Reprocessing Semicritical Items:
Outbreaks and New Developments

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DISCLOSURES

2017-2018

- Consultations
  - ASP (Advanced Sterilization Products), PDI
- Honoraria
  - PDI, Kennall
- Scientific Advisory Board
  - Kinnos
- Grants
  - CDC, CMS

www.disinfectionandsterilization.org

Reprocessing Semicritical Items

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- Outbreaks/Failures
- New Developments
  - Endoscopes (other channeled scopes)
  - Laryngoscopes
  - Endocavitary probe
  - Prostate biopsy probes

Sources of Healthcare-Associated Pathogens

Weinstein RA. Am J Med 1991:91 (suppl 3B):179S

- Endogenous flora (SSI, UTI, CLABSI): 40-60%
- Exogenous: 20-40% (e.g., cross-infection via contaminated hands [staff, visitors])
- Other (environment): 20%
  - Medical devices
  - Contact with environmental surfaces (direct and indirect contact)

DISINFECTION AND STERILIZATION

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

- 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 except for high numbers of bacterial spores
  - NONCRITICAL - objects that touch only intact skin require low-level disinfection

High-Level Disinfection of "Semicritical Objects"

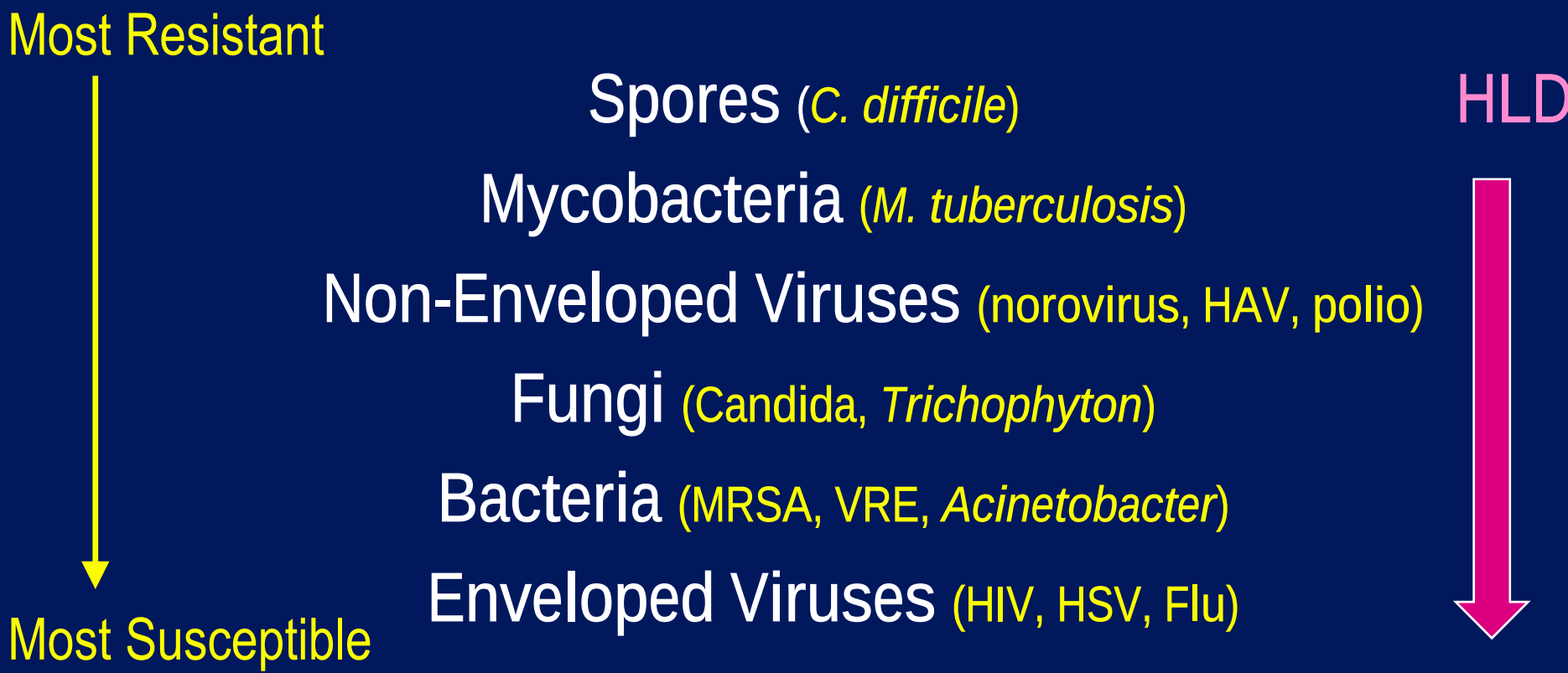
Exposure Time ≥ 8m-45m (US), 20°C

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

Microbiological Disinfectant Hierarchy

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



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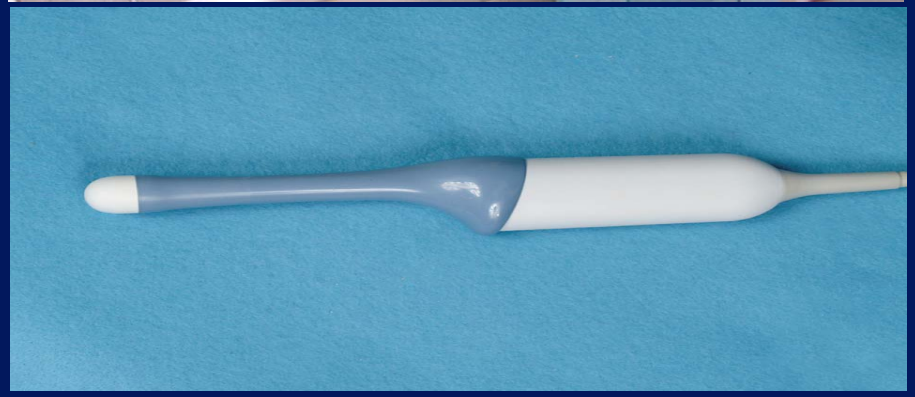
Semicritical Medical Devices

Rutala et al. AJIC 2016;44:e47



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

Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC, In preparation

Medical Device	No. Outbreaks/Infections	No. Outbreaks/Infections with Bloodborne Pathogens
Vaginal Probes	0	0
Ear-Nose-Throat Endoscopes	0	0
Cystoscopes	5	0
Hysteroscopes	0	0
Laryngoscopes	1	0
Ureteroscopes	1	0
Prostate Probes	3	0
TEE-Transesophageal echocardiogram	3	0
GI Endoscopes/Bronchoscopes	~130	4 (HBV-1 GI; HCV-3 GI; HIV-0)

Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber, AJIC, In preparation

- HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare
- Four reports related to breaches involved in GI endoscope reprocessing
- 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, complexity, and possible biofilm.
