's recommendation on volume. IB
- Soap and water-wet hands, apply amount of product recommended, rub hands together for 15 sec, covering all surfaces. Rinse with water and dry with disposable towel. IB

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Hand Hygiene Technique

- Avoid using hot water, repeated exposure may increase risk of dermatitis. IB
- Liquid, bar, leaflet, or powdered forms of plain soap are acceptable when washing with a non-antimicrobial soap. II
- Multiple-use cloth towels of the hanging or roll type are not recommended for use in healthcare settings. II

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Selection of Hand Hygiene Agents

- Provide personnel with efficacious hand hygiene products that have low irritancy potential. IB
- To maximize acceptance, solicit input from HCW regarding feel, fragrance, and skin tolerance. IB
- Prior to purchasing, evaluate dispenser systems to ensure function and delivery of appropriate volume. II

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Selection of Hand Hygiene Agents

- Solicit information from manufacturers about known interactions between products used to clean hands, skin care products, and the types of gloves used in the institution. II
- Do not add soap to a partially empty soap dispenser. This practice of "topping off' dispensers may lead to bacterial contamination of soap. IA.

228

Skin Care

- Provide HCW with hand lotions or creams in order to minimize the occurrence of irritant contact dermatitis associated with hand antisepsis or handwashing. IA
- Solicit information from manufacturers regarding any effects that hand lotions, creams, or alcohol-based hand antisepsis may have on the persistent effects of antimicrobial soaps being used. IB

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Other Aspects of Hand Hygiene

- Do not wear artificial fingernails or extenders when having direct contact with high-risk patients, such as those in intensive care units or operating rooms. IA
- Keep natural nail tips less than ¼ inch long. II
- Wear gloves when it can be reasonably anticipated that contact with blood or OPIM, mucous membranes, and non-intact skin will occur. IC

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Other Aspects of Hand Hygiene

- Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between patients. IB
- Change gloves during patient care if moving from a contaminated body site to a clean body site. II
- No recommendation on wearing rings in healthcare settings. Unresolved issue.

231

HCW Educational and Motivational Programs

- Educate staff regarding the types of patient care activities that can result in hand contamination and the adv/disadv of various methods used to clean their hands. II
- Monitor HCW adherence with recommended hand hygiene practices and provide personnel with information regarding their performance. IA
- Encourage patients and their families to remind HCW to decontaminate their hands. II

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Administrative Measures

- Make improved hand hygiene adherence an institutional priority and provide appropriate administrative support and financial resources. IB
- Implement a multidisciplinary program (e.g., education, feedback, engineering controls, reminders in workplace, avoid understaffing) designed to improve adherence of health personnel to recommend hand hygiene practices. IB
- As part of the multidisciplinary program, provide HCW with a readily accessible alcohol-based handrub. IA

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Administrative Measures

- In high workload and high intensity of patient care areas, make an alcohol-based handrub available at the entrance to the patient's room or at the bedside, in other convenient locations, and in individual pocket-sized containers carried by HCW. IA
- Store supplies of alcohol-based hand rubs in cabinets or areas approved for flammable materials. IC

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New CDC Hand Hygiene Guidelines

Major Difference

- Old CDC, APIC-non-antimicrobial between most patient contacts, antimicrobial before invasive procedures or caring for high-risk patients
- New CDC-if hands are not visibly soiled, use an alcohol-based handrub for decontaminating hands in all clinical situations; alternatively, wash hands with antimicrobial soap and water

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RATIONALE FOR HAND HYGIENE

- **Many infectious agents are acquired via hand contact with contaminated surfaces**
  - **Contact transmission: healthcare (MRSA, VRE), day care (MRSA), home (MRSA, "cold viruses", herpes simplex)**
  - **Fecal-oral transmission: day care (*Shigella*, *E. coli* O157:H7), home (*Salmonella*, *E. coli* O157:H7, *Cryptosporidium*)**
- **Hand hygiene effective in reducing or eliminating transient flora**
- **Hand hygiene demonstrated to be effective in preventing illness (especially fecal-oral diarrheal illnesses) in healthcare facilities, child care centers/homes, and households**
- **~40% of healthcare-associated infections due to cross-transmission**

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ASSOCIATION BETWEEN HAND HYGIENE COMPLIANCE AND HAI RATES

Author, year	Setting	Results
Casewell, 1977	Adult ICU	Reduction HAI due to *Klebsiella*
Maki, 1982	Adult ICU	Reduction HAI rates
Massanari, 1984	Adult ICU	Reduction HAI rates
Kohen, 1990	Adult ICU	Trend to improvement
Doebbeling, 1992	Adult ICU	Different rates of HAI between 2 agents
Webster, 1994	NICU	Elimination of MRSA*
Zafar, 1995	Newborn	Elimination of MRSA*
Larson, 2000	MICU/NICU	85% reduction VRE
Pittet, 2000	Hospitalwide	Reduction HAI & MRSA cross-transmission

