Cleaning, Disinfection, Sterilization and Asepsis

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

Director, Statewide Program for Infection Control and Epidemiology and Research Professor of Medicine, University of North Carolina at Chapel Hill, NC, USA

Former Director, Hospital Epidemiology, Occupational Health and Safety, UNC Health Care, Chapel Hill, NC

Cleaning, Disinfection, Sterilization and Asepsis

- CBIC-15 questions. Will test knowledge of the following:
  - Identify appropriate cleaning, sterilization and disinfection practices
  - Assess products under evaluation for their ability to be processed
  - Identify and evaluate critical steps of cleaning, high-level disinfection and sterilization

CDC Guideline for Disinfection and Sterilization

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

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

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

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

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

Medical/Surgical Devices

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

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

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

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

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

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

Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners before processing.(CBIC-enzymatic used once)
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used as soiled materials become dried onto the instruments.

Cleaning

- Mechanical cleaning machines-automated equipment may increase productivity, improve cleaning effectiveness, and decrease worker exposure
  - Utensil washer-sanitizer
  - Ultrasonic cleaner
  - Washer sterilizer
  - Dishwasher
  - Washer disinfector
- Manual

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; hemoglobin; carbohydrate; bilirubin; total organic carbon; cleaning indicators for washer disinfectors; boroscope
- This is due in part to the fact that no universally accepted test soils to evaluate cleaning efficiency and no standard procedure for measuring cleaning efficiency
- At a minimum, a cleaning process should: reduce the natural bioburden; remove organic/inorganic contaminants; provide devices that when sterilized have a SAL 10^{-6}

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

CBIC-Cleaning

- According to AAMI ST79, which of the following are among the recommendations of mechanical cleaning equipment in order to verify adequate cleaning?
  1. Verification should be carried out monthly
  2. Verification should be carried out upon installation
  3. Verification should be carried out after major repairs
  4. Verification should be when changing cleaning chemistry

  a. 1, 2, 3, 4
  b. 1, 2, 4
  c. 1, 2, 3
  d. 2, 3, 4

CBIC-Cleaning

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  a. 1, 2, 3, 4
  b. 1, 2, 4
  c. 1, 2, 3
  d. 2, 3, 4-Answer (verification of cleaners, weekly)

CBIC-Cleaning

- The purpose of cleaning medical devices before sterilization or HLD is to:
  1. Reduce bioburden
  2. Add an additional step in the process
  3. Replace the sterilization process
  4. Increase the amount of time it takes to clean an endoscope

Medical/Surgical Devices

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

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Critical Medical/Surgical Devices

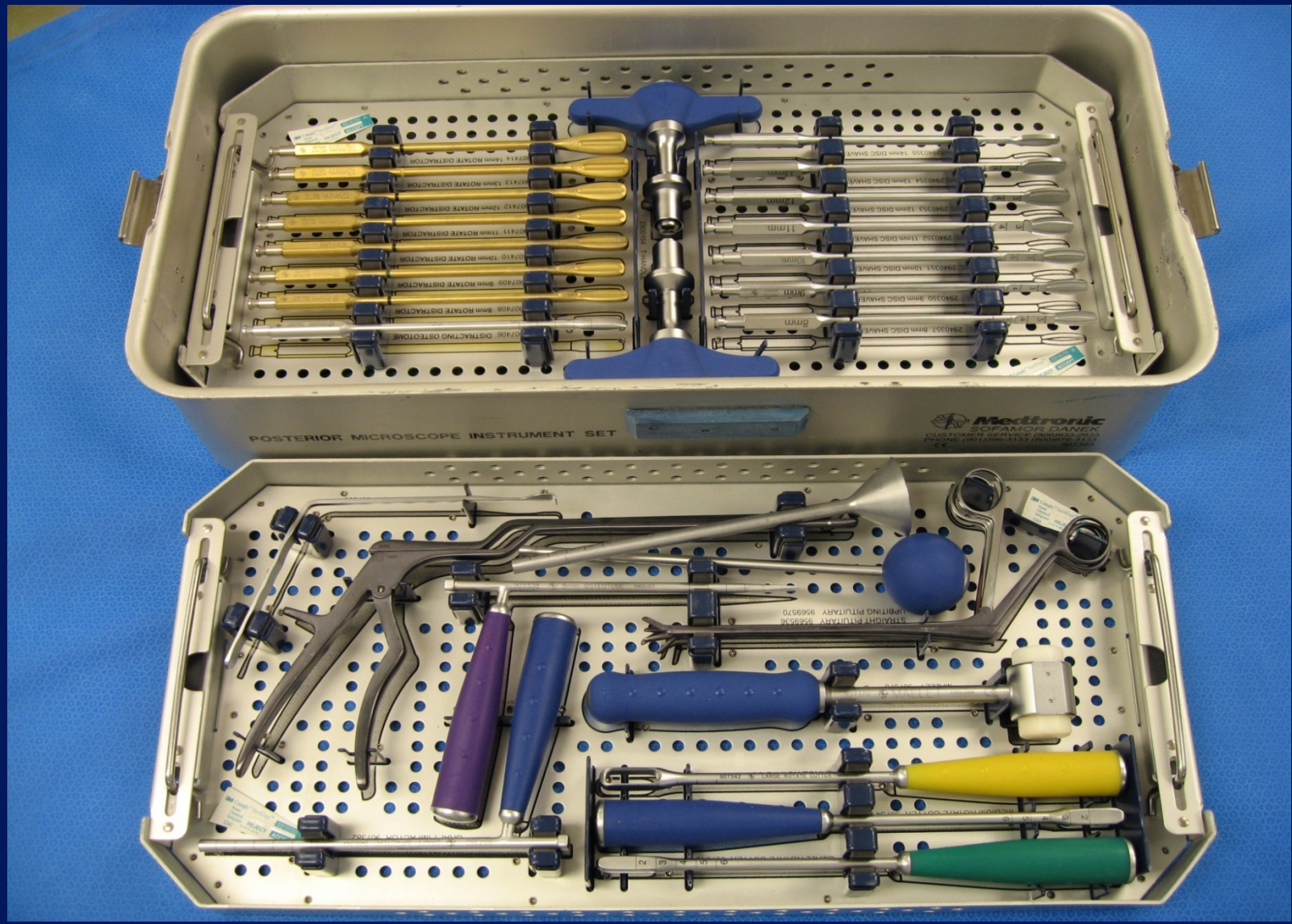
Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2016;44:e47

- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments
    - 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

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


POSTERIOR MICROSCOPE INSTRUMENT SET
Medtronic
SOFAMOR DANEK

Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

Methods in Sterilization

Sterilization of “Critical Objects”

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Ozone and hydrogen peroxide

Vaporized hydrogen peroxide

CBIC-Chemical Sterilization

- One disadvantage of liquid sterilization is:
  1. Liquid sterilants are highly toxic and items must be aerated before use
  2. It is a high heat process so it may not be used on heat-labile items
  3. It is not an appropriate process for critical items
  4. Items cannot be wrapped during the sterilization process so sterility can be maintained during storage

Chemical Sterilization of “Critical Objects”

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%)

