Reprocessing Semicritical Items: New Developments and Future Perspectives

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Former Director, Hospital Epidemiology, Occupational Health and Safety, UNC Health Care, Chapel Hill, NC (1979-2017)
DISCLOSURES
2022

• Consultations
  ■ Professional Disposables International (PDI)

• Honoraria
  ■ PDI

• Other
  ■ Ideate Medical, Kinnos
Reprocessing Semicritical Items: New Developments and Future Perspectives

- Overview DS
- Future Perspective
  - Transition from HLD to Sterilization
- HLD-New Developments
  - Duodenoscopes
    - FDA single use duodenoscopes, endcaps
    - New sterilization technology
  - Urologic endoscopes
    - FDA, no HLD use sterilization
  - Human papilloma virus
  - Ultrasound probes-HLD vs LLD
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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 and some bacterial spores.

**NONCRITICAL** - objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).
Semicritical Medical Devices

- **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, occasional outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex
## High-Level Disinfection of “Semicritical Objects”

**Exposure Time > 8m-45m (US), 20°C**

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Glutaraldehyde</strong></td>
<td><strong>&gt; 2.0%</strong></td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</td>
<td><strong>0.55%</strong></td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
<td>7.5%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>1.0%/0.08%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>7.5%/0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td><strong>Accelerated hydrogen peroxide</strong></td>
<td><strong>2.0%</strong></td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>0.2%</td>
</tr>
<tr>
<td>Glut and isopropanol</td>
<td>3.4%/26%</td>
</tr>
<tr>
<td>Glut and phenol/phenate**</td>
<td>1.21%/1.93%</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage; **efficacy not verified*
Microbiological Disinfectant Hierarchy
Rutala WA, Weber DJ, HICPAC. www.cdc.gov

Most Resistant

- Spores (*C. difficile*)
- Mycobacteria (*M. tuberculosis*)
- Non-Enveloped Viruses (norovirus, HAV, polio)
- Fungi (Candida, *Trichophyton*)
- Bacteria (MRSA, VRE, *Acinetobacter*)

Most Susceptible

- Enveloped Viruses (HIV, HSV, Flu)

HLD
Semicritical Medical Devices

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    - Reduced microbial load, less complex
Infections/Outbreaks Associated with Semicritical Medical Devices


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

<table>
<thead>
<tr>
<th>Instruments</th>
<th># Outbreaks/Infections</th>
<th># Outbreaks/Infections with bloodborne pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal probes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nasal endoscopes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hysteroscopes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Laryngoscopes</td>
<td>2-43-45</td>
<td>0</td>
</tr>
<tr>
<td>Urologic instrumentation (eg, cystoscopes, ureterscopes)</td>
<td>8-46-53</td>
<td>0</td>
</tr>
<tr>
<td>Transrectal-ultrasound guided prostate probes</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Transesophageal echocardiogram</td>
<td>52,54-57</td>
<td>0</td>
</tr>
<tr>
<td>Applanation tonometers</td>
<td>2-41.42</td>
<td>0</td>
</tr>
<tr>
<td>GI endoscopes/bronchoscopes</td>
<td>~130^8</td>
<td>3 HBV, HCV</td>
</tr>
</tbody>
</table>

GI, gastrointestinal; HBV, hepatitis B virus; HCV, hepatitis C virus. *These infections/outbreaks were found in the peer-review literature through PubMed and Google. **Does not include outbreaks associated with contaminated ultrasound gel used with vaginal probes or transmission via health care personnel.
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High-Level Disinfection
No Margin of Safety

0 margin of safety
Microbial contamination $10^7$-$10^{10}$: compliant with reprocessing guidelines. 10,000 microbes after reprocessing:
maximum contamination, minimal cleaning ($10^2$)/HLD ($10^4$)
Endoscope-$10^7$-$10^{10}$-crevices difficult to clean/disinfect

Surgical instruments-$<10^2$ bacteria
Reason for Endoscope-Related Outbreaks

- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain $10^7$-$10^{10}$
  - Cleaning results in 2-6 log$_{10}$ reduction
  - High-level disinfection results in 4-6 log$_{10}$ reduction
  - Results in a total 6-12 log$_{10}$ reduction of microbes
  - Level of contamination after processing: 4 log$_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms—could contribute to failure of endoscope reprocessing
HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare (3).

