Disinfection, Sterilization and Antisepsis: An Overview

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

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

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

DISCLOSURES

2022

- **Consultations**
  - PDI (Professional Disposables International)
- **Honoraria**
  - PDI
- **Other**
  - Kinnos, Ideate Medical

www.disinfectionandsterilization.org

Disinfection, Sterilization and Antisepsis

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

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Update: May 2019

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

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

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

Medical/Surgical Devices

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

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

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

SEMICRITICAL-medical devices that touch **mucous membranes** or skin that is not intact require a disinfection process (**high-level disinfection** [HLD]) that kills all microorganisms but high numbers of bacterial spores.

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

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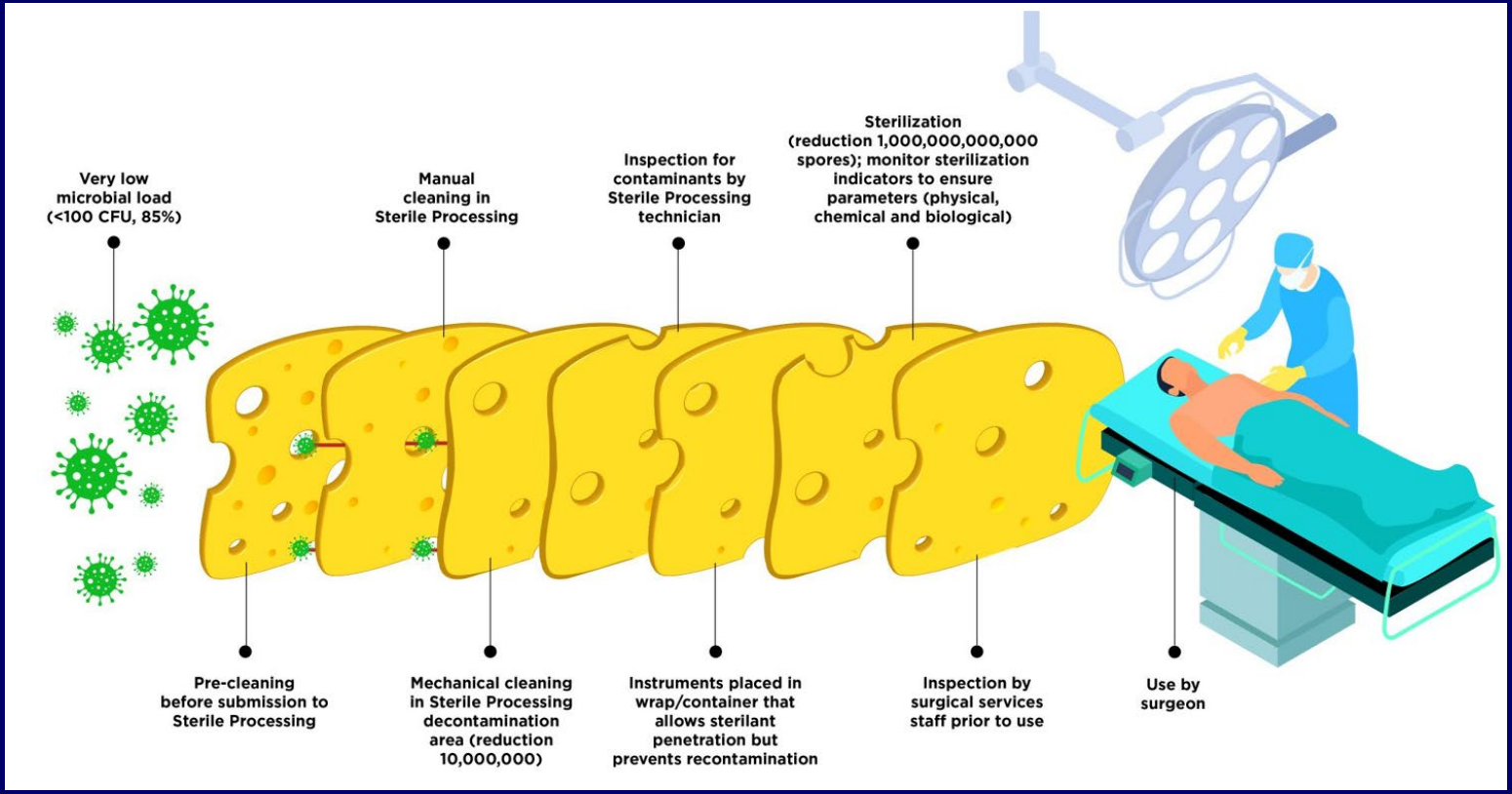
Critical Medical/Surgical Devices