Exposure time per manufacturers’ recommendations

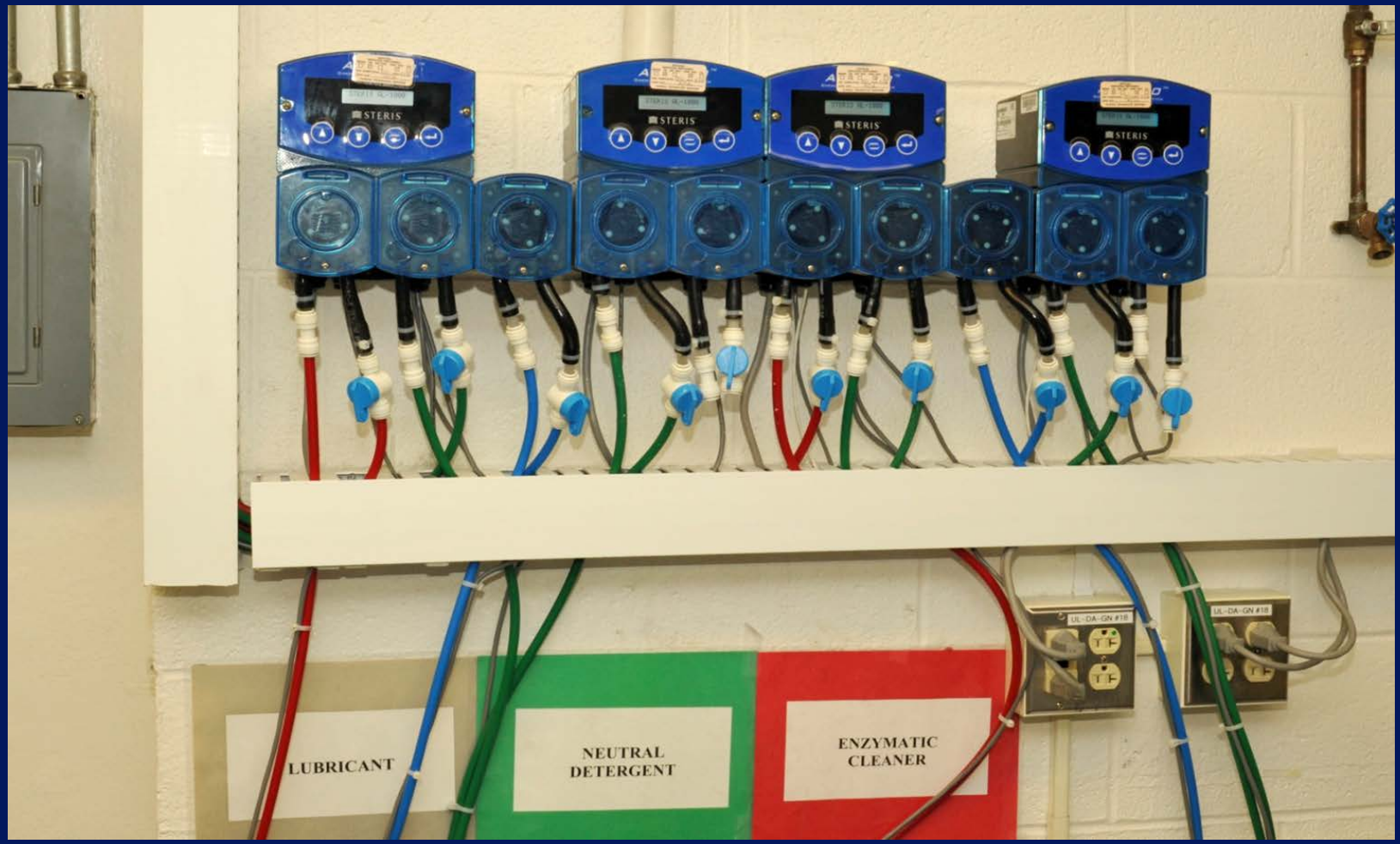
Sterilization Practices

Central Processing

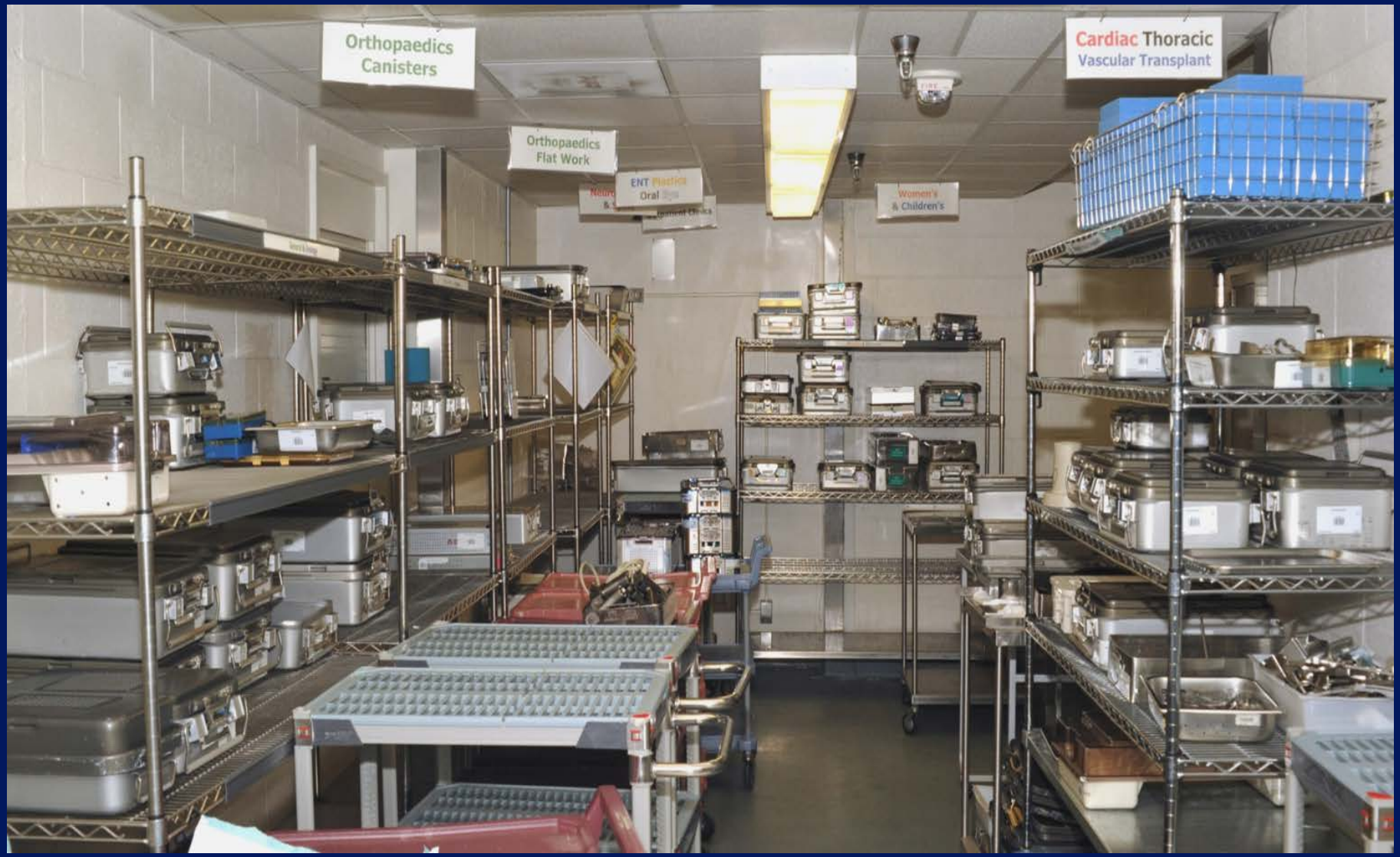
- Goal
  - Orderly processing of medical and surgical instruments to protect patients from infections while minimizing risks to staff and preserving the value of the items being reprocessed
  - Ensure consistency of sterilization practices requires a comprehensive program that ensures operator competence and proper methods of cleaning and packaging instruments, loading the sterilizer, operating the sterilizer, and monitoring the entire process

Central Processing
Physical Facilities

- Facility ideally divided into three areas:
  - Decontamination-reusable items are received, sorted, and decontaminated; negative pressure; 6AC/hr. Personnel wear gloves when handling contaminated instruments; face masks, eye protection, and gowns/aprons when splashing may occur.
  - Packaging-used for inspecting, assembling, and packaging clean, but not sterile, material.
  - Sterilization and storage-limited access area with a controlled temperature and relative humidity.


STERIS
STERIS
STERIS
STERIS
LUBRICANT
NEUTRAL DETERGENT
ENZYMATIC CLEANER


WASHER
#1
WASHER
#2


Orthopaedics
Canisters
Orthopaedics
Flat Work
ENT
Oral
Women's
& Children's
Cardiac Thoracic
Vascular Transplant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#6 GAS
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Central Processing

Sterrads

CBIC-Central Processing

- Which of the following is likely to result in the highest efficacy of the medical instrument cleaning:
  1. Use of central reprocessing area for all instrument cleaning
  2. Local instrument reprocessing within the area of care
  3. Use of an acidic cleaner
  4. Allowing the instrument to dry after use and before cleaning

Objectives of Monitoring the Sterilization Process

- Assures probability of absence of all living organisms on medical devices being processed
- Detect failures as soon as possible
- Removes medical device involved in failures before patient use

Sterilization Monitoring

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

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

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

High-Level Disinfection

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, >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

Semicritical Items

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

High-Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 8m-45m (US), 20ºC

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Accelerated hydrogen peroxide	2.0%
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

Low-Level Disinfection

Noncritical Medical Devices

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

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

LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES (EPA)

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

Exposure time ≥ 1 min

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

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

Cleaning solution container must be labeled with the chemical content, name and expiration date. No "topping off"

ALL “TOUCHABLE” (HAND CONTACT) SURFACES SHOULD BE WIPED WITH DISINFECTANT

“High touch” objects only recently defined (no significant differences in microbial contamination of different surfaces) and “high risk” objects not epidemiologically defined. Cleaning and disinfecting is one-step with disinfectant-detergent. No pre-cleaning necessary unless spill or gross contamination.

CBIC

- Which of the following practices is most likely to result in improved infection prevention?
  1. Strictly adhering to EPA-registered product label contact time for LLD of environmental surfaces
  2. Utilizing a 1-minute contact time for LLD of environmental surfaces regardless of the EPA-registered product label contact time
  3. Thoroughly cleaning and disinfecting all surfaces in a room that have potentially come into contact with hands
  4. Thoroughly cleaning and disinfecting all high touch surfaces in a room

C. difficile CONTROL MEASURES

Orenstein et al. ICHE 2011;32:1137

- In units with high endemic *C. difficile* infection rates or in an outbreak setting, use dilute solutions of 5.25-6.15% sodium hypochlorite (e.g., 1:10 dilution of bleach) for routine disinfection. (Category II).
- We now use chlorine solution in all CDI rooms for routine daily and terminal cleaning (use to use QUAT in patient rooms with sporadic CDI). One application of an effective product covering all surfaces to allow a sufficient wetness for > 1 minute contact time. Chlorine solution normally takes 1-3 minutes to dry.
- For semicritical equipment, glutaraldehyde (20m), OPA (12m) and peracetic acid (12m) reliably kills *C. difficile* spores using normal exposure times

INACTIVATION OF MURINE AND HUMAN NOROVIRUES

Disinfectant, 1 min	MNV Log_{10} Reduction	HNV Log_{10} Reduction
70% Ethanol	>4 (3.3 at 15sec)	2
70% Isopropyl alcohol	4.2	2.2
65% Ethanol + QUAT	>2	3.6
79% Ethanol + QUAT	3.4	3.6
Chlorine (5,000ppm)	4	3
Chlorine (24,000ppm)	2.4	4.3
Phenolic, QUAT, Ag, 3% H_20_2	≤1	≤1 (2.1 QUAT)
0.5% Accel H_20_2	3.9	2.8

