Issues and Controversies in Instrument Reprocessing

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Disclosure

This presentation reflects the techniques, approaches and opinions of the individual presenter. This Advanced Sterilization Products ("ASP") sponsored presentation is not intended to be used as a training guide. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for use of the device(s).

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Issues and Controversies in Instrument Reprocessing

- Overview of instrument reprocessing of critical, semicritical and noncritical patient care equipment
- Issues and Controversies
  - Sterilization of critical items -how to monitor cleaning and Immediate-use steam sterilization
  - High-level disinfection of semicritical items -endoscopes, laryngoscopes, endocavitary probe, prostate biopsy probes, tonometers

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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 .

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, gas, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, ozone or chemical sterilization.

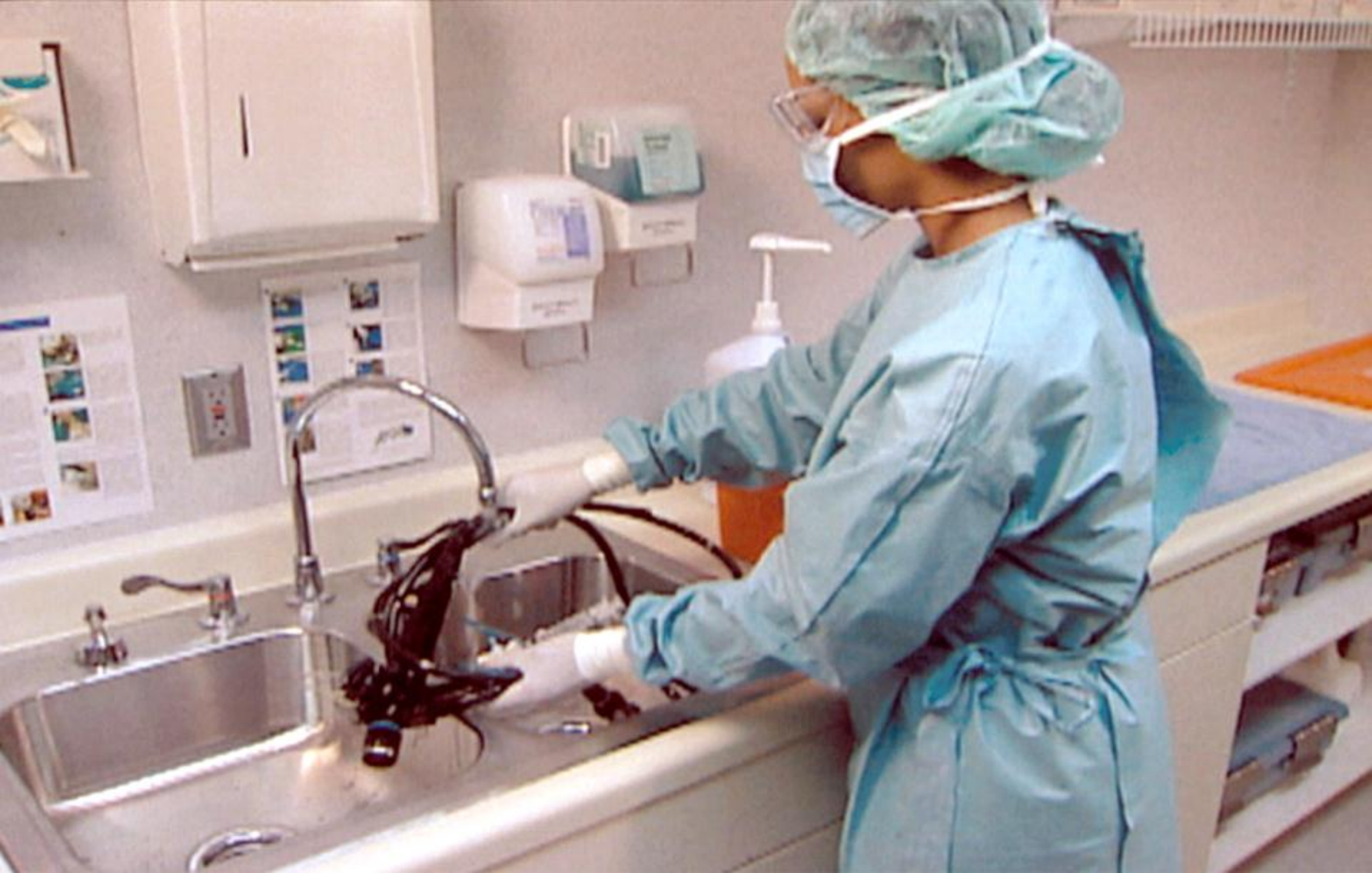
Sterilization of “Critical Objects”