- Other semicritical medical devices are rarely associated with infections related to inadequate reprocessing

Reprocessing Semicritical Medical Devices

- Failures
  - Use Quat/Alcohol wipe rather than HLD (ENT, vaginal probes)
  - Do not monitor concentration of HLD (or done randomly)
  - Staff did not flush and brush all channels
  - Channels not perfused with HLD (cystoscopes)
  - Time and/or temperature on AER was wrong

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 www.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

Health Care Facilities Need to Immediately Medical Device Reprocessing Procedures

Train Staff, Audit Adherence to Steps, Provide Feedback on Adherence

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
September 11, 2015, 12:15 EDT (12:15 PM EDT)
CDCHAN-00382

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

Summary

The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety. Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.

Background

Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These events involved failures to follow manufacturers' reprocessing instructions for critical[1] and semi-critical[2] items and highlight the need for healthcare facilities to review policies and procedures that protect patients.

Recommendations

Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures. This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer. The following actions should be performed:

Training

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
  - 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.

High Level Disinfection (HLD) Certificate Class

Class size is limited to 24 students

When: Tuesday, July 7, 2015
9am – noon

Where: On Campus
MacNider 18
Chapel Hill

At this class you will:

- Learn how to high-level disinfect semi-critical devices
- Understand your responsibilities related to HLD
- Learn the pitfalls of inadequate high-level disinfection
- Learn about OSHA regulations related to high level disinfectants
- *Earn 3 nursing contact hours!*

Faculty:
Judie Bringhurst, MSN, RN, CIC

Registration:
By email **ONLY** please. Email your **name**, your **clinic** name, and your **phone number** to Judie Bringhurst, Hospital Epidemiology: jbringhu@unch.unc.edu You will receive confirmation of your registration by return email.

Parking:
Staff without on-campus parking assignments may want to park in the visitor's parking deck on Manning Drive.