Rutala WA, Folan MP, Tallon LA, Lyman WH, Park GW, Sobsey MD, Weber DJ. 2007

GUIDELINE FOR THE PREVENTION OF NOROVIRUS OUTBREAKS IN HEALTHCARE, HICPAC, 2011

- Avoid exposure to vomitus or diarrhea. Place patients with suspected norovirus on Contact Precautions in a single room (IB)
  - Continue Precautions for at least 48 hours after symptom resolution (IB)
  - Use longer isolation times for patients with comorbidities (II) or <2 yrs (II)
- Consider minimizing patient movements within a ward (II)
  - Consider restricting movement outside the involved ward unless essential (II)
  - Consider closure of wards to new admissions (II)
- Exclude ill personnel (IB)
- During outbreaks, use soap and water for hand hygiene (IB)
- Clean and disinfect patient care areas and frequently touched surfaces during outbreaks 3x daily using EPA approved healthcare product (IB)
- Clean surfaces and patient equipment prior to disinfection. Use product with an EPA approved claim against norovirus (IC)

MacCannell T, et al. http://www.cdc.gov/hicpac/pdf/norovirus/Norovirus-Guideline-2011.pdf

CBIC-Instrument Reprocessing

- Which of the following items can generally be reprocessed by only using low-level disinfectants:
  1. Blood pressure cuffs
  2. Anesthesia equipment
  3. Bronchoscopes
  4. Surgical instruments

Critical Items

Sterilization

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

Sterilization of “Critical Objects”

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Ozone and hydrogen peroxide

Vaporized hydrogen peroxide

CBIC-Sterilization of Instruments

- Which of the following are used for sterilization of medical instruments:
  1. Gravity-displacement steam sterilizer
  2. Pasteurizer
  3. Ethylene oxide sterilizer
  4. Ultrasonic cleaner

CBIC-Sterilization of Instruments

- Which of the following are used for sterilization of medical instruments:
  1. Gravity-displacement steam sterilizer
  2. Pasteurizer
  3. Ethylene oxide sterilizer
  4. Ultrasonic cleaner

  Answer: 1, 3

“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


#7 GAS
STERIS
#8 GAS
STERIS

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

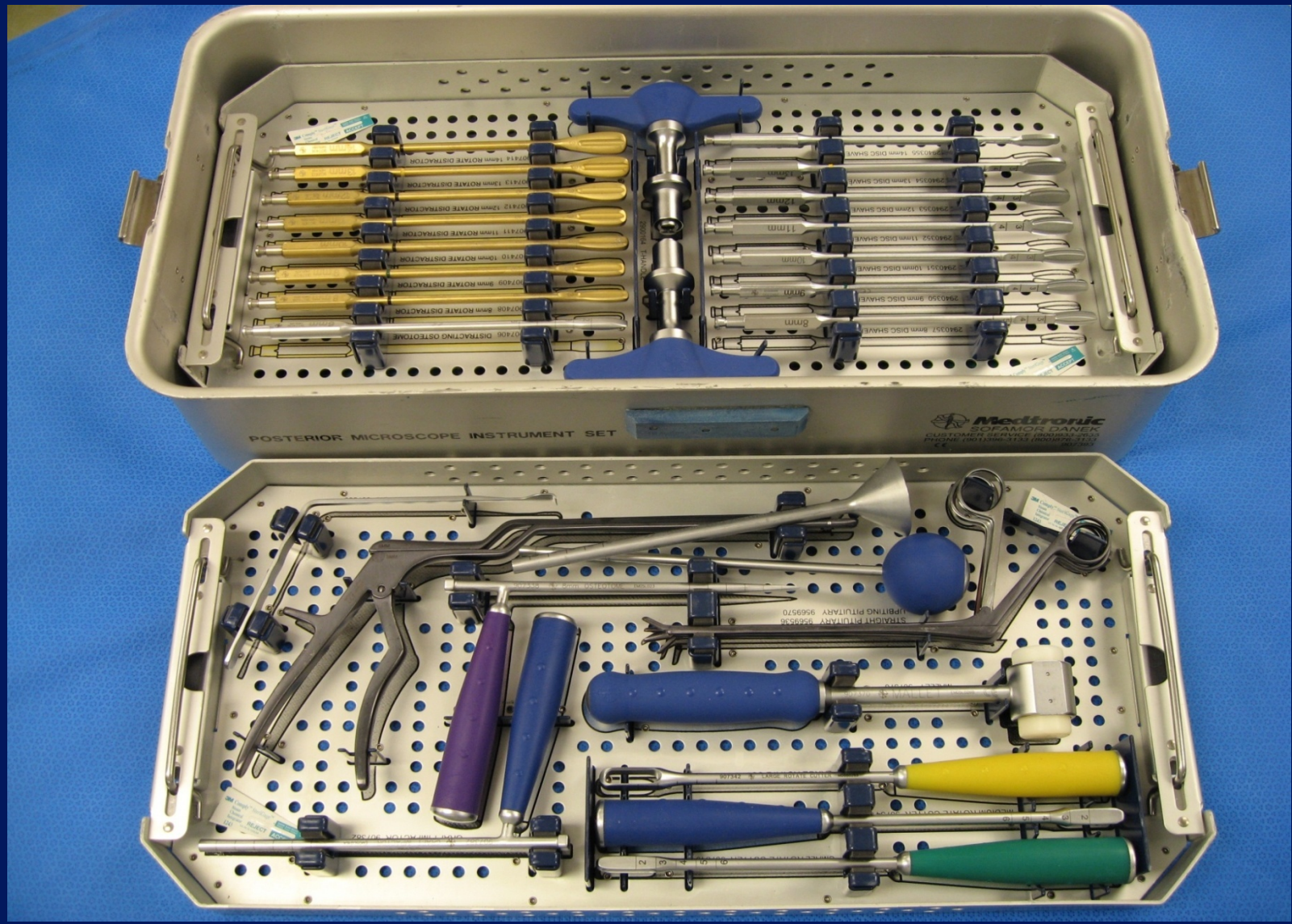
Inadequate Cleaning and Sterilization of Cataract Surgery (CBIC)

- May result in a an adverse event after cataract surgery
  - Toxic Shock
  - Posterior Segment Syndrome
  - Anterior Syndrome
  - Toxic Anterior Segment Syndrome

TASS is a sterile, non-infectious acute postoperative anterior segment inflammation that is caused by a noninfectious substance that enters the anterior segment, resulting in toxic damage to intraocular tissues

Mechanical Cleaning Equipment in CP (CBIC)

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


POSTERIOR MICROSCOPE INSTRUMENT SET
Medtronic
SOFAMOR DANEK

Steam Sterilization

Rutala, Weber AJIC 2016;44:e1-e6

- 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

Minimum Steam Sterilization Times

Time at 132°C in Prevacuum Sterilizer

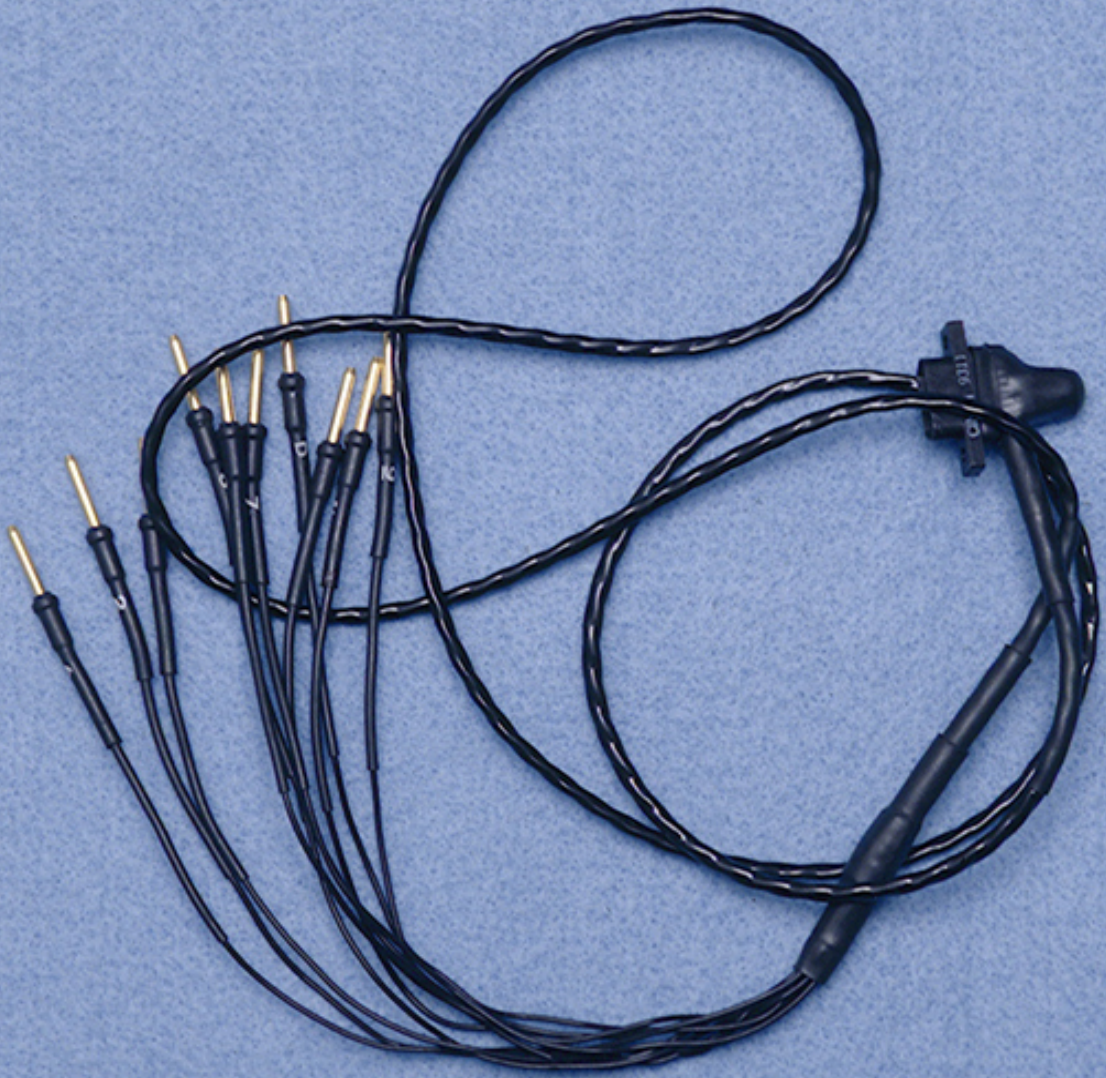
Item	Minimum exposure	Minimum drying time
Wrapped instruments	4 min	30 min
Textile packs	4 min	5 min