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Vaporized hydrogen peroxide



Processing "Semicritical" Patient Care Objects

Classification:	Semicritical objects come in contact with mucous membranes or skin that is not intact.
Object:	Free of all microorganisms except high numbers of bacterial spores.
Level germicidal action:	Kills all microorganisms except high numbers of bacterial spores
Examples:	Respiratory therapy and anesthesia equipment, GI endoscopes, endocavitary probes, etc.
Method:	High-level disinfection

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

Blood Pressure Cuff
Non-Critical Patient Care Item

Processing "Noncritical" Patient Care Objects

Classification:	Noncritical objects will come in contact with intact skin.
Object:	Can be expected to be contaminated with some microorganisms.
Level germicidal action:	Kill vegetative bacteria, fungi and lipid viruses.
Examples:	Bedpans; crutches; bed rails; EKG leads; bedside tables; walls, floors and furniture.
Method:	Low-level disinfection (or detergent for housekeeping surfaces)

Low-Level Disinfection for "Noncritical" Objects

Exposure time ≥ 1 min

Germicide	Use Concentration
Ethyl or isopropyl alcohol	70-90%
Chlorine	100ppm (1:500 dilution)
Phenolic	UD
Iodophor	UD
Quaternary ammonium	UD
Improved hydrogen peroxide	0.5%-1.4%

UD=Manufacturer's recommended use dilution

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Cleaning Critical Items Issues

No standard to define when a device is clean


STERILIZATION CASE

Cleaning

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

Cleaning

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

Washer/disinfectors are very effective (>5 $\log_{10}$ reduction) in removing/inactivating microorganisms from instruments

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 ($6\mu g/cm^2$); 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}

Immediate Use Steam Sterilization Issues

Over-used…intended for immediate use only

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" 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