HAI, healthcare-associated infections *Other infection control measures also instituted

Boyce JM, Pitter D. MMWR 2002;51(RR-16)

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HAND HYGIENE ADHERENCE AN INSTITUTIONAL PRIORITY

- Multidisciplinary Program
  - Administrative support (IOC, Executive Staff, Dept Heads)
  - Monitor HCWs adherence to policy and provide staff with information about performance
  - Provide HCWs with accessible hand hygiene (HH) products to include alcohol based hand rubs
  - Education regarding types of activities that result in hand contamination and indications for hand hygiene
  - Reminders in the workplace (e.g., posters)
  - Considering ways to include HH in management standards (loss of hospital privileges, tickets for non-compliance, coffee coupons)

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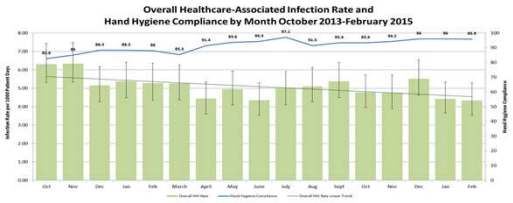
HAI Reductions and Associations with Hand Hygiene

Sickbert-Bennett, DiBiase, Weber, Rutala. Emerg Inf Dis 2016;22:1628-1630.



- **Over 17 months, we noted a significantly increased overall hand hygiene compliance rate (p<0.001) and significantly decreased overall HAI rate (p=0.0066) with 197 fewer infections.**
- **The association of hand hygiene compliance and HAIs adjusting for unit-level data was p=0.086 with a *10% improvement in HH associated with a 6% reduction in overall HAI*.**
- **The association of hand hygiene compliance and *C. difficile* adjusting for unit-level data was p=0.070 with a *10% improvement in HH associated with a 14% reduction in C. difficile HAI*.**

239

Summary of Best Antiseptics

JM Boyce. AJIC 2019.47:A17-A22; Boyce AJIC 2023;51:A58-A63

- **Preoperative showers**-CHG is preferred; significant impact on SSIs not proven
- **Preoperative skin preparation**-alcohol-containing products (with CHG or iodophor-SHEA 2014)
- **Surgical hand antisepsis**-alcohol-containing products reduce bacteria on hands best
- **Vascular access site preparation**-alcohol preparation containing >0.5% CHG (SHEA/IDSA 2014)
- **Routine daily bathing of patients**-CHG appear to be more effective than standard soap and water

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Daily CHG Bathing/Skin Treatment

JM Boyce. AJIC 2019.47:A17-A22;

- ICU
  - Daily use of CHG-impregnated cloths reduced central-line associated bloodstream infections
  - Type of infection most commonly reduced was BSI, especially CLABSI (caused by pram-positive pathogens).
  - Reduced other HAIs in a few studies
- Non-ICU
  - Impact on HAI rates of daily CHG bathing of non-ICU patients is not as clear. Some studies were associated with a reduction in HAIs caused by MRSA and VRE.

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Hand Hygiene Agents

- Non-antimicrobial
- Antimicrobial
  - Chlorhexidine gluconate (CHG)
  - Triclosan-FDA banned use in the US
  - Quaternary Ammonium Compounds (QAC)
  - Parachlorometaxylenol (PCMX)
  - Alcohols (ethyl, isopropanol, n-propanol)
  - Iodine and Iodophors

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Relative Efficacy of Antiseptics

Rutala, Boyce, Weber. AJIC 2023;51:#-A12

Group, typical concentration	Gram-positive bacteria	Gram-negative bacteria	Myco-bacteria	Fungi	Viruses enveloped	Viruses non-enveloped
Alcohols, 60-70%	+++	+++	+++	+++	+++	++
Chlorhexidine (0.5-4% aqueous)	+++	++	+	+	++	+
Iodophors	+++	+++	++	++	++	++
Phenol derivative (e.g., chloroxylenol)	+++	+	+	+	+	±
Triclosan	+++	++	±	±	?	?
Quaternary ammonium compounds (e.g., benzethonium chloride)	++	+	±	±	+	?

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Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection and sterilization principles
- Issues
  - Sterilization
  - High-level disinfection
  - Antisepsis

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THANK YOU!

www.disinfectionandsterilization.org

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