Reprocessing Semicritical Items

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Rutala, Weber, AJIC, In preparation

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The Joint Commission surveyors have been checking on several high visibility items

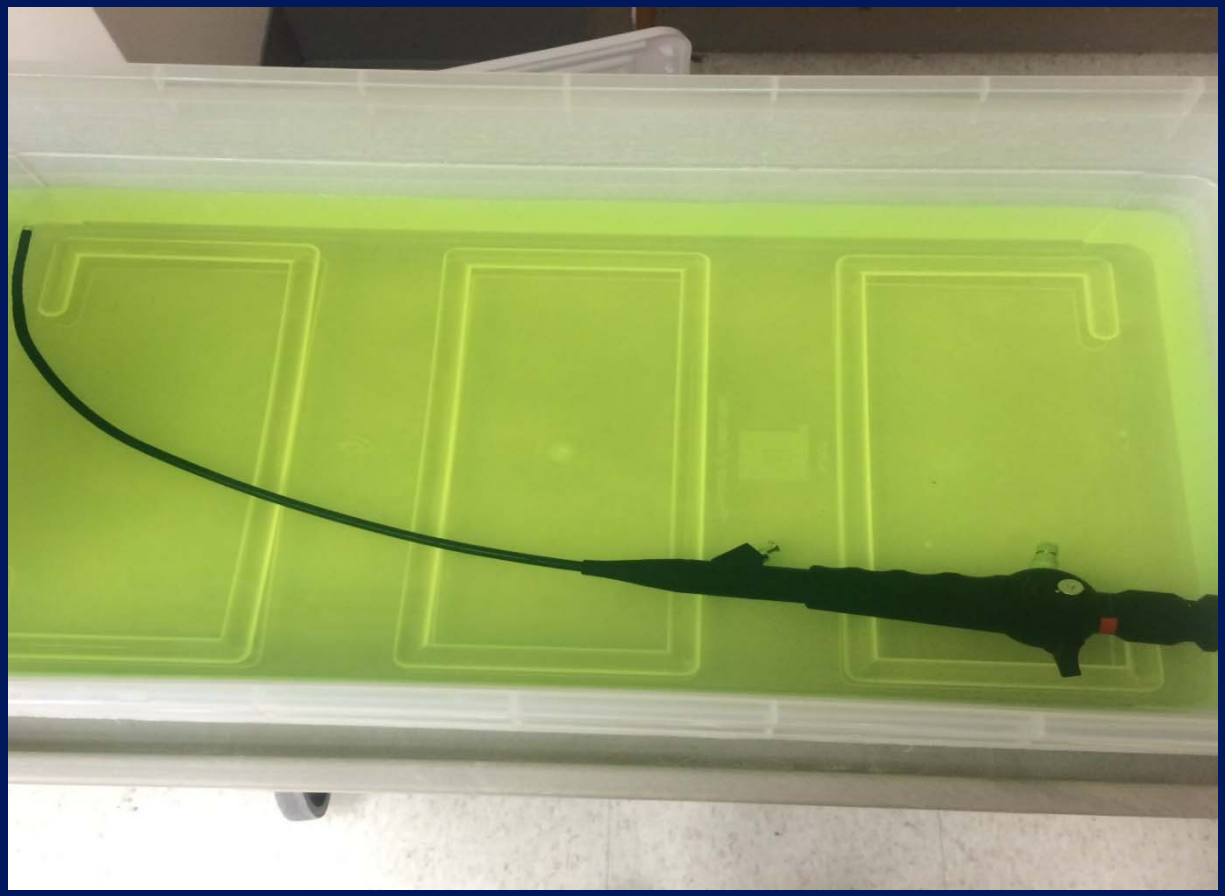
Reprocessing channeled endoscopes (GI, bronchoscopes, others)