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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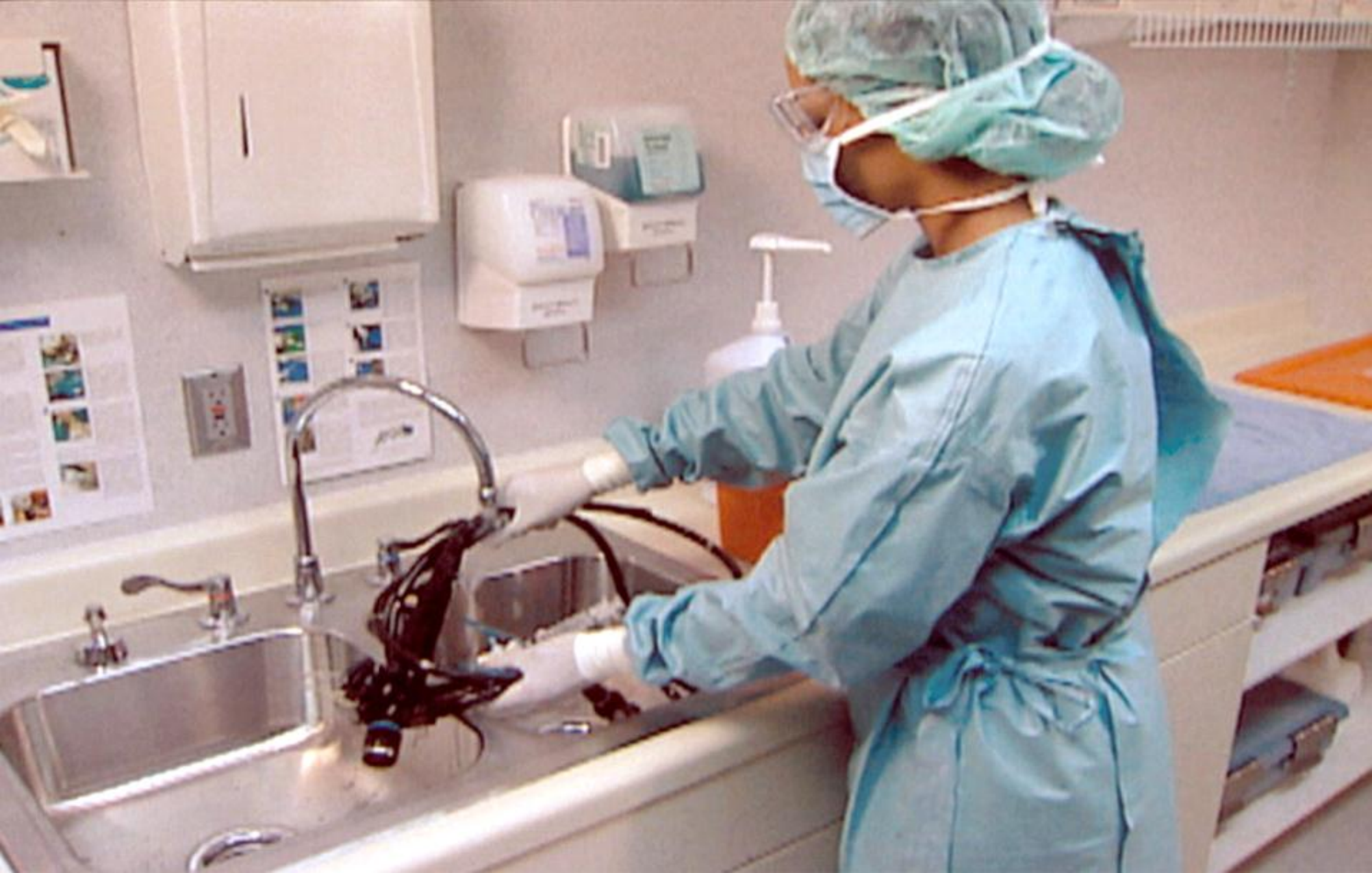
Semicritical Equipment

- Reprocessing semicritical items has been shown to have a narrow margin of safety
- Generally, the narrow margin of safety attributed to high microbial load and complex instruments with lumens
- Any deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection
- Problems encountered with reprocessing semicritical equipment often related to improper cleaning