No articles related to possible transmission of HIV via medical device.

Greatest evidence of transmission associated with GI endoscopes/bronchoscopes (~130 outbreaks) likely due to microbial load and complexity.

Several other semicritical medical devices are associated with infections related to inadequate reprocessing.
GASTROINTESTINAL ENDOSCOPIES
A NEED TO SHIFT FROM DISINFECTION TO STERILIZATION?

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

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

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

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

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

EH Spaulding believed that how an object will be disinfected depended on the object’s intended use (modified).

CRITICAL - objects which directly or secondarily (i.e., via a mucous membrane such as duodenoscope, cystoscope, bronchoscope) enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

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

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The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

Update as of April 4, 2022: The FDA provided new information supporting the transition to fully disposable duodenoscopes and those with disposable components as well as new information on completed postmarket surveillance studies (also known as 522 studies).
Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

Date Issued: April 5, 2022

The U.S. Food and Drug Administration (FDA) is updating the April 2020 Safety Communication to provide new information supporting the transition to fully disposable duodenoscopes and those with disposable components as well as new information on completed postmarket surveillance studies (also known as 522 studies).

Given the cleaning concerns and contamination data with fixed endcap duodenoscopes and the increasing availability of duodenoscope models that facilitate or eliminate the need for reprocessing, hospitals and endoscopy facilities should complete transition to innovative duodenoscope designs that include disposable components such as disposable endcaps, or to fully disposable duodenoscopes. The use of a removable component to facilitate cleaning leads to significantly less contamination; interim results from one
FDA Cleared at least 6 Duodenoscopes with Disposable Components or Fully Disposable

**Fully Disposable:**
- [Ambu Innovation GmbH, Duodenoscope model aScope Duodeno](https://www.fda.gov) (fully disposable duodenscope cleared under K201098)
- [Boston Scientific Corporation, EXALT Model D Single-Use Duodenoscope](https://www.fda.gov) (fully disposable duodenscope cleared under K193202)

**Disposable Components:**
- [Fujifilm Corporation, Duodenoscope model ED-580XT](https://www.fda.gov) (disposable endcap duodenscope cleared under K181745)
- [Olympus Medical Systems, Evis Exera III Duodenovideoscope Olympus TJF-Q190V](https://www.fda.gov) (disposable endcap duodenscope cleared under K193182)
- [Pentax Medical, Duodenoscope model ED34-i10T2](https://www.fda.gov) (disposable elevator duodenscope cleared under K192245 and K210710)
- [Pentax Medical, Duodenoscope model ED32-i10](https://www.fda.gov) (disposable elevator duodenscope cleared under K202365)

**No Longer Marketed:**
- [Pentax Medical, Duodenoscope model ED34-i10T](https://www.fda.gov) (disposable endcap duodenscope cleared under K163614 and K181522)
Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes

Duodenoscopes with disposable endcap

Sterile, single-use duodenoscope for ERCP
Best solution to reducing the risk of disease transmission by duodenoscopes is through innovative device design that make reprocessing easier, more effective, or unnecessary.

Postmarket surveillance studies on fixed endcap design indicate that as high as 6.6% (56/850) of samples tested positive with high concern organisms (e.g., *E. coli*, *Pa*). Interim results with removable components show 0.5% (2/417) tested positive with high concern organisms.

As a result, Pentax and Olympus are withdrawing their fixed endcap duodenoscopes from the market, and Fujifilm has completed withdrawal.
UPDATE: Change in Reprocessing Methods with Certain Karl Storz Urological Endoscopes – Letter to Health Care Providers

April 4, 2022

As the U.S. Food and Drug Administration (FDA) continues to evaluate the risk of patient infections and contamination issues associated with reprocessed urological endoscopes, the FDA is aware that the current reprocessing instructions for certain urological endoscopes manufactured by Karl Storz are inadequate and are being changed updated by Karl Storz. The affected urological endoscopes include cystoscopes, ureteroscopes, cystourethroscopes and ureterorenoscopes, used for viewing and accessing the urinary tract.