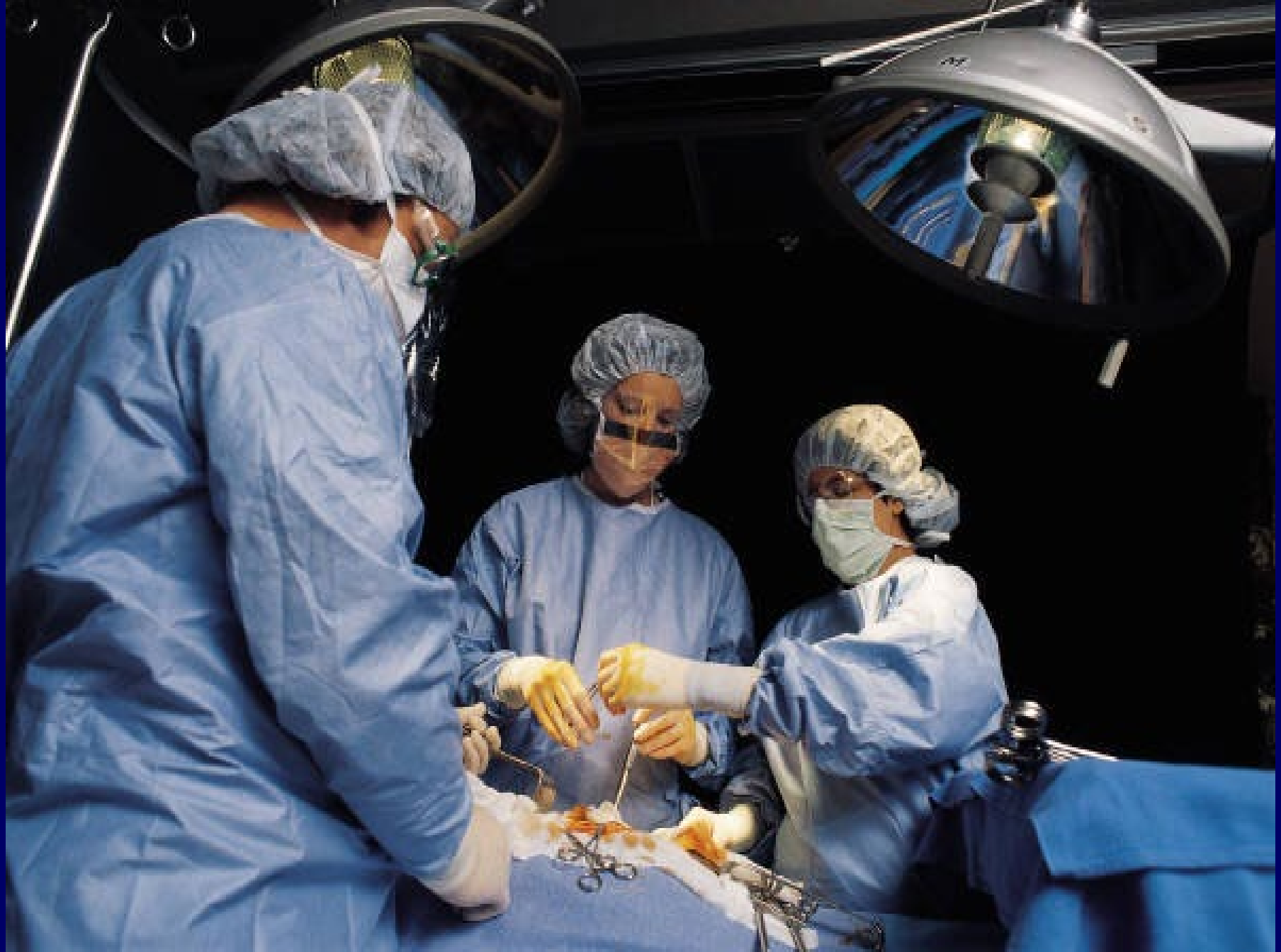
Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2016;44:e47

