An Update on High Level Disinfection and Sterilization Options for Flexible Endoscopes

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Learning Objectives

Upon completion of this program, you will be able to:
• Review current standards and guidelines regarding flexible endoscopes
• Discuss the advantages and disadvantages of high level disinfection and sterilization methods

Definitions

• Regulations
  • A rule or directive made and maintained by an authority
  • Mandatory
• Standards
  • Provide requirements and specifications that can be used to ensure consistency and fit for purpose
  • National and International (often the same, often not)
  • Voluntary, but can become mandatory
    • Act of legislation – New Jersey adoption of standards published by Association for the Advancement of Medical Instrumentation (AAMI)
    • If you claim compliance

Definitions

• Guidelines, Recommended Practices, Technical Information reports
  - Technical guidance, information or preferred procedures regarding a given topic
    • e.g., AAMI TIRs, AORN Guidelines for Perioperative Practice
  - Voluntary but with interpretation

Agencies with Regulations and Mandatory Standards
Agencies that Provide Accreditation Services

Groups That Provide Standards and Guidelines

Association for the Advancement of Medical Instrumentation

User Standards

- **ANSI/AAMI ST 91, 2015**: Flexible and semi-rigid endoscope processing in health care facilities
- **ANSI/AAMI ST 58, 2013**: Chemical sterilization and high-level disinfection in healthcare facilities, 3rd edition
- **AAMI/ANSI ST 41, 2008**: Ethylene oxide sterilization in healthcare facilities, safety and effectiveness
- **AAMI TIR 34: 2014**: Water for reprocessing of medical devices

What is ANSI/AAMI ST58?

Guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers for use in hospitals and other health care facilities.
**What is ANSI/AAMI ST 91?**

Flexible and semi-rigid endoscope reprocessing in health care facilities

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**AAMI TIR34 (2014), Endoscopy Water**

- Utility water: Rinsing following cleaning
- Critical water: Rinsing following disinfection
  - Some systems provide extensively treated water
- Control of any water storage or distribution systems is essential
- Biofilm development and cross-contamination

<table>
<thead>
<tr>
<th>Type of Water</th>
<th>Utility Water</th>
<th>Critical Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Use</td>
<td>Filling/flushing</td>
<td>Rinsing/Prior Rinse</td>
</tr>
<tr>
<td>Specifications</td>
<td></td>
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</tr>
</tbody>
</table>

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**Guidelines**

- ASGE/SHEA/SGNA/APIC: Multi-society guideline on reprocessing flexible gastrointestinal endoscopes (2011)
- SGNA: Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes (2016)

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**Increased Focus on Reprocessing Validations**

- Quality of Reprocessing Instructions
- Attention to Human Factors
- Cleaning Validations

"IT IS IMPORTANT TO NOTE THAT CLEANING, DISINFECTION AND STERILIZATION ARE DISTINCTLY DIFFERENT PROCESSES"* FDA

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**New FDA Guidance on Reprocessing (March 17, 2015)**

**6. Semi-Critical Devices**

Semi-critical devices are defined as contact intact mucous membranes or non-intact skin. They do not violate any prohibition or otherwise require sterility or disinfection (e.g., contact intact mucous membranes, temporary indwelling catheters, endotracheal tubes, intravenous catheters, portable x-ray equipment, endoscopes, endoscopy biopsy forceps, drainage filters, and gastrointestinal endoscopes).

Examples of semi-critical devices include flexible endoscopes, multi-lumen lumbar puncture needle, portable x-ray equipment, endotracheal tubes, intravenous catheters, endoscopes, and portable x-ray equipment.

*"It is important to note that cleaning, disinfection and sterilization are distinctly different processes."* FDA
Spaulding Classification

<table>
<thead>
<tr>
<th>Patient Contact</th>
<th>Examples</th>
<th>Device Classification</th>
<th>Minimum Inactivation Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact skin</td>
<td><img src="image1.png" alt="Image" /></td>
<td>Non-Critical</td>
<td>Cleaning and/or Low/Intermediate Level Disinfection</td>
</tr>
<tr>
<td>Mucous membranes or non-intact skin</td>
<td><img src="image2.png" alt="Image" /></td>
<td>Semi-Critical</td>
<td>Cleaning and Sterilization (or High Level Disinfection)</td>
</tr>
<tr>
<td>Sterile areas of the body, including blood contact</td>
<td><img src="image3.png" alt="Image" /></td>
<td>Critical</td>
<td>Cleaning and Sterilization</td>
</tr>
</tbody>
</table>

FDA Panel, May 2015

- Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee
  - duodenoscopes should be redesigned
  - devices should be reclassified as critical
  - contact with blood or normally sterile tissue

"To date, only liquid chemical sterilants have been cleared by FDA specifically for sterilization of complex endoscopes, such as duodenoscopes. Ethylene oxide sterilizers have general claims and do not have specific claims for sterilization of duodenoscopes." *

*FDA Executive Summary: Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures, pg. 40