Endoscopes
Issues

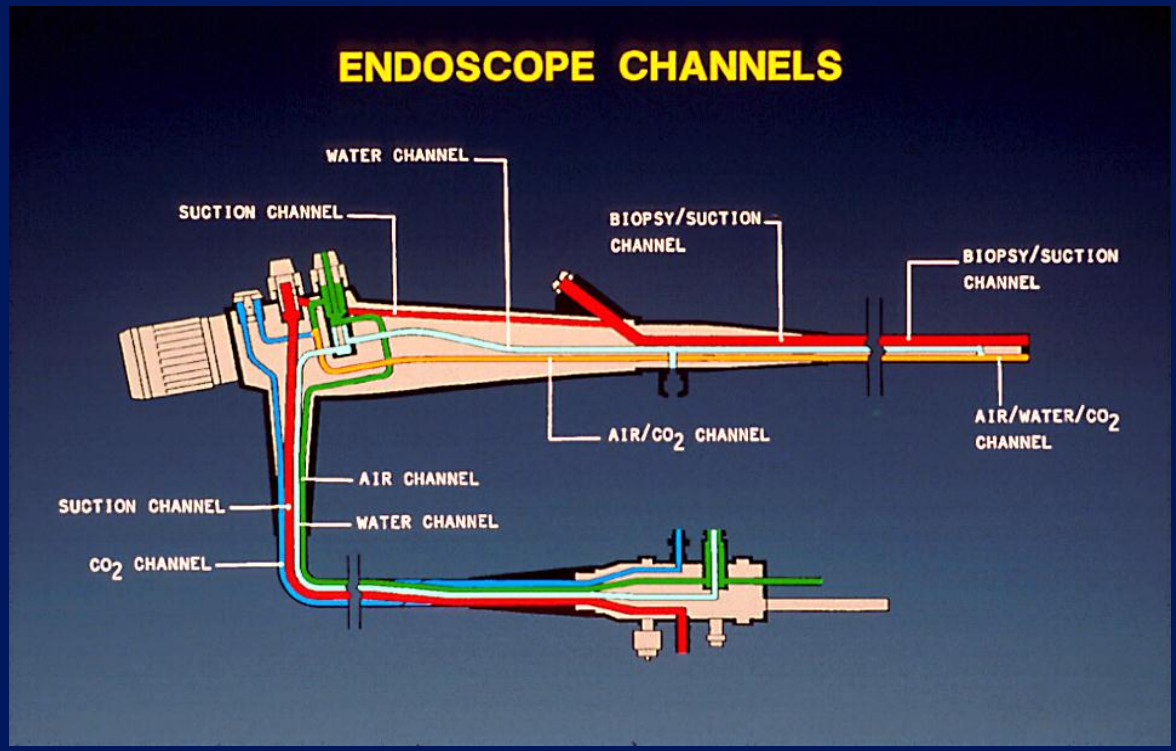
Lapses in endoscope reprocessing, unsafe injection practices and unresolved issues

GI ENDOSCOPES AND BRONCHOSCOPES

- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI 10^9 in/10^5 out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- In the inanimate environment, although the incidence remains very low, endoscopes represent a risk of disease transmission

FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

- Require low temperature disinfection
- Long narrow lumens
- Right angle turns
- Blind lumens
- May be heavily contaminated with pathogens
- Use of AERs has led to a new set of problems



MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2011

Petersen et al. ICHE. 2011;32:527

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JUNE 2011, VOL. 32, NO. 6

ASGE-SHEA GUIDELINE

Multisociety Guideline on Reprocessing Flexible GI Endoscopes: 2011

Bret T. Petersen, MD, FASGE; Jennifer Chennat, MD; Jonathan Cohen, MD, FASGE; Peter B. Cotton, MD, FASGE; David A. Greenwald, MD, FASGE; Thomas E. Kowalski, MD; Mary L. Krinsky, DO; Walter G. Park, MD; Irving M. Pike, MD, FASGE; Joseph Romagnuolo, MD, FASGE; for the ASGE Quality Assurance in Endoscopy Committee; and William A. Rutala, PhD, MPH; for the Society for Healthcare Epidemiology of America

The beneficial role of GI endoscopy for the prevention, diagnosis, and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires reprocessing before being used on subsequent patients. The most commonly used methods for reprocessing endoscopes result in high-level disinfection. To date, all published occurrences of pathogen transmission related to GI endoscopy have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Despite the strong published data regarding the safety of endoscope reprocessing, concern over the potential spread gaps in infection prevention practices.[10] Given the ongoing occurrences of endoscopy-associated infections attributed to lapses in infection prevention, an update of the multisociety guideline is warranted.

This document provides an update of the previous guideline, with additional discussion of new or evolving reprocessing issues and updated literature citations, where appropriate. Specific additions or changes include review of expanded details related to critical reprocessing steps (including cleaning and drying), reprocessing issues for various endoscope attachments such as flushing catheters, discussion of risks related to selected periprocedural practices including

ENDOSCOPE REPROCESSING

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
- 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

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Since 2003, changes in
  - High-level disinfectants
  - Automated endoscope reprocessors
  - Endoscopes
  - Endoscopic accessories
- However, efficacy of decontamination and high-level disinfection is unchanged and the principles guiding both remain valid
- Additional outbreaks of infection related to suboptimal infection prevention practices during endoscopy or lapses in endoscope reprocessing (unfamiliarity with endoscope channels, accessories, attachments; gaps in infection prevention at ASC) as well as unsafe injection practices