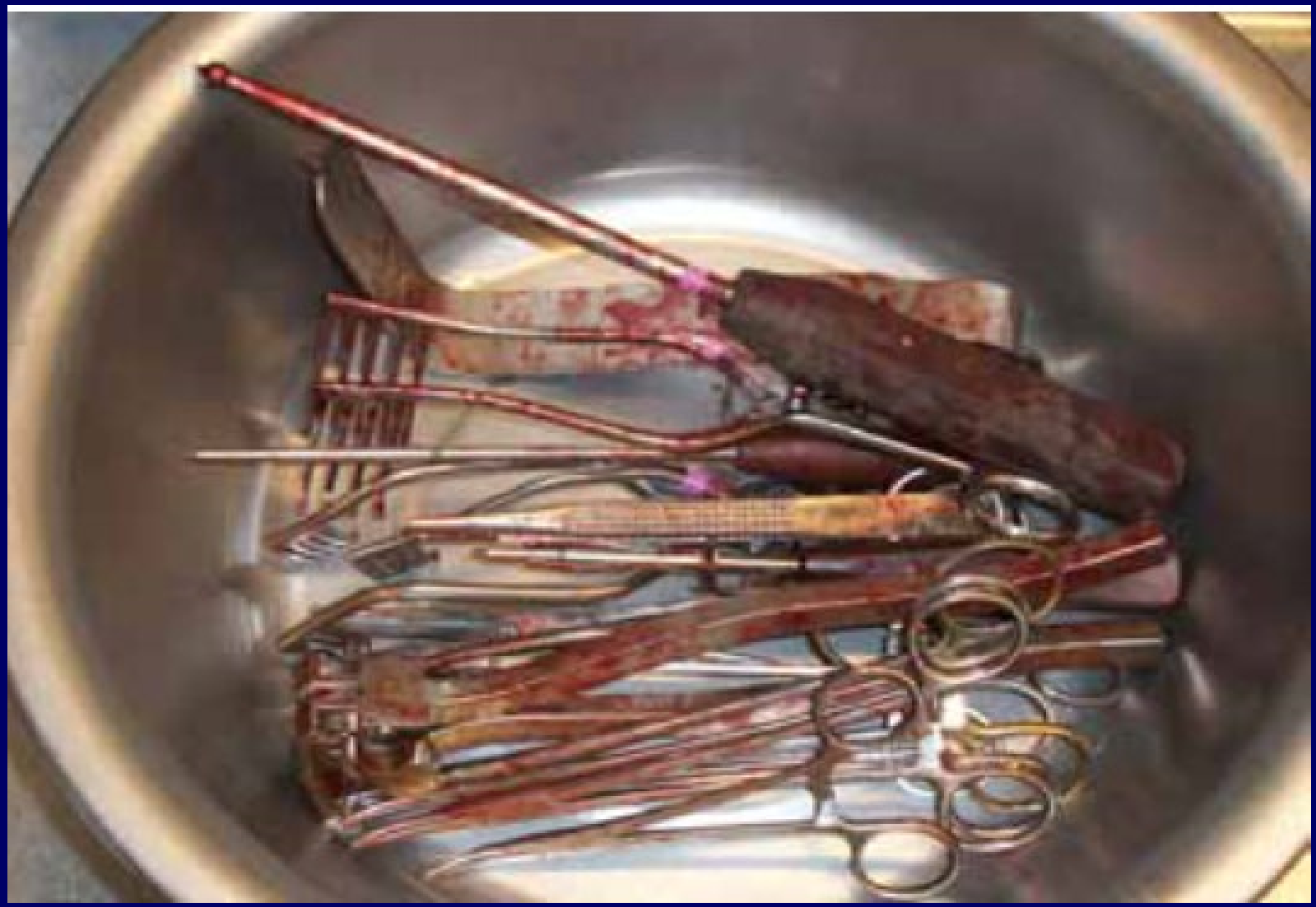
- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments, implants
    - Enormous margin of safety, rare/no outbreaks
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores

Risk of Infection Transmission via Surgical Instruments-Essentially Zero

Rutala et al. AJIC. 2019;47:A62-66. Rutala, Weber; JAMA 2014;312:1405-6; Rutala, Weber. ICHE 2014;35:1068-1070; Rutala et al. ICHE 2014;35:883-885; Rutala et al. ICHE 2021







Pre-Cleaning in the Operating Room

Point-of-Use

- Point-of-use pre-cleaning by clinicians or technicians post-procedures is critical to removing bioburden and debris
- Ideally, instruments should arrive in Central Processing free on visible contamination (results in greater efficiency in CP)
- Wetting and wiping instruments and keeping lumens flushed throughout surgery prevents drying of debris. Soiled instruments that will not be reused should be allowed to soak in a basin of sterile water for the remainder of the procedures.
- Keep instruments moist (e.g., enzymatic sprays, foams, gels) until manual cleaning

Cleaning

- **Manual**
- **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

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.

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

- There is currently no universal standard to define when a device is "clean", cleanliness controlled by visual
- Potential methods: level of detectable bacteria; protein (6µg/cm^2); endotoxin; ATP; lipid; hemoglobin; carbohydrate; bilirubin; total organic carbon; cleaning indicators for washer disinfectors; borescope
- 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}

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^{o}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^{o}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

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

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

Cleaning Indicators for Washers

- Monitor the automated washer and instrument cleaning chemistry functionality
- Complete soil removal of the dried test soil pattern is a "pass"
- Indicator includes proteins, lipids, and polysaccharides to mimic common challenging test soils