Reprocessing Channeled Endoscopes

Cystoscopes, Ureteroscopes, Hysteroscopes

Reprocessing Channeled Endoscopes

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



Reprocessing Channeled Endoscopes

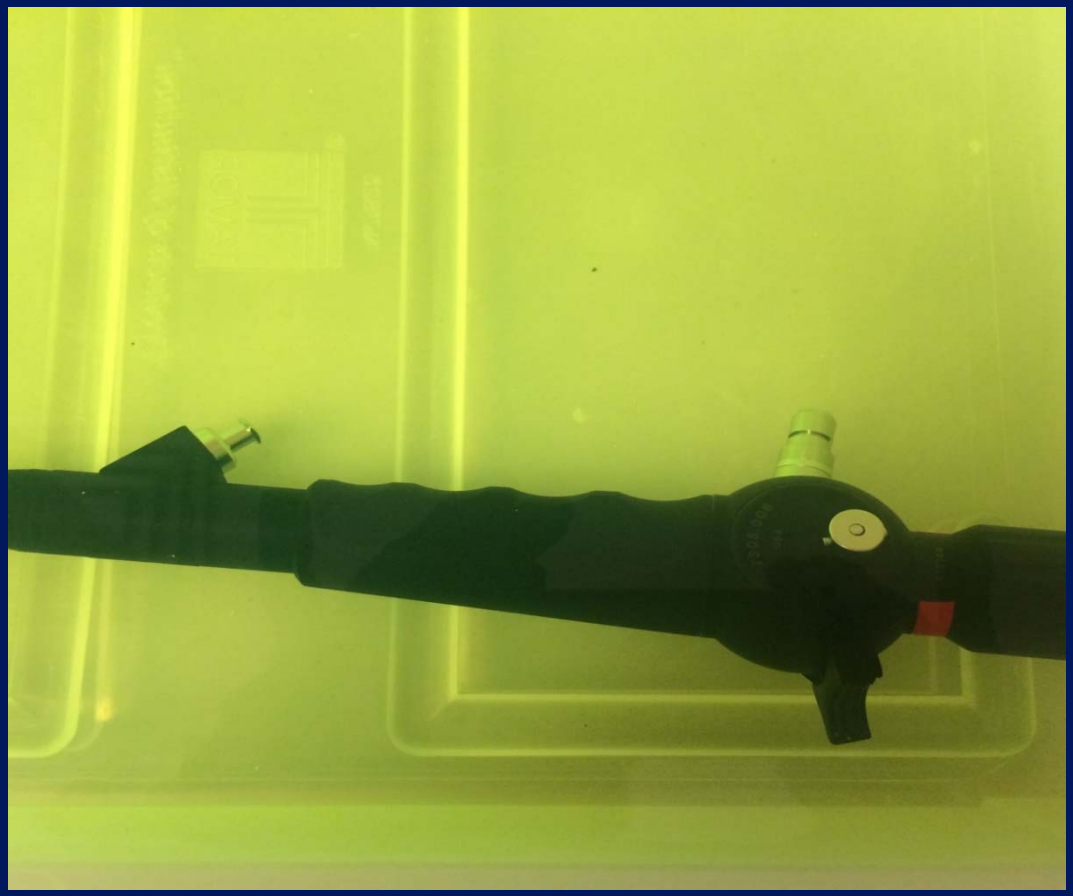
Rutala, Gergen, Bringhurst, Weber. ICHE. 2016;37:228-231