Endoscope Reprocessing, Worldwide

- Worldwide, endoscopy reprocessing varies greatly
  - **India, of 133 endoscopy centers, only 1/3 performed even a minimum disinfection (1% glut for 2 min)**
  - **Brazil, "a high standard …occur only exceptionally"**
  - **Western Europe, ≥30% did not adequately disinfect**
  - **Japan, found "exceedingly poor" disinfection protocols**
  - **US, 25% of endoscopes revealed >100,000 bacteria**

Schembre DB. Gastroint Endoscopy 2000;10:215

TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
  - **>300 infections transmitted**
  - **70% agents *Salmonella sp.* and *P. aeruginosa***
  - **Clinical spectrum ranged from colonization to death (~4%)**
- **Bronchoscopy**
  - **90 infections transmitted**
  - ***M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa***

Spach DH et al Ann Intern Med 1993: 118:117-128 and Weber DJ, Rutala WA Gastroint Dis 2002;87

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Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Transmission categorized as:
  - Non-endoscopic and related to care of intravenous lines and administration of anesthesia or other medications
    - Multidose vials
    - Reuse of needles and syringes
    - Intravenous sedation tubing
  - Endoscopic and related to endoscope and accessories
    - Failure to sterilize biopsy forceps between patients
    - Lapses in reprocessing tubing used in channel irrigation

HCV from Unsafe Injection Practices at an Endoscopy Clinic in Las Vegas, 2007-2008

Fischer et al. Clin Infect Dis. 2010;51; 267

- Background-in January 2008, 3 persons with acute HCV underwent endoscopy at a single facility in Nevada.
- Method-reviewed clinical and laboratory data
- Results- 5 additional cases of HCV were identified and quasispecies analysis identified two clusters. 7/38 (17%) who followed source patient were HCV infected. Reuse of syringes on single patients with use of single-use propofol vials for multiple patients was observed.
- Conclusion- patient-to-patient transmission of HCV resulted from contamination of single-use medication vials that were used for multiple patients during anesthesia administration. The resulting notification of >50,000 persons was the largest of its kind in US health care.

SAFE INJECTION PRACTICES

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Unresolved Issues
  - Interval of storage after which endoscopes should be reprocessed before use
    - Data suggest that contamination during storage for intervals of 7-14 days is negligible, unassociated with duration, occurs on exterior of instruments and involves only common skin organisms
    - Data are insufficient to proffer a maximal outer duration for use of appropriately cleaned, reprocessed, dried and stored endoscopes
    - Without full data reprocessing within this interval may be advisable for certain situations (endoscope entry to otherwise sterile regions such as biliary tree, pancreas)

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RUSCH
Msc. 2/s
RUSCH

Laryngoscope Issue

High-level disinfect blades and handles


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

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.

ASP STERRAD® Chemical Indicator Strip
REF 14100
Use in STERRAD® Sterilizer only.
Bar changes from red to yellow (or lighter) as compared to the color bar when exposed to H_2O_2 during processing in the STERRAD® Sterilizer.
LC-14100-004 Rev. A

3M Comply™ SteriGage™.
Class 5 Steam
BIER Chemical
1243 Integrator
DARK BAR MUST PASS THIS POINT
REJECT ACCEPT STEAM