Immediate Use Steam Sterilization

- “Flash” originally defined as sterilization of an unwrapped object at 132^{o}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” 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-CBIC

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



New Trends in Sterilization of Patient Equipment

- Alternatives to ETO-CFC

  ETO-CO_2, ETO-HCFC, 100% ETO
- New Low Temperature Sterilization Technology

  Hydrogen Peroxide Gas Plasma

  Ozone and hydrogen peroxide

  Vaporized Hydrogen Peroxide


#7 GAS
STERIS
#8 GAS
STERIS

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)

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

Sterilization Practices

Objectives of Monitoring the Sterilization Process

- Assures probability of absence of all living organisms on medical devices being processed
- Detect failures as soon as possible
- Removes medical device involved in failures before patient use

Sterilization Monitoring

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

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

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

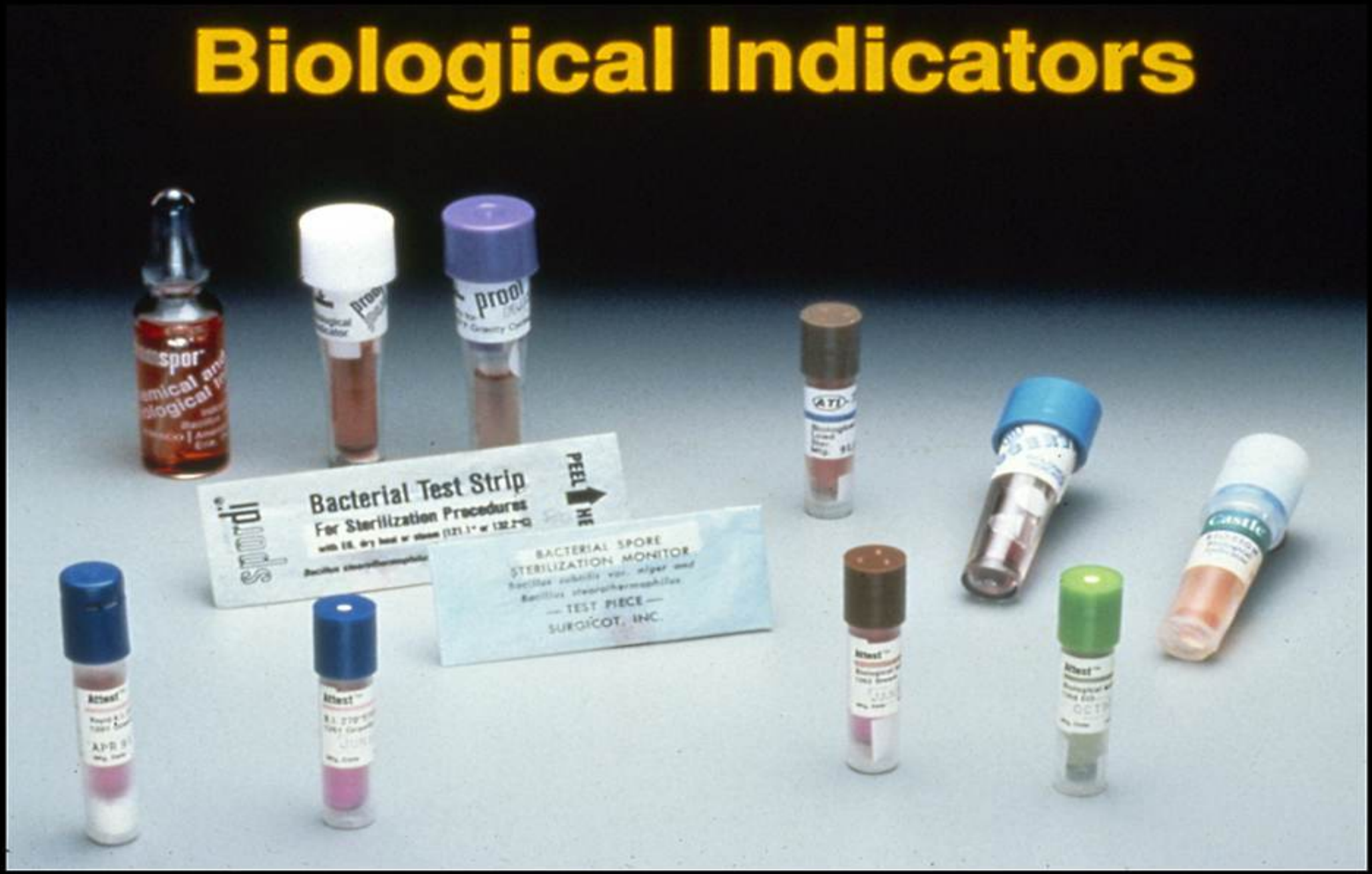
CBIC-Which is most accurate for assessing correct processing?

Sterilility Indicators Table

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

6/23/97

Biological Indicators



Biological Monitors

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

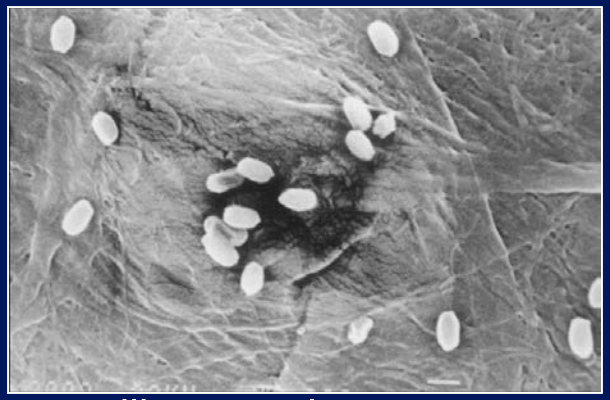
- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus (formerly B. subtilis)*
- ETO - *B. atrophaeus*
- New low temperature sterilization technologies

  HP gas plasma (Sterrad) - *G. stearothermophilus*

  Ozone-*G. stearothermophilus*

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

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

Super Rapid Readout Biological Indicators

Commercially available

1491 BI (blue cap)

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

1492V BI (brown cap)

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

CBIC-BIs

- The purpose of an biological indicator in an autoclave is:
  1. To determine whether the items being autoclaved are properly sterilized, which is indicated by a positive BI result
  2. To determine whether the items being autoclaved are properly sterilized, which is indicated by a negative BI result
  3. To determine whether the items being autoclaved are properly cleaned, which is indicated by a positive BI result
  4. To determine whether the items being autoclaved are properly cleaned, which is indicated by a negative BI result


ASP
STERRAD® 50

Recommendations
Monitoring of Sterilizers
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Monitor each load with mechanical 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

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. CBIC-Positive BI, load must be reprocessed
- 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.

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)

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.

Proper Storage of Sterile, Reprocessed Items

- Items stored (CBIC)
  - 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%)

Sterile, Reprocessed Item (CBIC)

- 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

Ultrasonic Cleaners (CBIC)

- 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 cleaning that removes all visible and accessible soiling is carried out and before sterilization

OR, CSS (CBIC)

- Report of an:
  - Infestation of fruit flies in the sterile instrument storage room
  - Steam intrusion and wetness
  - Significant construction debris
- OR staff want to know whether they can use the sterile packs. These conditions can affect the integrity of the packaging and contaminate the contents
  - The instruments should be unwrapped, visibly inspected, cleaned if necessary, and reprocessed

Reuse of Single Use Devices

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.

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

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)

Sterile Single-use Needle Guides

BK Medical now offers sterile single-use needle guides for our unique Prostate Triplane 8818 and Prostate Biplane 8808e transducers.