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

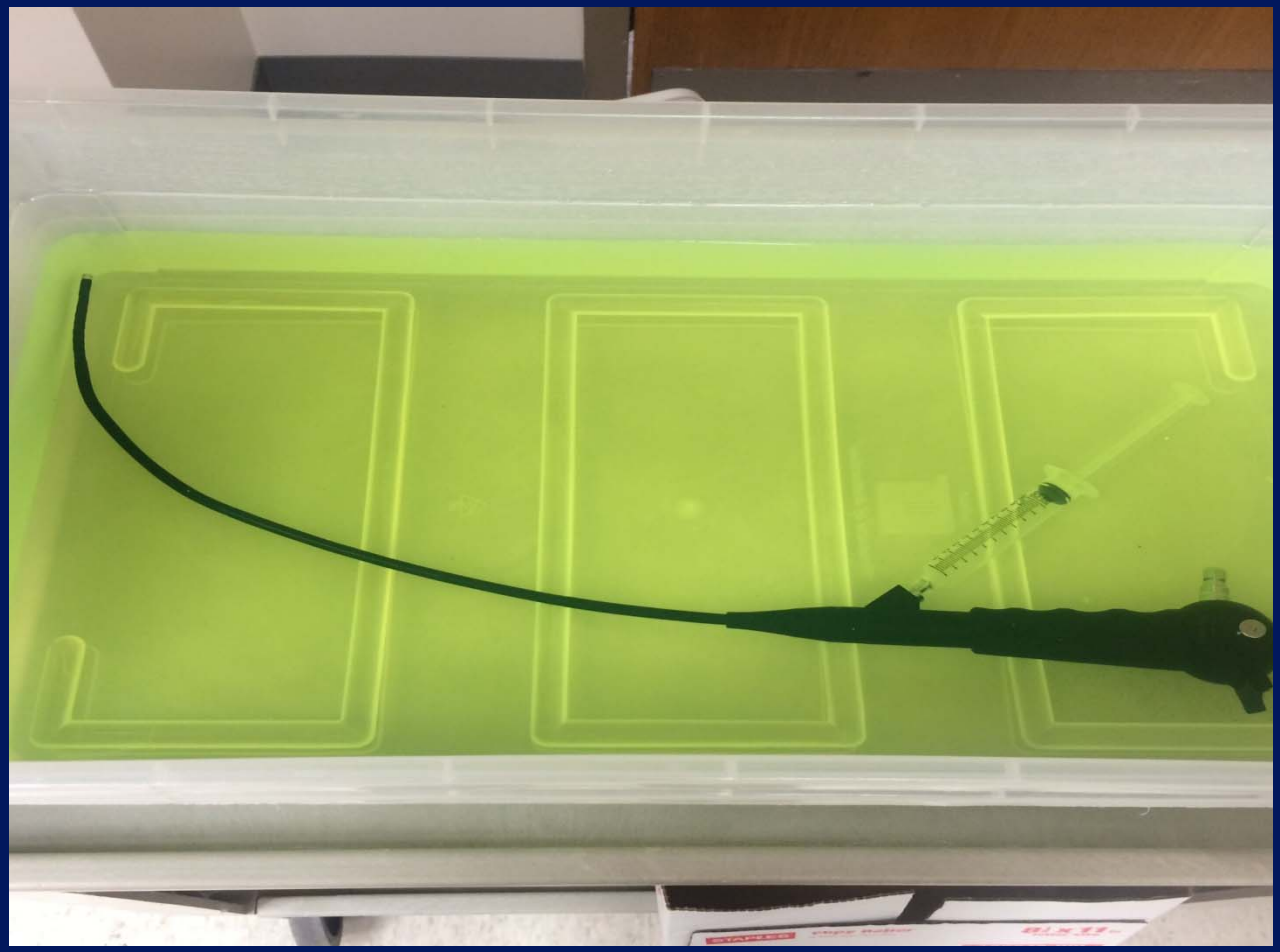
Reprocessing Channeled Endoscopes

Cystoscope-air pressure in channel stronger than fluid pressure at fluid-air interface



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 Instruments

Cadnum et al, SHEA 2017 Poster

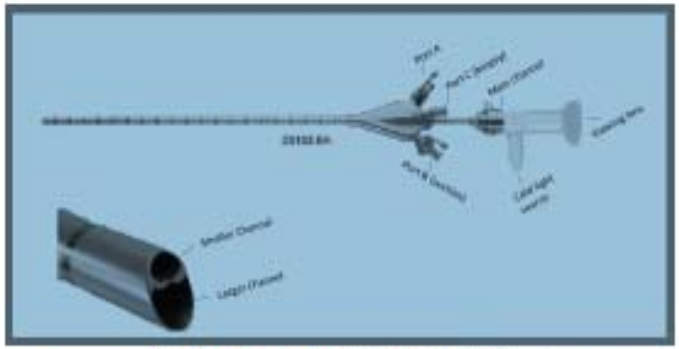


Figure 2. Hysteroscope Diagram

Table 1. Recovery of *E.coli* from hysteroscope lumens after OPA soak with passive filling

Conditions:	Control Hysteroscope log_{10} CFU/mL	Test Hysteroscope log_{10} CFU/mL
Valves disassembled: 12 min OPA soak (N=4)		
Main Channel (5mm)	5.0-7.0	0
Side Port A(≤1.5mm)	5.0-7.0	3.5
Side Port B (≤1.5mm)	5.0-7.0	3.8
Side Port C (≤1.5mm)	5.0-7.0	3.8
Without disassembly of valves: 4 hour OPA soak (N=1)		
All Lumens	5.0-7.0	4.2

- For the hysteroscope, a 12m soak in OPA eliminated >6 log_{10} CFU of the test organisms from the larger central channel (~3.5mm)
- A 12 minute or 4 hour soak did not completely eliminate contamination from the 1.5mm channel
- Narrow channels limit full exposure to the disinfectant (air pressure stronger than fluid pressure)