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

Efficacy of Disinfection/Sterilization

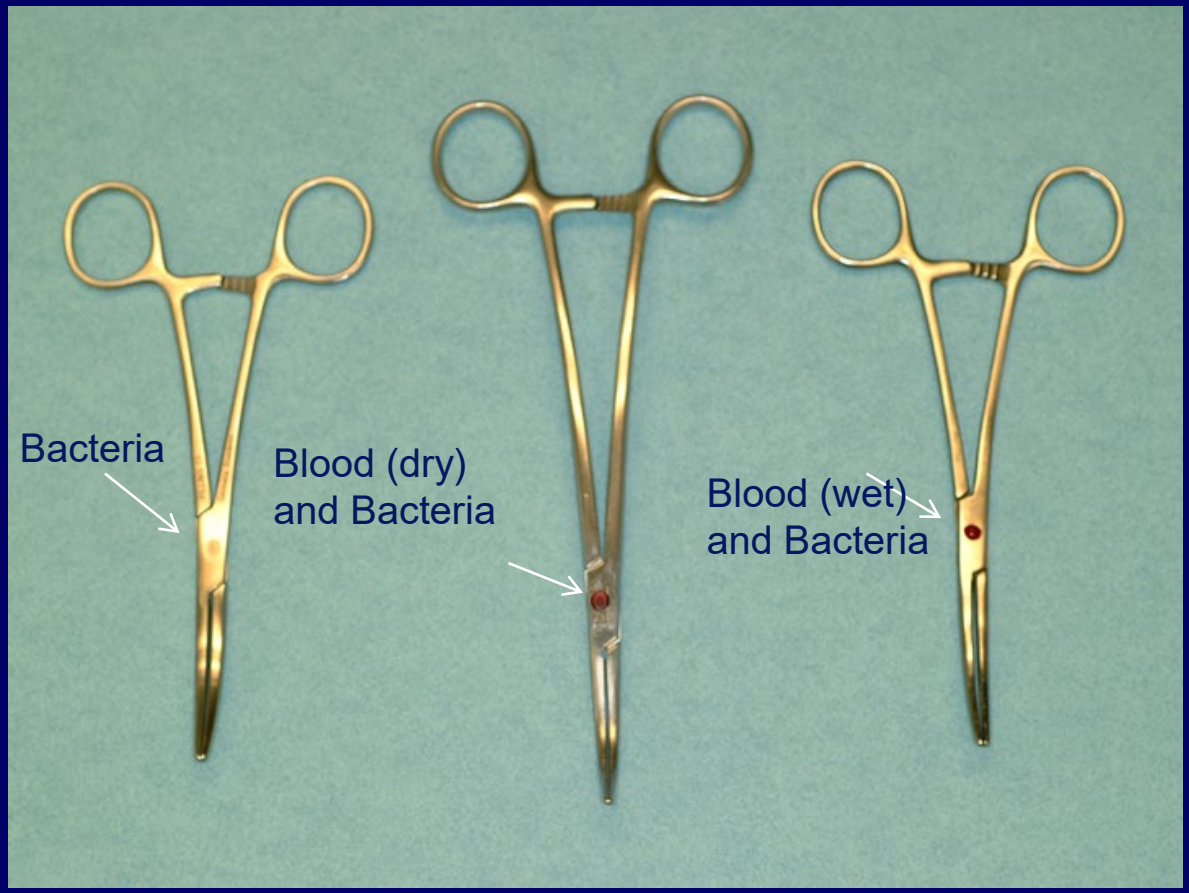
Influencing Factors

- 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

Sterilization-SAL 10^{-6} Robustness

“Dirty” (non-cleaned) Instruments with Blood and Bacteria

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



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 blood[2]	Instrument Quantitation (Mean)	% Positive
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	~ 1.56×10^5	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich[2])	~ 1.99×10^5	0/12 (0)
Mycobacterium terrae	Steam Sterilization	Dirty	~ 4.25×10^6	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.

Steam sterilization is the most effective sterilization technology with the largest margin of safety, followed by ETO and hydrogen peroxide gas plasma.

Table 1. Effectiveness of the Microbicidal Activity of Sterilization Technologies in the Presence of Blood on "Dirty" Instruments[a]

Test Organism	Method of Sterilization	Instruments "Dirty" (Uncleaned) With or Without Blood[b]	Instrument Quantitation (Mean)	No. of Positives/ No. of Runs (% Positive)
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	~ 1.56×10^5	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich[b])	~1.99×10^5	0/12 (0)
	ETO	Dirty	~1.53×10^5	0/10 (0)
		Dirty with blood	~2.35×10^5	0/11 (0)
	HPGP	Dirty	~1.58×10^5	5/10 (50)
		Dirty with blood	~2.35×10^5	9/15 (60)
Mycobacterium terrae	Steam Sterilization	Dirty	~4.25×10^6	0/10 (0)
P. aeruginosa	HPGP	Dirty	~1.81×106	3/15 (20)
Bacillus atrophaeus (spores)	ETO	Dirty	~ 2.30×10^7	6/10 (60)
		Dirty with blood	~4.08×10^7	9/10 (90)
MRSA	ETO	Dirty	~2.62×10^6	0/10 (0)
		Dirty with blood	~1.72×10^6	0/10 (0)
	HPGP	Dirty	~1.10×10^6	4/10 (40)
		Dirty with blood	~1.27×10^6	4/10 (40)
	Steam sterilization	Dirty	2.56×10^6	0/10 (0)
		Dirty with blood	5.20×10^5	0/10 (0)
VRE	ETO	Dirty	~2.27×10^6	0/10 (0)
		Dirty with blood	~3.59×10^6	0/10 (0)
	HPGP	Dirty	~2.63×10^6	3/10 (30)
		Dirty with blood	~2.34×10^6	9/10 (90)
	Steam sterilization	Dirty	1.90×10^6	0/10 (0)
		Dirty with blood	2.72×10^5	0/10 (0)

Note. ETO, ethylene
[a]Study conditions no
[b]Sandwich consists
experiment was don

rmophilus

Steam sterilization is the most effective sterilization technology with the largest margin of safety, followed by ethylene oxide and hydrogen peroxide gas plasma.

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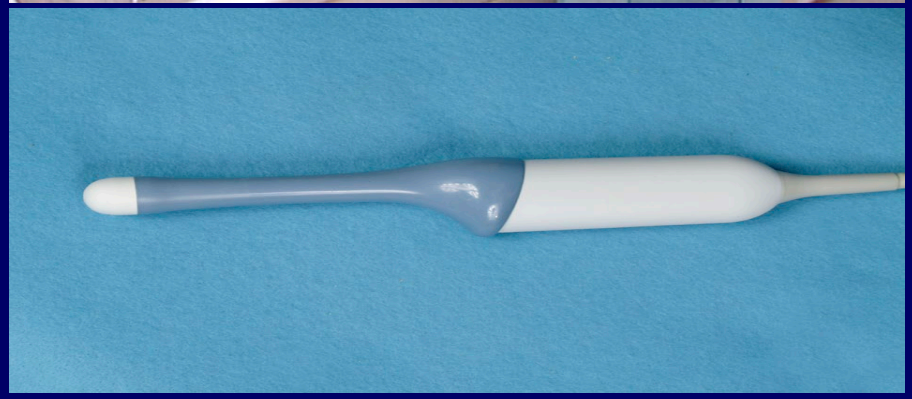
Semicritical Medical Devices