Our new needle guides are individually sterile-packed, which means:

- No risk for cross-contamination
- One patient, one guide
- Easy to use
- Pre-assembled and ready to use
- No need for additional preparation or cleaning following the exam

UA1322-S14

UA1329-S

UA1323-S

UA1257-S14

For the 8818:

UA1322-S14 Biplane guide

For the 8808e:

UA1322-S14 Biplane guide

Disinfection and Sterilization of Emerging Pathogens

Disinfection and Sterilization of Emerging Pathogens

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

Disinfection and Sterilization of Emerging Pathogens

Standard disinfection and sterilization procedures for patient care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood and other body fluids from persons infected with emerging pathogens

Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY FEBRUARY 2010, VOL. 31, NO. 2

SHEA GUIDELINE

Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments

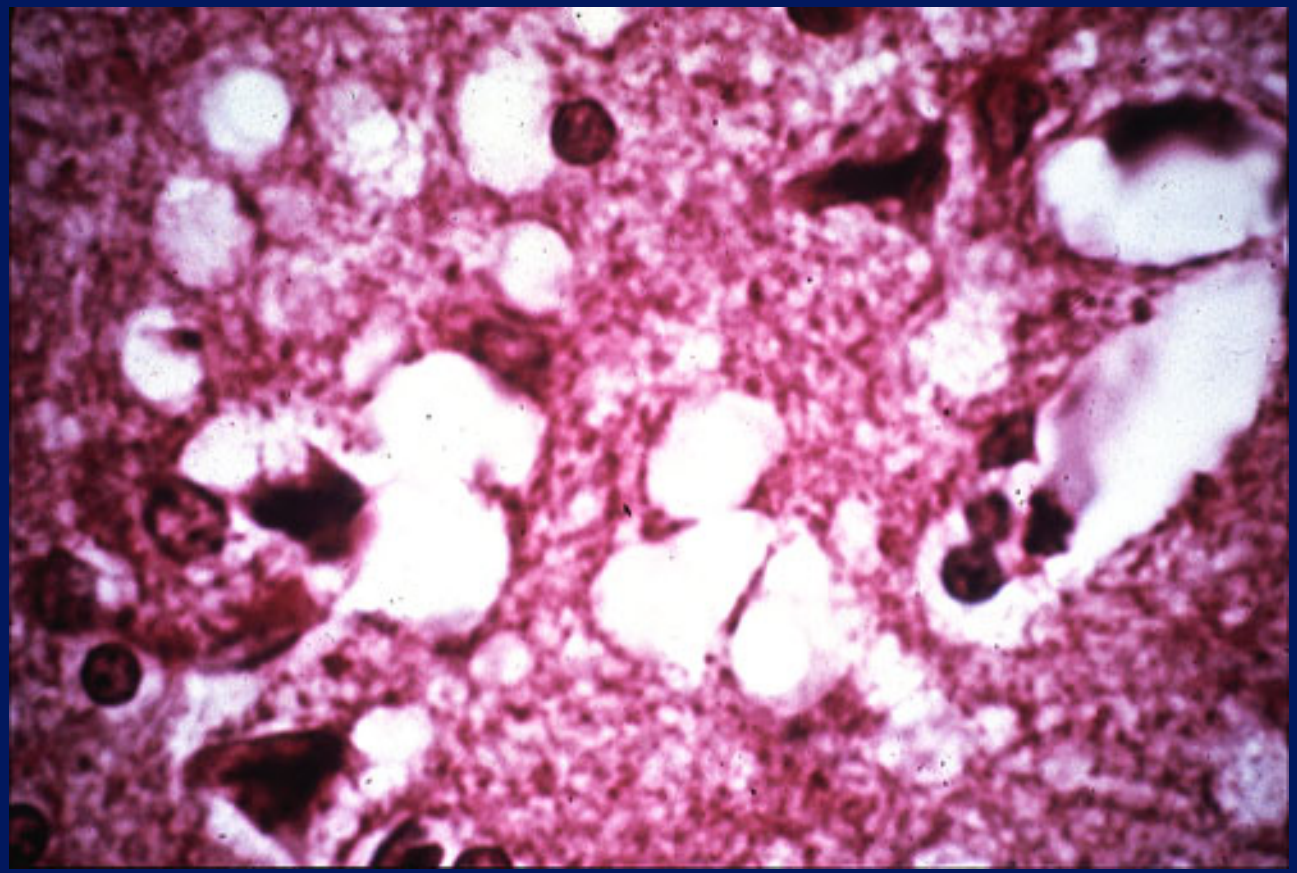
William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

EPIDEMIOLOGY OF THE CREUTZFELDT-JAKOB DISEASE PRION

Creutzfeldt-Jakob disease (CJD) is a degenerative neurologic disorder of humans with an incidence in the United States of approximately 1 case per million population per year.[1-3] tains. To date, no evidence for transmission of chronic wasting disease of deer and elk to humans has been identified.[7-10]

TRANSMISSION OF CJD VIA MEDICAL DEVICES

CJD



Transmissible Spongiform Encephalopathies (TSEs) of Humans

- Kuru-now eradicated
- Gertsmann-Straussler-Scheinker (GSS)-1/40M
- Fatal Familial Insomnia (FFI)-<1/40M
- Creutzfeldt-Jakob Disease (CJD)-1/1M
- Variant CJD (vCJD), (221 cases, August 2011)
  Acquired from cattle with BSE.1995: 172 UK, 25 France, 4 Ireland, 2 Italy, 3 USA, 2 Canada,1 Saudi Arabia, 1 Japan, 3 Netherlands, 2 Portugal, 5 Spain, 1 Taiwan

Epidemiology of CJD in the US

Rutala, Weber. ICHE 2010;31:107-117

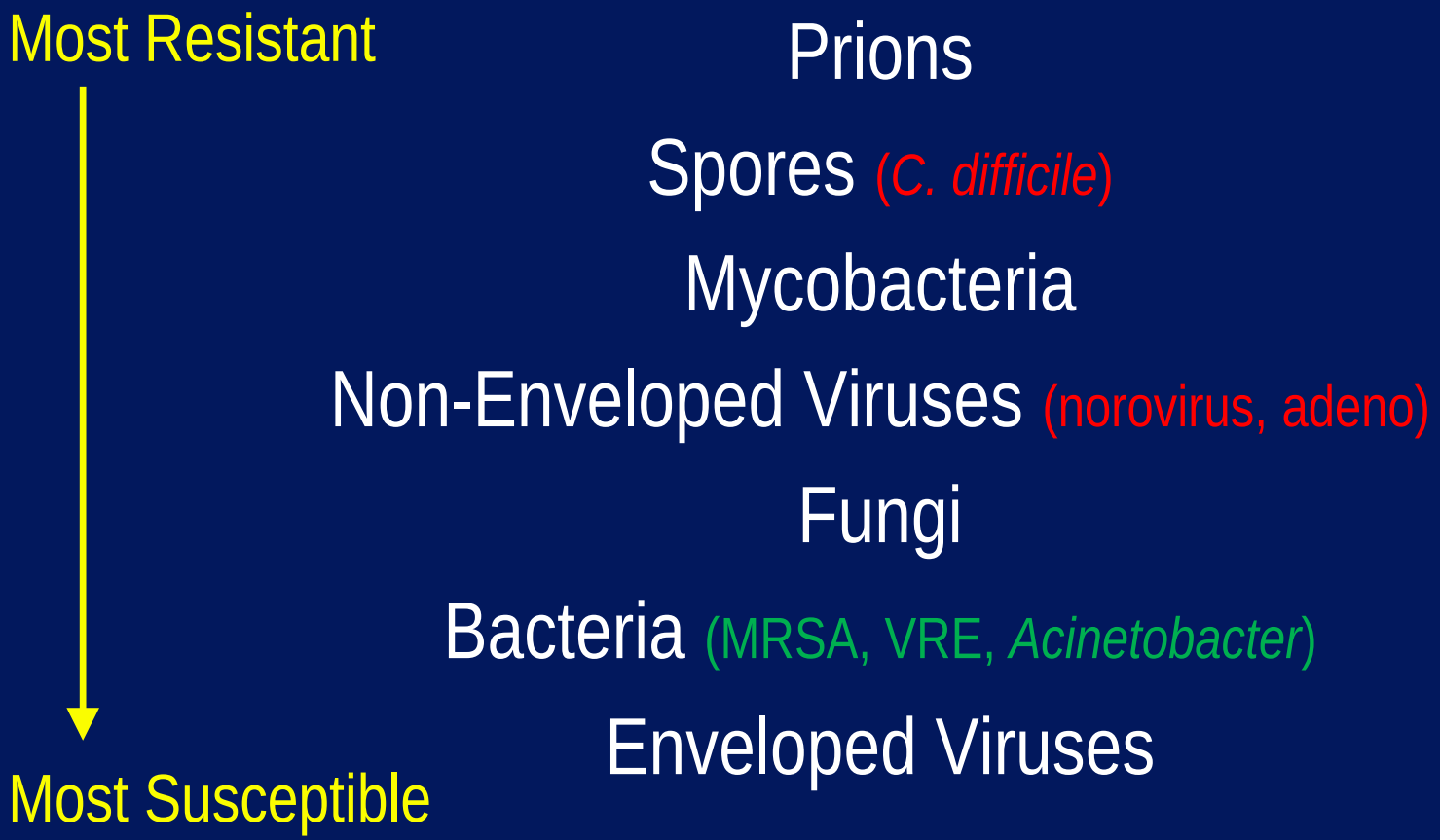
- Degenerative neurologic disorder
- CJD (a prion) incidence
  - One death/million population
  - No seasonal distribution, no geographic aggregation
  - Both genders equally affected
  - Age range 50-80+ years, average 67
- Long incubation, rapid disease progression after onset
- Prions resistant to conventional disinfection/sterilization