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Disposable vs Reusable Laryngoscopes

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


RUSCH
Mac: 2/s
RUSCH


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Mac 2 Fo

Reprocessing of Rigid Laryngoscopes

JHI 2008, 68:101; ICHE 2007, 28:504; AJIC 2007, 35: 536; AJIC 2013,41:S60

- Limited guidelines for reprocessing laryngoscope's blades and handles
- For years, many hospitals consider blade as semicritical (HLD) and handle as noncritical (LLD)
- Blades linked to HAIs; handles not directly linked to HAIs but contamination with blood/OPIM suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCH-blades and handles sterilized).

Contamination of Laryngoscope Handles

Rutala, Weber. AJIC 2013. 41:S60-S66; 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.

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Endocavitary Probes

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

- Probes-Transesophageal echocardiography probes, vaginal/rectal probes used in sonographic scanning
- Probes with contact with mucous membranes are semicritical
- Guideline recommends that a new condom/probe cover should be used to cover the probe for each patient and since covers may fail (1-80%), HLD (semicritical probes) should be performed

Endocavitary Probe Covers

Rutala, Weber. AJIC 2013. 41:S60-S66; Rutala, Weber. AJIC 2016.44:e53-e62

- 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)

Hydrogen Peroxide Mist
(uses HP mist to achieve HLD in 7m)

Effectiveness of HP Mist System in Inactivating Healthcare Pathogens on Probes

Rutala, Gergen, Sickbert-Bennett. ICHE 2016;37:613-614

TABLE 1. Proportion of Surface and Endocavitary Probes Positive After System Processing According to the Presence or Absence of an Organic Challenge*

5% Fetal Calf Serum-FCS	Probes with vancomycin-Resistant *Enterococcus* (VRE), No./Total	Probes with CR *Klebsiella pneumoniae*, No./Total	Probes with *Mycobacterium terrae*, No./Total (mean $\log_{10}$ reduction and 95% CI)	Probes with *Clostridium difficile* spores, No./Total (mean $\log_{10}$ reductions and 95% CI)
Present	0/7	0/6	4/9 (5.19 [4.61–5.76])	3/6 (5.12 [4.42–5.83])
Absent	0/6	0/6	1/6 (4.62 [4.07–5.17])	1/9 (6.23 [6.02–6.43])

- Automated, closed system that uses HP mist for HLD of ultrasound probes
- >10^6 pathogens inoculated onto probe at 2-3 sites
- Inactivated bacteria and good but not complete kill of mycobacteria, spores
- Alternative to high-level disinfection by high-level disinfectants

Human Papilloma Virus

- Human Papilloma Virus (HPV)
  - HPV is transmitted through sexual and direct/indirect contact
  - Medical devices can become contaminated during use
  - If adequate disinfection of devices (e.g., endocavitary probes) does not occur, the next patient may be at risk for HPV infection
  - Based on two publications from the same researchers, currently FDA-cleared HLDs were not effective against HPV

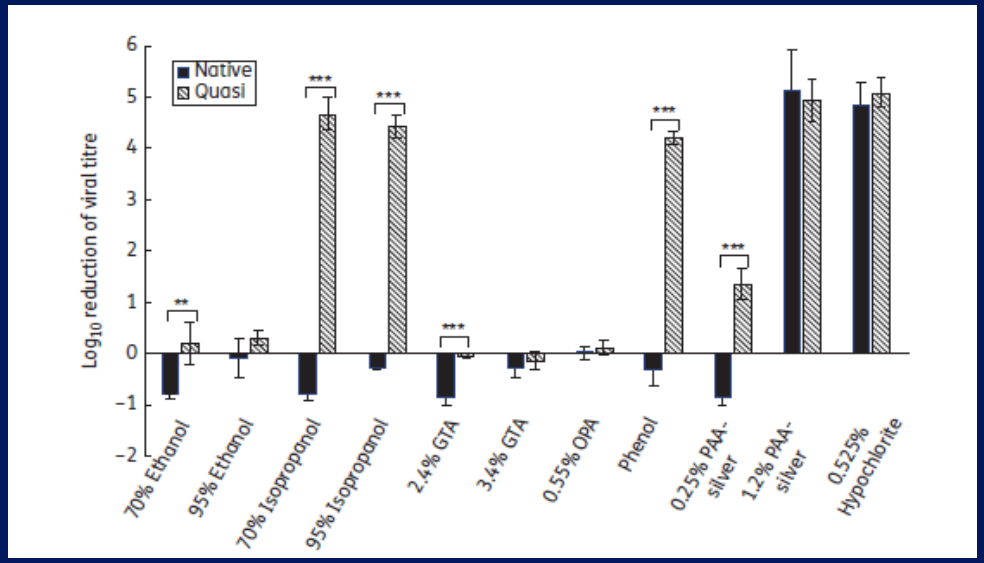
Human Papillomavirus Contamination of Gynecologic Equipment