In April 2021, the FDA communicated about reported patient infections and possible contamination issues with reprocessed urological endoscopes. At the FDA’s request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following high-level disinfection. Inadequate reprocessing of urological endoscopes may increase the risk of patient infection.
Sterilize Karl Storz Urological Endoscopes

www.fda.gov

- At FDA request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following HLD.
- Do not use HLD methods or liquid chemical sterilization to reprocess affected urological endoscopes (HLD not achieved for affected products).
- Sterilize affected urological endoscopes after each use by using sterilization methods recommended in MIFU.
- Do not use affected urological endoscopes if you do not have access to an appropriate sterilization method.
Urgent Medical Device Recall Notice
Certain KARL STORZ Flexible Endoscopes for Urological Use

For Attention of: Representatives for medical product safety, users, operators, importers, distributors

Commercial name(s): See Appendix
Device Model/Catalogue/part numbers: See Appendix
Affected serial numbers: All serial numbers of devices listed
FSN Type: New FSN, Ref.: 22-0002
## APPENDIX

### Affected Endoscopes and Reprocessing Methods

<table>
<thead>
<tr>
<th>Scope Base Part Number</th>
<th>Scope Kit Number</th>
<th>Product Description</th>
<th>Current IFU</th>
<th>Affected Reprocessing Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>11272C1</td>
<td>N/A</td>
<td>Flexible Cysto-Urethroscope Fiberscope</td>
<td>Z18449US-BD (08-2018)</td>
<td>X</td>
</tr>
<tr>
<td>11272CU1</td>
<td>11272CUK1</td>
<td>Flexible Cystoscope</td>
<td>Z18449US-BD (08-2018)</td>
<td>X</td>
</tr>
<tr>
<td>11272V</td>
<td>N/A</td>
<td>Flexible CMOS Video Cysto Urethroscope</td>
<td>Z18446US-BE (01/2020)</td>
<td>X</td>
</tr>
<tr>
<td>11272VA</td>
<td>11272VAK</td>
<td>Flexible CMOS Video Cysto Urethroscope</td>
<td>Z18446US-BE (01/2020)</td>
<td>X</td>
</tr>
<tr>
<td>11272VN</td>
<td>11272VNK</td>
<td>Flexible Video Urethro Cystoscope</td>
<td>Z18442US-BD (08/2018)</td>
<td>X</td>
</tr>
<tr>
<td>11272VNU</td>
<td>11272VNUK</td>
<td>Flexible Video Urethro Cystoscope</td>
<td>Z18442US-BD (08/2018)</td>
<td>X</td>
</tr>
<tr>
<td>11272VU</td>
<td>11272VUK</td>
<td>Flexible CMOS Video Cysto Urethroscope</td>
<td>Z18446US-BE (01/2020)</td>
<td>X</td>
</tr>
<tr>
<td>11272VUA</td>
<td>11272VUK</td>
<td>Flexible CMOS Video Cysto Urethroscope</td>
<td>Z18446US-BE (01/2020)</td>
<td>X</td>
</tr>
<tr>
<td>11272VUE</td>
<td>11272VUEK</td>
<td>Flexible Video Cysto-Urethroscope</td>
<td>96136031USCA V1.1 (04/2021)</td>
<td>X</td>
</tr>
</tbody>
</table>
Did supplemental measures work?
Hospitals performing ERCPs should do one of the following; FDA adopted these recommendations

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

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

Microbial Load/Complex Instruments

New Guidelines
- Multi-society guideline-2021
- AAMI, ST91-2021
- SGNA-2021
- AORN-2016
- Must educate/comply but confident will not prevent all infections and patient exposures due to microbial load and instrument complexity
“Given the choice of improving technology or improving human behavior, technology is the better choice”

Robert A. Weinstein, MD
Future Approaches to Endoscope Reprocessing to Improve Patient Safety

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

- Optimize current LTST or new LTST proving SAL $10^{-6}$ achieved
- **Disposable endoscopes** (device innovations)
  - Partially-endcaps, decrease bacterial contamination after HLD
  - Fully-GI and bronchoscopes; cost, scope performance
- Steam sterilization for GI and other endoscopes
- Use of non-endoscopic methods to diagnose or treat disease
- **Stop HLD for affected Storz urological endoscopes**, transition to sterilization
NEW STERILIZATION TECHNOLOGY