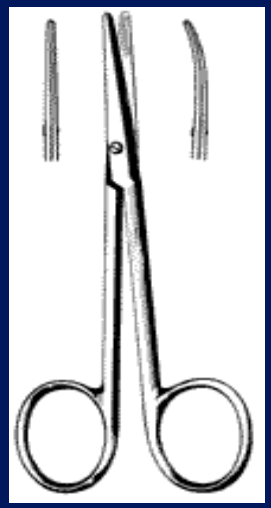
Prion Diseases

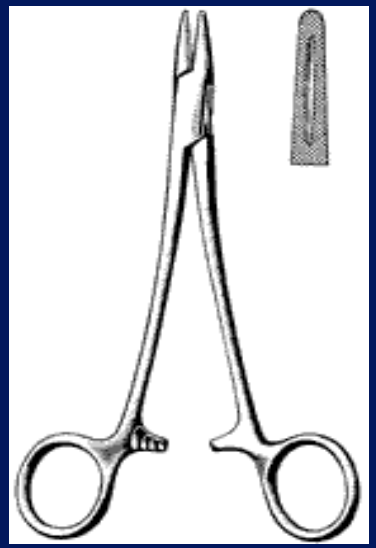
Rutala, Weber. ICHE 2010;31:107-117

- Etiology
  - Prions (proteinaceous infectious agent)
    - No agent-specific nucleic acid
    - Host protein (PrP^{c}) converts to pathologic isoform (PrP^{sc}); PrP gene resides on chromosome 20
    - Mutation in this gene may trigger transformation
    - Accumulates in neural cells, disrupts function, cell death
    - Resistant to conventional D/S procedures

Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants







CJD : potential for secondary spread through contaminated surgical instruments

CJD and Medical Devices

Rutala, Weber. ICHE 2010;31:107-117

- Six cases of CJD associated with medical devices
  - 2 confirmed cases-depth electrodes; reprocessed by benzene, alcohol and formaldehyde vapor
  - 4 cases-CJD following brain surgery, index CJD identified-1, suspect neurosurgical instruments
- Cases occurred before 1980 in Europe
- No cases since 1980 and no known failure of steam sterilization

A New Practical Diagnostic Test for Creutzfeldt-Jakob Disease

Brown, Farrell. ICHE. 2015;36:849

- 14-3-3 protein in spinal fluid has proved to be an invaluable diagnostic aid for 2 decades but recognized as “marker protein” not causally related to CJD
- Two published independent studies of a newly modified prion protein amplification test named RT-QuIC (real-time quaking-induced conversion)
- Two studies yielded high sensitivity (85-96%) and specificity (99-100%)
- Tests results are available within 24 hours of specimen collection

Risk Assessment: Patient, Tissue, Device

Rutala, Weber. ICHE 2010;31:107-117

- Patient
  - Known or suspected CJD or other TSEs
  - Rapidly progressive dementia
  - Familial history of CJD, GSS, FFI
  - History of dura mater transplant, cadaver-derived pituitary hormone injection
- Tissue
  - High risk-brain, spinal cord, eyes (CBIC-tissues considered high risk)
- Device
  - Critical or semicritical

CJD: Recommendations for Disinfection and Sterilization

Rutala, Weber. ICHE 2010;31:107-117

- High risk patient, high risk tissue, critical/semicritical device-special prion reprocessing
- High risk patient, **low/no risk tissue**, critical/semicritical device-conventional D/S or special prion reprocessing
- **Low risk patient**, high risk tissue, critical/semicritical device-conventional D/S
- High risk patient, high risk tissue, **noncritical device**-conventional disinfection

CJD: Disinfection and Sterilization

Conclusions

Rutala, Weber. ICHE 2010;31:107-117

- Critical/SC-cleaning with special prion reprocessing
  - 134^{o}C for 18m (prevacuum)
  - 132^{o}C for 60m (gravity)
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, 121^{o}C 30 m)
- No low temperature sterilization technology effective*
- Noncritical-four disinfectants (e.g., chlorine, Environ LpH) effective (4 log decrease in LD_{50} within 1h)

*VHP reduced infectivity by 4.5 logs (Lancet 2004;364:521)

CJD: Disinfection and Sterilization

Conclusions

Rutala, Weber. ICHE 2010;31:107-117

- Epidemiologic evidence suggest nosocomial CJD transmission via medical devices is very rare
- Guidelines based on epidemiologic evidence, tissue infectivity, risk of disease via medical devices, and inactivation data
- Risk assessment based on patient, tissue and device
- Only critical/semicritical devices contaminated with high-risk tissue from high risk patients requires special treatment

CBIC-CJD

- The director of surgical services has received a call from a neurosurgeon who would like to schedule a brain biopsy on a person suspected of Having CJD. The staff have expressed concern cleaning and sterilizing the surgical instruments. Your response is:
  1. Surgical instruments are very expensive and should be cleaned and sterilized after the procedure
  2. The recommendations are unclear as to how to clean and sterilize instruments
  3. There are no special requirements for cleaning and sterilizing of surgical instruments
  4. The instrument used in these cases require special reprocessing

Prevent Patient Exposure to CJD

Question: How do hospitals minimize patient exposure to neurosurgical instruments from a patient who is later given a diagnosis of CJD?

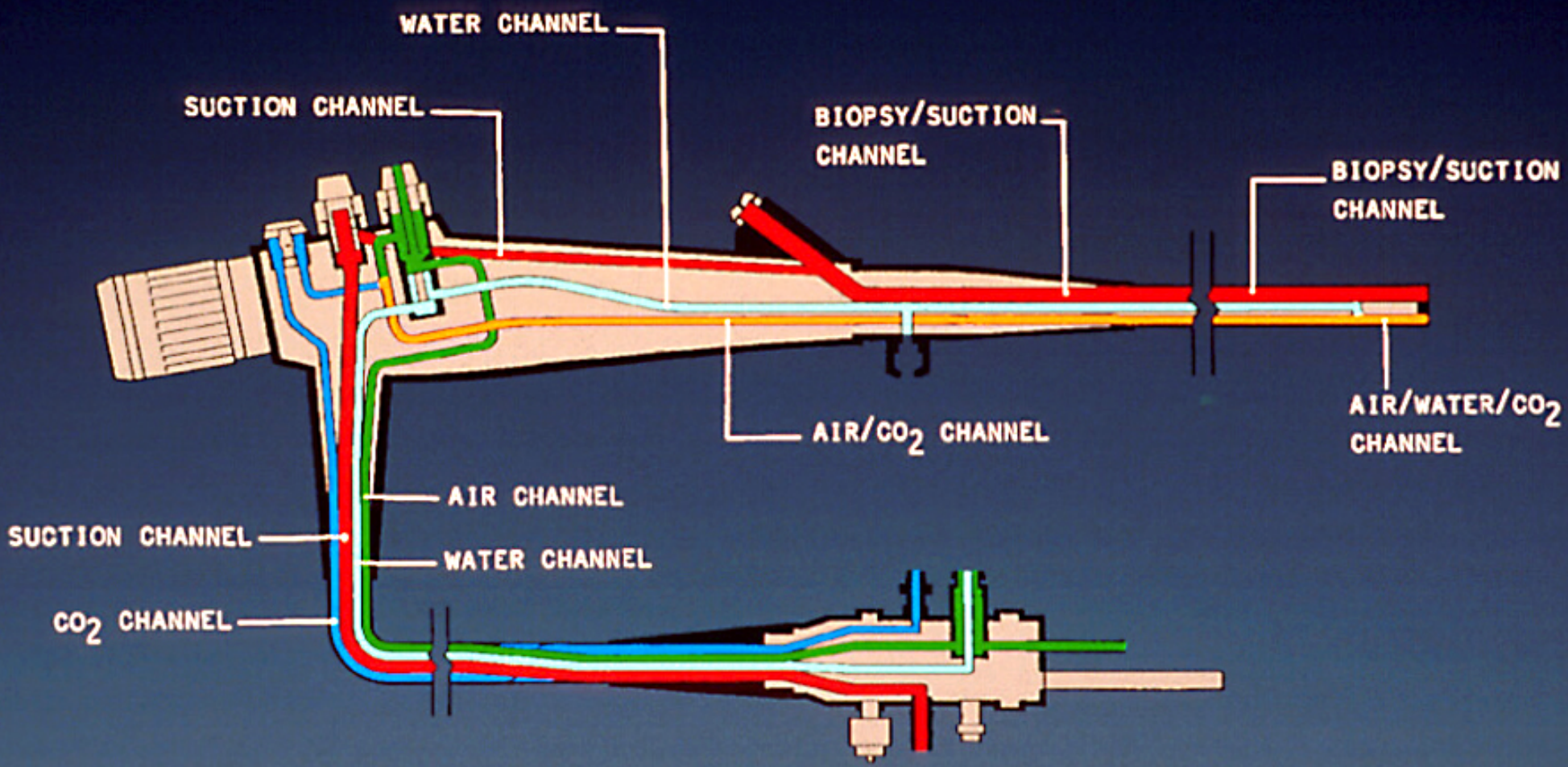
Answer: Consider using the reviewed sterilization guidelines for neurosurgical instruments used on patients undergoing brain biopsy when a specific lesion (e.g., tumor) has not been demonstrated. Alternatively, neurosurgical instruments used in such cases could be disposable.

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

ENDOSCOPE CHANNELS



Transmission of Infection by Endoscopy

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

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

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

Reason for Endoscope-Related Outbreaks

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

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

ENDOSCOPE REPROCESSING

Rutala, Weber, CDC Guideline 2008. www.cdc.gov; Multi-Society Guideline on Endoscope Reprocessing, 2011

- 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^{o}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

MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2017

Petersen et al. Gastro Endoscopy. In press

GIE®

SPECIAL ARTICLE

Society of Gastroenterology Nurses and Associates, Inc.