ADULT
LARYNGOSCOPE SET
DO NOT DISCARD REUSABLE
PLACE ALL CONTENTS OF BAG
IN GREEN TUBS IN DIRTY
UTILITY ROOM

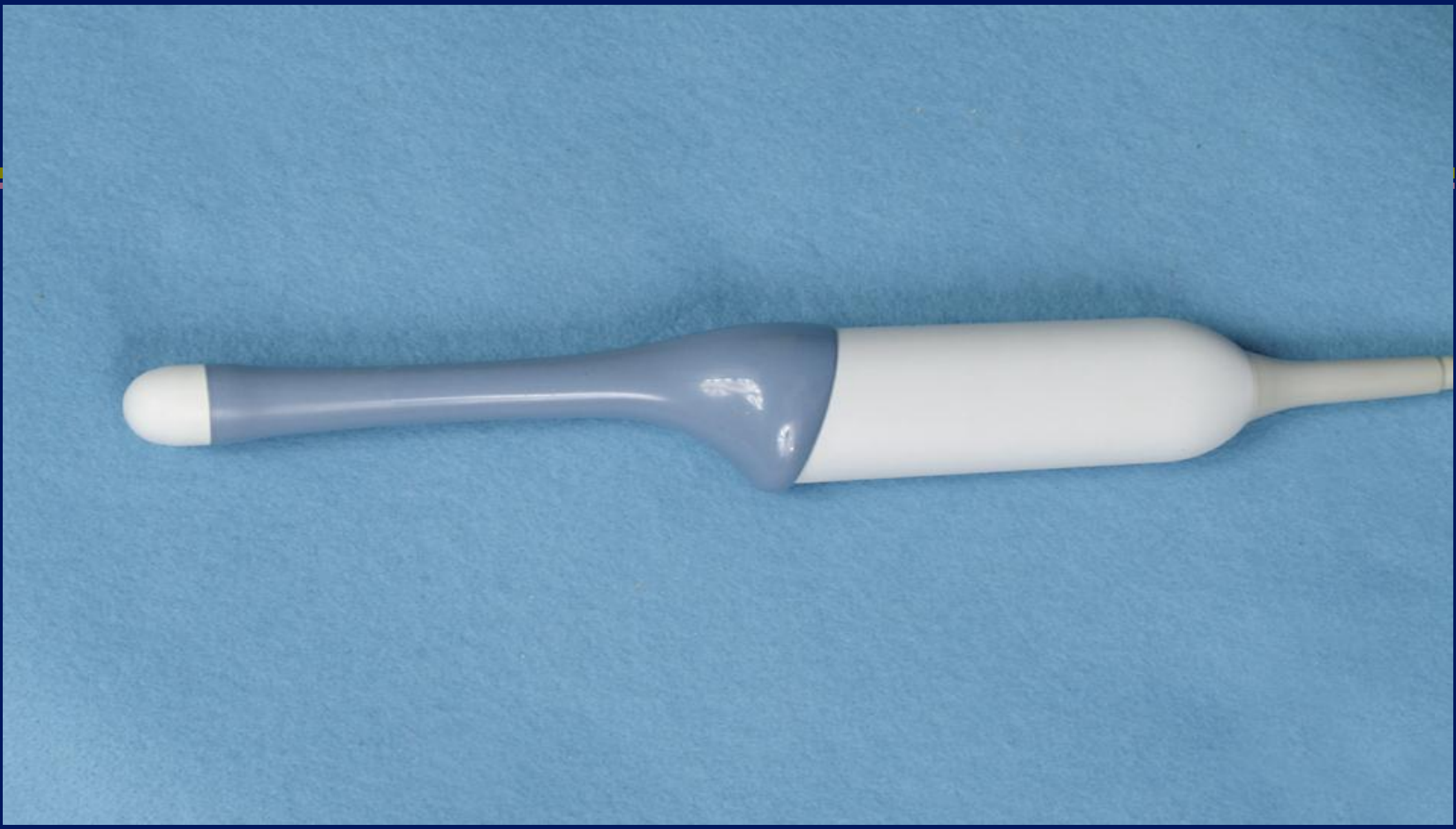
Laryngoscopes Blades

The Joint Commission, FAQ, October 24, 2011

- How should we process and store laryngoscope blades?
  - **Processed via sterilization or HLD**
  - **Packaged in some way**
  - **Stored in a way that prevents recontamination. Examples of compliant storage include, but are not limited to, a peel pack post steam sterilization (long-term) or wrapping in a sterile towel (short term)**
  - **Should not place unwrapped blades in an anesthesia drawer**

Endocavitary Probes Issue

Clean and high-level disinfect even if sheath, cover or condom used



Endocavitary Probes

- 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

Endocavitary Probe Covers

- Sterile transvaginal probe covers had a very high rate pf 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)