- Hydrogen Peroxide Gas Plasma sterilizer designed specifically for the terminal sterilization of flexible endoscopes
- Incorporates a proprietary vapor diffusion technology to direct Vaporized Hydrogen Peroxide (VHP) into the internal lumen channels of an endoscope
  - Utilizes a pressure differential in each internal endoscope channel to rapidly diffuse VHP to sterilize all endoscope channels
  - Achieves the required VHP efficacy concentration in all internal endoscope channels (up to 4 meters) in < 20 secs
  - Uses lower overall concentration of $\text{H}_2\text{O}_2$ with shorter exposure times, thereby eliminating potential damage to the endoscope
- Incorporates a proprietary sterilization container that interfaces with the sterilizer during the sterilization process and facilitates sterile storage (6 months) of the endoscope after processing
- Incorporates a proprietary pre-sterile single-use channel connector that is pressure activated. It seals during VHP transfer and then releases to allow sterilization of the mated connector interface
- Based on initial testing, we were able to sterilize an Olympus duodenoscope (TJF-Q160F) 125 times with no damage to the device
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Human Papillomavirus

- Human Papillomavirus (HPV)
  - HPV is transmitted through sexual contact
  - Medical devices can become contaminated
  - If adequate disinfection of devices does not occur, the next patient may be at risk for HPV infection
  - Based on one publication, there are currently no FDA-cleared HLDs that are effective against HPV
ENDOSCOPE REPROCESSING: CHALLENGES
Susceptibility of Human Papillomavirus

• 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)
Two recently published studies identified methodological artifacts (did not use refined virus) and question the validity of the original results.


- Egawa et al. EBioMedicine 2021; 63:103177. Showed that refined raft-derived HPV18 and HPV pseudovirus and mouse papilloma virus were inactivated.

Based on findings by Ozbun and Egawa, we believe that aldehydes are effective against HPV.
Fig. 5. Evaluation of disinfectant efficacy using in vitro infection assay

(a, b) Measurement of viral infectivity (E1^E4 viral gene transcripts or reporter gene activity shown as Mean and SD) of HPV18, MmuPV1 and PsV in HaCaT cells following incubation with viruses treated with disinfectants or their neutralised equivalent (except 70% ethanol). AU, arbitrary unit; ND, not detected. Data were obtained with biological triplicates and shown as Mean and SD.
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Do ultrasound transducers used for placing peripheral or central venous access devices require HLD/sterilization?
Transducer Disinfection for Insertion of Peripheral and Central Catheters

Association of Vascular Access Guideline. June 2018; AIUM 2017

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

The AVA recommendations are similar to guidelines from the American Institute for Ultrasound in Medicine (AIUM): that is, internal probes [vaginal]-HLD; “interventional percutaneous procedure probes that are used for percutaneous needle or catheter placement…should be cleaned using LLD and be used in conjunction with a single-use sterile probe cover”, if probe cover compromised HLD the probe.

Some publications have interpreted CDC and AIUM recommendations differently (AJIC 2018:46:913-920): ultrasound guided CVC insertion (critical-sterilize or HLD with sterile sheath and sterile gel); scan across unhealthy skin (semicritical-HLD and use with clean sheath and clean gel).
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Summary

- Transition from HLD to sterilization is essential to prevent infections associated with endoscopes.
- High-level disinfection guidelines must be followed to prevent exposure to pathogens that may lead to infection (e.g., ultrasound probes, endocavitary probes)
THANK YOU!

www.disinfectionandsterilization.org
New Developments in Reprocessing Semicritical Items (2018-2022)

- GI endoscopes and bronchoscopes
- Urologic endoscopes
- Ultrasound transducers
- Outpatient care/reprocessing
- Applanation tonometers
- Endocavitary probes (vaginal)
- Transrectal ultrasound-guided prostate probes
- Infrared coagulation
- Laryngoscopes
- Other channeled endoscopes (hysteroscopes)