Association for Professionals in Infection Control and Epidemiology

The Society for Healthcare Epidemiology of America

AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

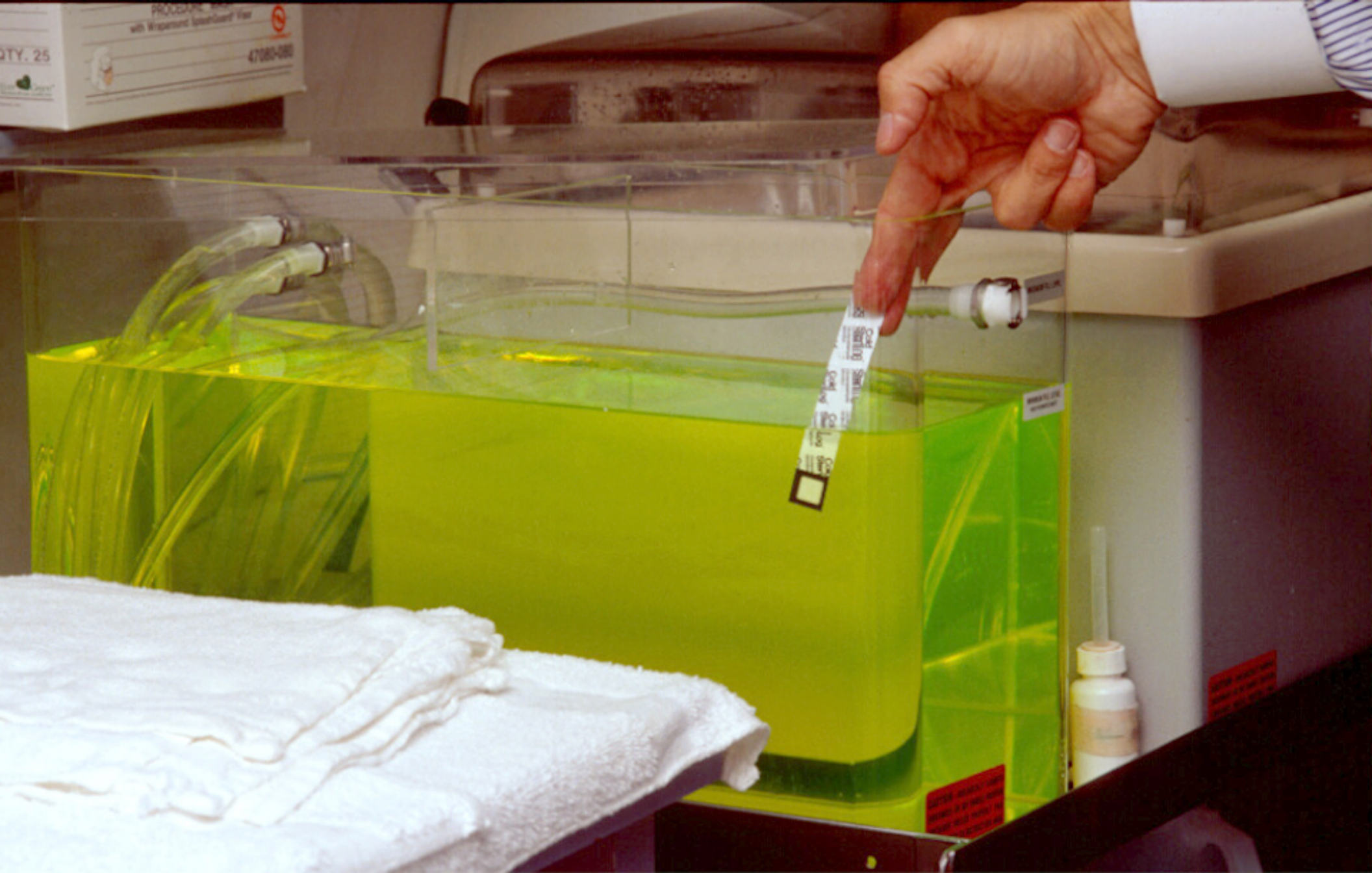
Prepared by: REPROCESSING GUIDELINE TASK FORCE

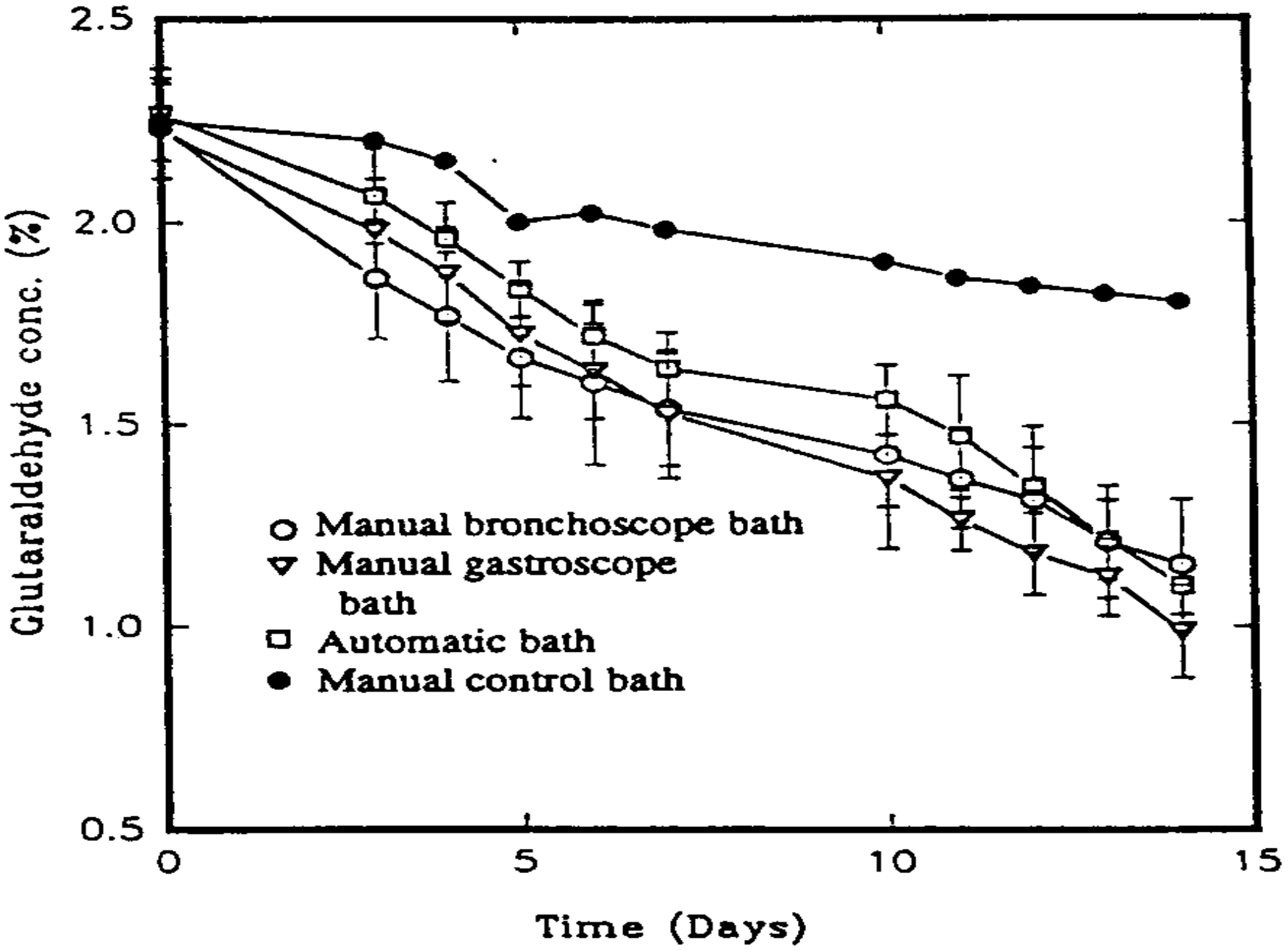
Bret T. Petersen, MD, FASGE, Chair, Jonathan Cohen, MD, FASGE, Ralph David Hambrick, III, RN, Navtej Buttar, MD, David A. Greenwald, MD, FASGE, Jonathan M. Buscaglia, MD, FASGE, James Collins, RN, Glenn Eisen, MD, MPH, FASGE

This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

Endoscope Outbreak Reporting (CBIC)

- Infection Control
- Physician responsible for care of patient
- Appropriate public health agency (FDA, CDC)
- And the manufacturer of the endoscope, disinfectant and AER