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

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)

Infections/Outbreaks Associated with Semicritical Medical Devices

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[51,54-57]	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.

High-Level Disinfection of "Semicritical Objects"

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

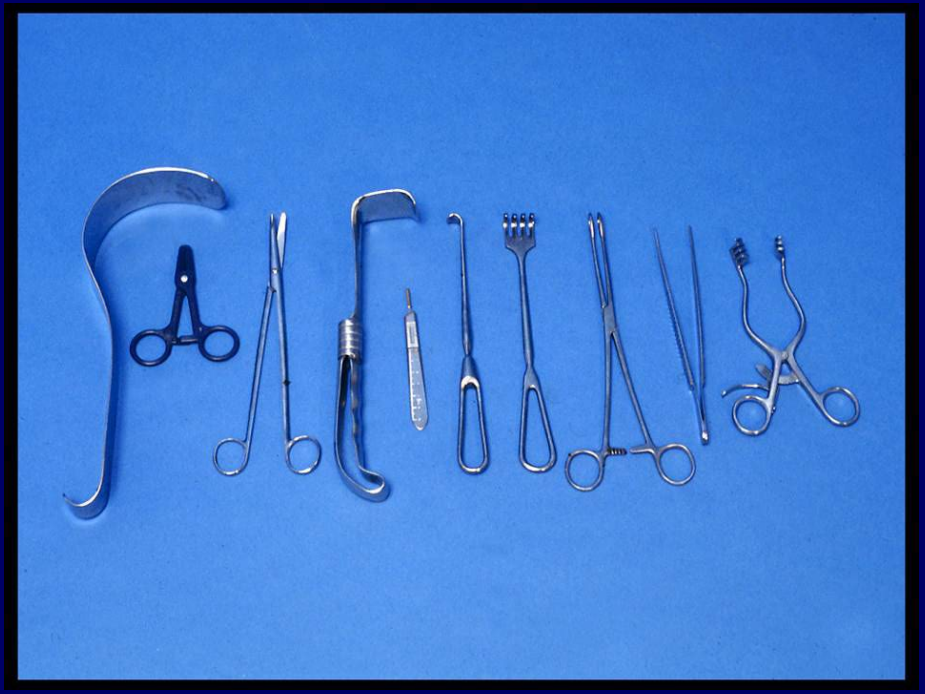
Germicide	Exposure Time ≥ 8m-45m (US), 20°C Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Accelerated hydrogen peroxide	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

ENDOSCOPE REPROCESSING: CHALLENGES

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

Surgical instruments-<10^{2} bacteria



Reason for Endoscope-Related Outbreaks

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

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

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,

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 (modified).

CRITICAL - objects which directly or 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).

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

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 (puts next patient at infection risk)

LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

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

Best Practices in Disinfection of Noncritical Surfaces in the Healthcare Setting: A Bundle Approach

NL Havill AJIC 2013;41:S26-30; Rutala, Weber. AJIC 2019;47:A96-A105

A Bundle Approach to Surface Disinfection (prevents infection to new patient)

- 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 (and new strategies)

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Antiseptic Agents

(used alone or in combination)

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

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

Summary of Best Antiseptics

JM Boyce. AJIC 2019.47:A17-A22

- **Preoperative showers**-CHG is preferred; significant impact on SSIs not proven
- **Preoperative skin preparation**-alcohol-containing products (with CHG or iodophor)
- **Surgical hand scrub**-alcohol-containing products reduce bacteria on hands best
- **Vascular access site preparation**-alcohol preparation containing >0.5% CHG
- **Routine daily bathing of patients**-CHG appears to reduce infections (CLABSI) in ICU

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Summary

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