Gallay et al. Sex Transm Infect. 2016. 92:19-23

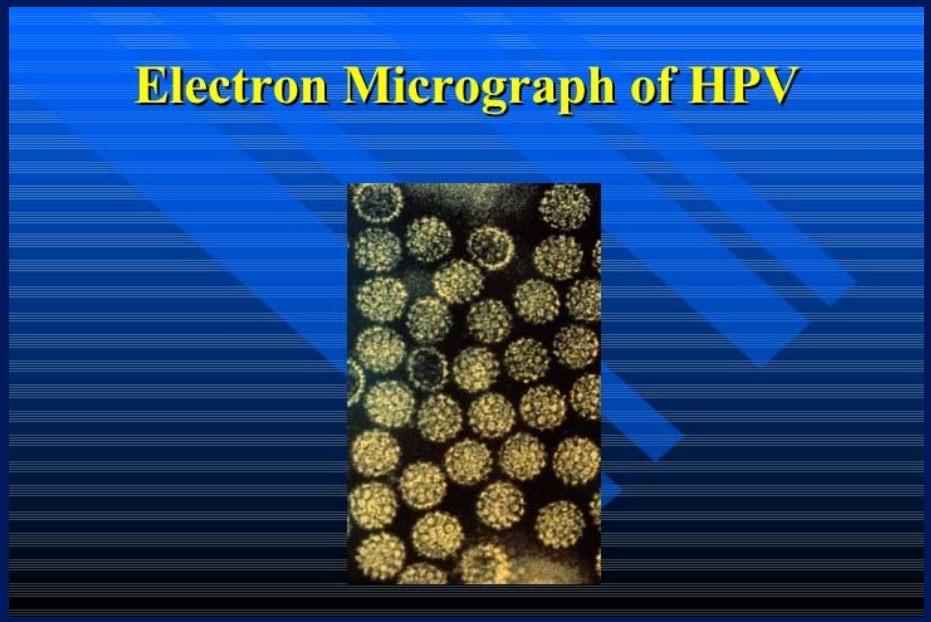
- Assess presence of HPV on equipment used in GYN practice
- Samples from fomites (glove box, lamp on GYN chair, gel tubes, colposcope, speculum) in 2 hospitals and 4 private practices
- Samples analyzed by real-time PCR
- 32 (18%) HPV-positive samples found
- Higher risk of HPV contamination in GYN private practices
- Colposcope had the highest risk of contamination
- Equipment and surfaces contaminated, need strategies to prevent contamination and transmission

ENDOSCOPE REPROCESSING: CHALLENGES
Susceptibility of Human Papillomavirus
J Meyers et al. J Antimicrob Chemother, Epub Feb 2014

- Most common STD
- In one study, FDA-cleared HLD (OPA, glut), no effect on HPV
- Finding inconsistent with other small, non-enveloped viruses such as polio and parvovirus
- Further investigation needed: test methods unclear; glycine; organic matter; comparison virus
- Conversation with CDC: validate and use HLD consistent with FDA-cleared instructions (no alterations)