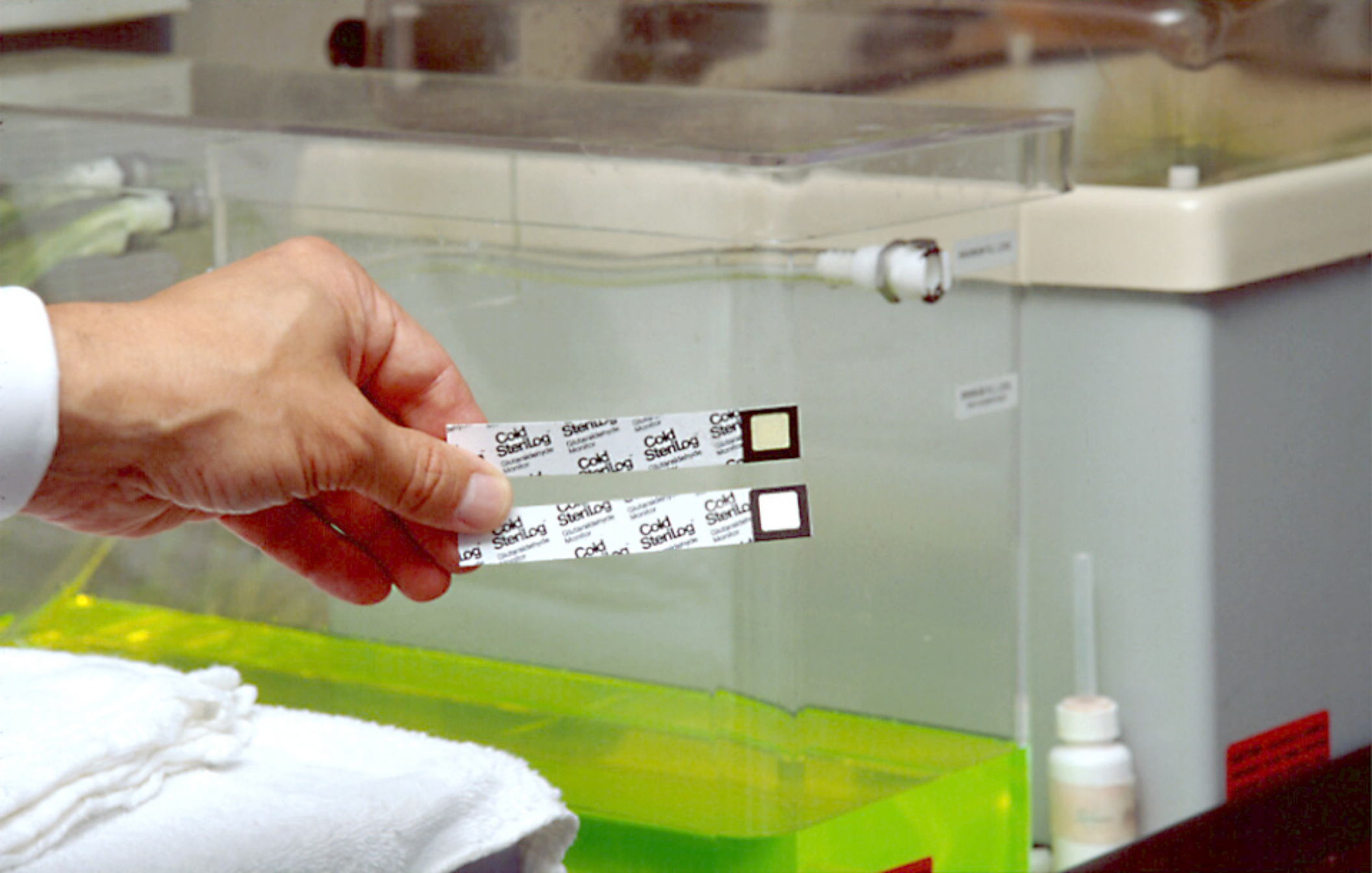



2.5
2.0
1.5
1.0
0.5
Glutaraldehyde conc. (%)
0
5
10
15
Time (Days)
Manual bronchoscope bath
Manual gastroscope bath
Automatic bath
Manual control bath

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
- 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)
- Record results


Cold SteriLog
Cold SteriLog
Cold SteriLog
Cold SteriLog


Check Sheet Log Sheet

Health Care Facilities Need to Immediately Medical Device Reprocessing Procedures

- Reprocessing lapses resulting in patient infections and exposures
- Healthcare facilities urged to immediately review current reprocessing practices to ensure comply with device manufacturer and guidelines (CBIC)
  - Training (upon hire and at least annually), demonstrate and document competency
  - Audit should assess all reprocessing steps including cleaning, disinfectants (conc, contact time), sterilizer (chemical, biological indicators). Feedback from audits to personnel regarding adherence.

Endocavitary Probes

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. CBIC-HLD even though probe cover

Endocavitary Probe Covers

Rutala, Weber. AJIC 2016:44;e53-e62

- 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)

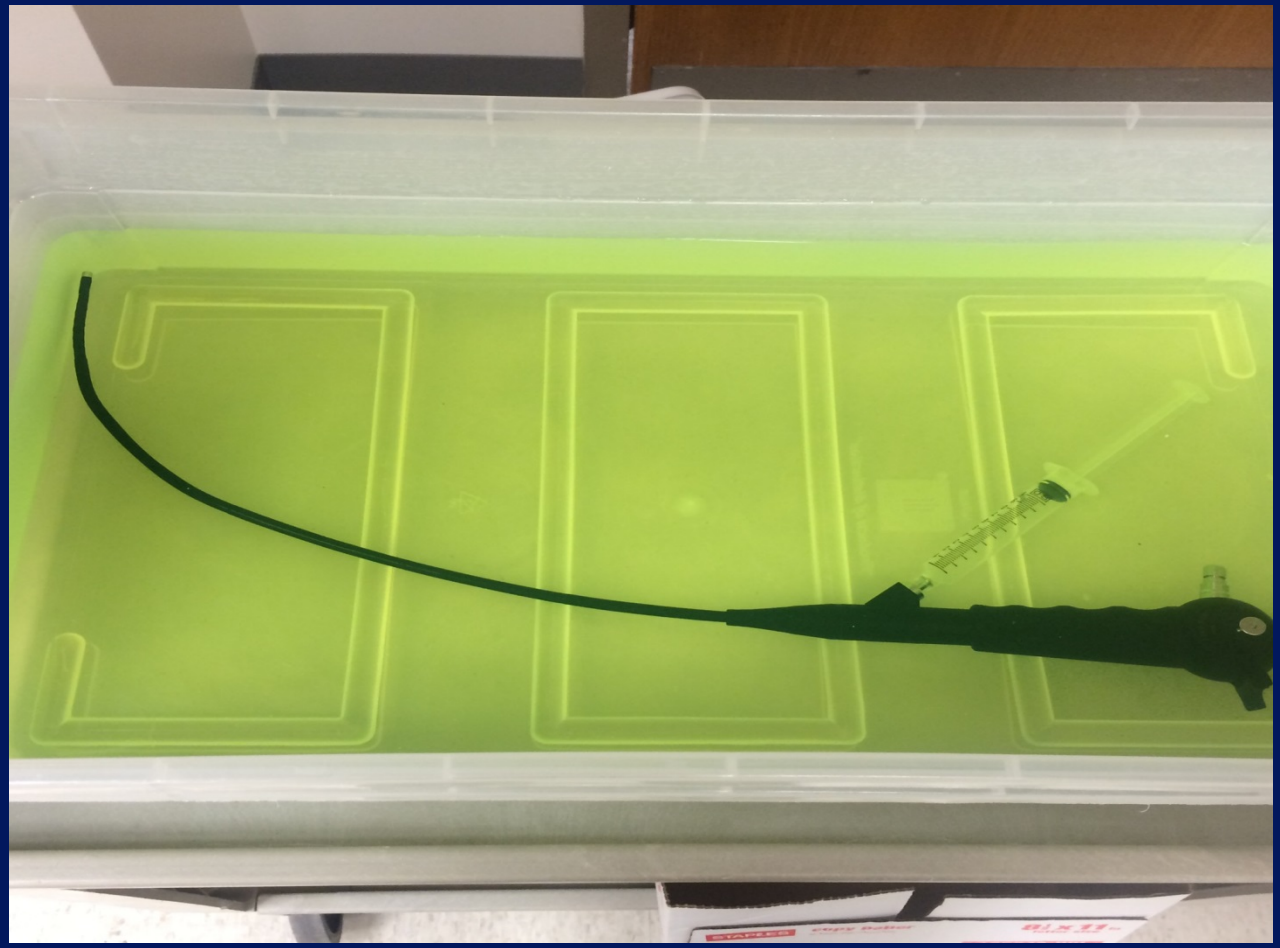
Storage of Semicritical Items

Rutala, Weber, SHEA Handbook, 2016. In press

- In 2011, TJC recommended that laryngoscope blades be packaged in a way that prevent recontamination
- Examples of compliant storage include, but not limited to, a peel pouch or a closed plastic bag
- Examples of non-compliant storage would include unwrapped blades in an anesthesia drawer as well as unwrapped blades on top of or within a code cart
- Packaging not only prevents recontamination but also distinguishes a processed from non-processed semicritical item such as a specula, endoscope, etc
- The use of a tagging system that separates processed from non-processed items minimizes the use of a semicritical item that has not been reprocessed, and minimizes unnecessary patient exposures and risk of disease transmission

Reprocessing Channeled Endoscopes

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe filled and emptied until no air exits the scope nor air in barrel of syringe-syringe and lumen filled with HLD)



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


TYPE 8551
7 MHz

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


RUSCH
Mac. 2/s
RUSCH


RUSCH
RUSCH
Mac. 2

Reprocessing of Rigid Laryngoscopes

JHI 2008, 68:101; ICHE 2007, 28:504; AJIC 2007, 35: 536

- Limited guidelines for reprocessing laryngoscope's blades and handles
- 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 blood/OPIM suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCHC-blades wrapped in a tray-Sterrad; handle wrapped in tray [without batteries]-steam); the blades and handles placed together in a Ziploc bag. Blades and handles checked for function prior to packaging.

Contamination of Laryngoscope Handles

Rutala, Weber. AJIC 2016:44;e53-e62

J Hosp Infect 2010;74:123

- 55/64 (86%) of the handles deemed “ready for patient use” positive for *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.

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^{o}C for 0 minutes rather than the intended 4 minutes. A central processing technician turned the timer to 0 minutes in error.

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

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

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

CBIC-Asepsis

- Aseptic techniques is defined as:
  1. No touch techniques
  2. A process used in the operating room
  3. An absence of organisms
  4. The process for keeping away disease producing organisms

Antisepsis

Antiseptic Agents

(used alone or in combination)

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

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

Antiseptics

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

Summary of Best Antiseptics

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

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

THANK YOU!

www.disinfectionandsterilization.org