Prostate Biopsy Probes Issue

Clean and high-level disinfect ; needle-guide disassembled from the transducer assembly

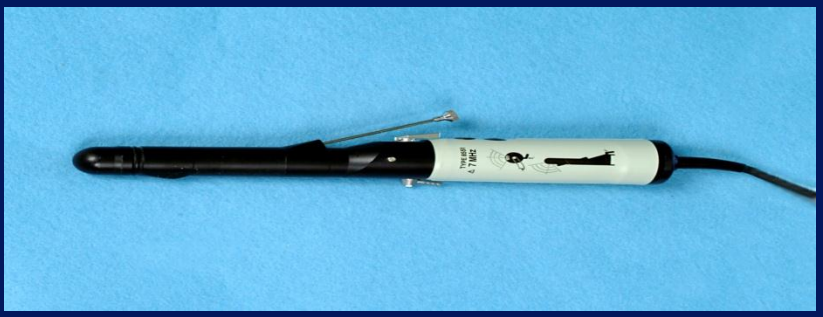
Prostate Biopsy Probe

- 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


TYPE 8551
7 MHz

Disinfection of Prostate Probe

Rutala, Gergen, Weber. ICHE. 2007;28:916



Needle guide must be removed from the probe for disinfection

TABLE 1. Effectiveness of Glutaraldehyde Disinfection of Various Components of a Probe Used in Ultrasound-Guided Prostate Biopsy

Inoculation site and status	Experiment set	Size of *P. aeruginosa* inoculum, cfu	No. of positive results/no. of experiments	*P. aeruginosa* yield on culture, mean cfu
Internal lumen of needle guide in probe	A	1.56×10^7	0/5	No growth
Outside surface of needle guide in probe	B	1.21×10^7	6/6	1.2×10^6
Internal lumen of probe				
Needle guide not removed from probe	C	1.69×10^7	6/6	2.82×10^6
Needle guide removed from probe	D	1.81×10^7	0/5	No growth
Inside and outside of needle guide removed from the probe	E	1.81×10^7	0/5	No growth

NOTE. CFU, colony forming units; *P. aeruginosa*, *Pseudomonas aeruginosa*.

Disinfection of Prostate Probe

Rutala, Gergen, Weber. ICHE; 2007;28:916

TABLE 2. Recommendations for Reprocessing Probes Used in Transrectal Ultrasound–Guided Prostate Biopsy

- Cleaning
  - Clean immediately after use
  - Disassemble the transducer (ie, remove needle guide from the probe)
  - Brush clean (if possible) or flush each lumen and thoroughly clean all surfaces of reusable components with enzymatic or nonenzymatic detergent
  - Rinse with tap water
  - Dry with disposable cloth and/or towel or air dry
  - Perform visual inspection to ensure the device is clean
- High-level disinfection or sterilization
  - Steam sterilize all heat stable reusable components
  - Alternatively, perform high-level disinfection of the probe and the needle guide separately following disassembly
  - Perform high-level disinfection for all heat-sensitive components to ensure that the disinfectant reaches all areas inside the lumens and that the minimum effective concentration of the high-level disinfectant is used
  - Rinse with sterile water, filtered water, or tap water (the US Food and Drug Administration specifies use of sterile water for rinsing)
  - If filtered water or tap water is used, follow with an alcohol rinse (not immersion of the probe in alcohol) to enhance drying and ensure that no residual water is left for microbial growth
  - Dry
  - Store appropriately to ensure the device is not recontaminated

NOTE. Users should be familiar with the manufacturer's recommendations for use and disinfection of the specific device used by the facility.

Applanation Tonometer Issue

Clean and high-level disinfect using disinfectant active against adenovirus


120
180

Adenovirus 8

A Common Cause of Epidemic Keratoconjunctivitis

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.

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

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)

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

CDC Guidelines

- 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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Summary

D/S guidelines must be followed to prevent exposure to pathogens that may lead to infection

THANK YOU!

www.disinfectionandsterilization.org