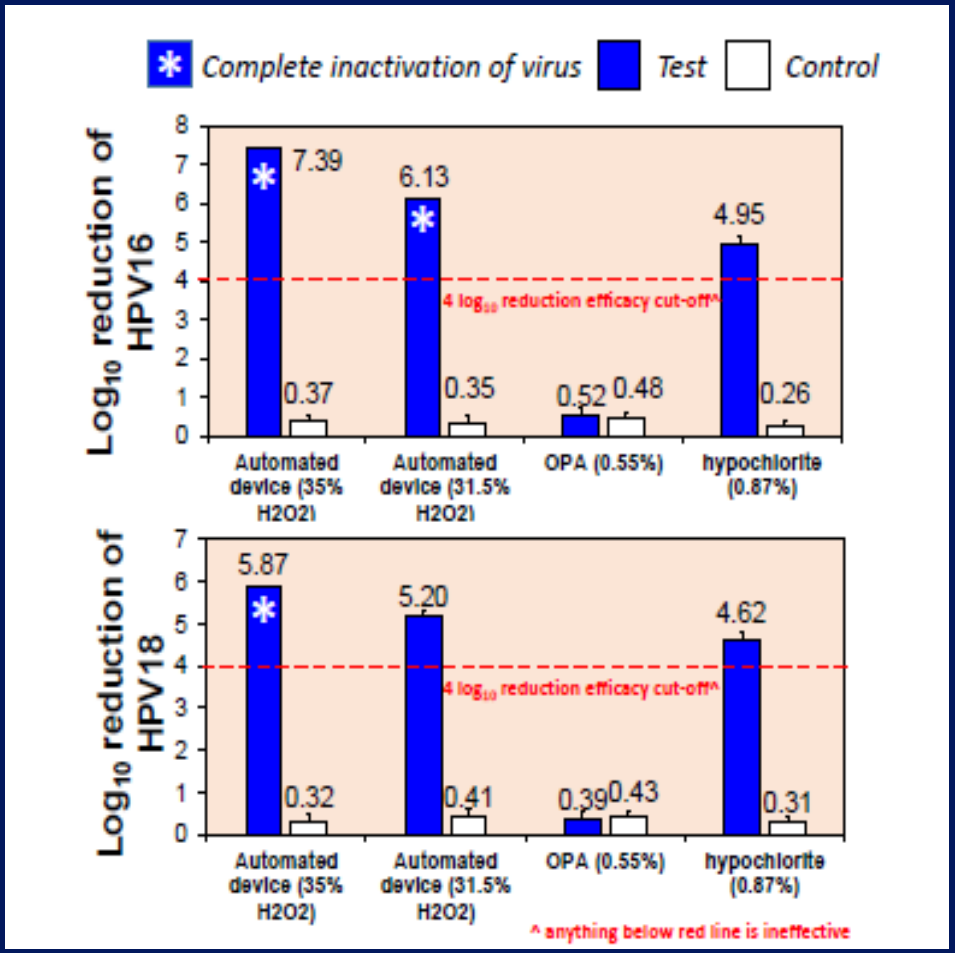
What if HPV is Resistant to Aldehydes?



- If unlike all other non-enveloped viruses that are susceptible to aldehydes
- Upsets the Spaulding classification scheme (HLD kills all viruses)
- If only oxidizing agents kill HPV (transition to PA or HP alone or combination) or HP mist device (for probes)

Efficacy of Hydrogen Peroxide Mist Against HPV

Meyers C et al. SHEA Poster, 2015



- HLD widely used to reprocess semicritical items including endocavitary probes
- Tested OPA, hypochlorite and HP mist
- HP mist and hypochlorite >4 log_{10} reduction, OPA achieved <1 log_{10} reduction

Effectiveness of HP Mist System in Inactivating Viruses

Becker et al. GMS Hyg Infect Control 2017;12

- A ≥4 log10 reduction of virus was demonstrated with murine norovirus, adenovirus, and parvovirus

Test virus	Level in the device	Soil load	Residual virus	RF
AdV	top	clean	yes	4.61±0.35
	middle	clean	yes	4.63±0.37
	bottom	clean	yes	4.11±0.43
MNV	top	clean	yes	≥4.75±0.54
	middle	clean	yes	≥4.98±0.77
	bottom	clean	yes	≥4.63±0.51
MVM	top	clean	yes	4.04±0.56
	middle	clean	yes	4.57±0.64
	bottom	clean	yes	4.67±0.70

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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*.

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

UA1323-S Endfire guide

For the 8808e:

UA1322-S14 Biplane guide

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Reprocessing Semicritical Items:
Outbreaks and New Developments

- Greatest evidence of transmission associated with semicritical medical devices is GI endoscopes/bronchoscopes(~130 outbreaks). This is likely due to microbial load, complexity, and possibly biofilm
- High-level disinfection guidelines must be followed to prevent exposure to pathogens that may lead to infection (endoscopes, laryngoscopes, endocavitary probes)
- Ensure channeled scopes are perfused with HLD
- Do not reuse single-use devices

THANK YOU!

www.disinfectionandsterilization.org