CDC HEALTH ADVISORY, 9/11/2015

- Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices
- Provide training to all personnel who reprocess devices
- Regularly monitor and document adherence to cleaning, disinfection, sterilization, and device storage procedures
- Provide feedback from audits to personnel regarding their adherence
- Allow adequate time for reprocessing
- Maintain documentation of reprocessing activities
- Protocols ensure that healthcare personnel can readily identify devices that have been properly reprocessed
- Follow manufacturer IFUs for maintenance and repair of devices

Infections Associated with Reprocessed Flexible Bronchoscopes:

FDA Safety Communication, 9/17/2015:

- Sub-set of devices
- Greater likelihood of microbial transmission
- Represent a high risk of infection if they are not adequately reprocessed
- Persistent device contamination despite following IFUs
- Failure to meticulously follow manufacturer instructions for reprocessing
- Continued use of devices despite integrity, maintenance and mechanical issues

Infections and Outbreaks
Centers for Disease Control

- "Endoscopes most commonly linked to health care-associated outbreaks and pseudo-outbreaks"
- Flexible endoscopes represent high-risk devices
  - High levels of bacterial contamination
    - Mouth - 200+ species
    - Large intestine - 1,000 species
- Complex designs
- Numerous reports of breaches in reprocessing

January 15, 2016
Senate Committee: Scope Outbreak Worse Than Reported
Industry silence, hospital missteps, porous regulation cited

- The global wave of "superbug" infections linked to contaminated duodenoscopes was much wider than previously believed and could have been largely avoided, Senate investigators have concluded.
- Between 2012 and 2015, at least 250 people in 25 outbreaks worldwide were sickened by the tainted instruments
- The FDA, in turn, failed to alert hospitals, health care workers and the public for 17 months after learning of the potential hazard

by Adam Marcus (Gastro and Endoscopy News)

What Technology Hazards are Lurking in your Hospital?
1. Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens
2. Missed Alarms Can Have Fatal Consequences
3. Failure to Effectively Monitor Post-operative Patients for Opioid-Induced Respiratory Depression Can Lead to Brain Injury or Death
4. Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm
5. Unsafe Injection Practices Expose Patients to Infectious Agents

CLEANR Study: Documented non-adherence with several essential steps (n = 69)
Multiple manual cleaning steps skipped 45% of the time

Current risks are outdated and inaccurate (Ofstead et al, 2013; Dirlam-Langlay et al, 2013)
- Most outbreaks not published
- Most outbreaks not investigated
- Difficult to link to contaminated endoscopes
- Reviews of reprocessing practices show widespread lapses in essential steps
- Risks are greater than just infections (e.g., toxicity with aldehydes)

Manual cleaning n = 69; p = 0.001
Nosocomial Infections via GI Endoscopes

- Infections traced to deficient practices
- Inadequate cleaning (clean all channels)
- Inappropriate/ineffective disinfection
- Failure to follow recommended disinfection practices (tap water rinse)
- Flaws and complexity in design of endoscopes or AERs
- Improper use of reprocessing equipment
- Improper drying/storage

Protein Was Never Removed During Reprocessing

- Complex Design
- Heat labile
- Long, narrow lumens
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels
- Heavily contaminated with pathogens, $10^7-10^{10}$
- Cleaning (4-6 log$_{10}$ reduction) and HLD (4-6 log$_{10}$ reduction) essential for patient safe instrument

Features Predispose to Disinfection Failures
C-Diff Hits the News

- $5 billion/year in healthcare costs
- Hospital costs >40% per case
- It's all about 100% spore kill!

Recent Transmissions

- Manual
  - FDA clearance
  - Review claims and instructions for use
  - Automate and standardize processing steps
  - Reduced chemical exposure
  - Defined flow of lumens
  - Specific design-dependant
  - Pre-cleaning still required
  - Flow connector design
  - Filtered tap water
  - Correct use dependant on operators
  - Routine maintenance

- Automated

Definitions

- High level disinfectant
  - Product that is expected to kill all microbial organisms but not necessarily large numbers of bacterial spores, when used according to labeling
  - Often a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass an FDA-defined spore inactivation test
  - Disinfection and rinsing need to be controlled

In 2015, It’s About ERCP Scopes!

- Deadly superbug infected patients at Seattle hospital
  - ‘Superbug’ linked to 2 deaths at UCLA hospital
  - Superbug outbreak extends to Cedars Sinai hospital, linked to scope
  - 281 Hartford Hospital Patients Exposed to Drug-Resistant E. Coli

Definitions

- High level disinfectant
Definitions

Liquid chemical sterilant
- Product validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim (often at longer exposure times)

Sterilization
- Validated process used to render a product free from viable microorganisms, including bacterial spores.
- Liquid or gaseous process

Key Points with Disinfection

Label claims vary:
- Manufacturer IFUs (e.g. temperature, immersion time, ‘rinse thoroughly’)
- Single use or multiple use
- Multiple use disinfectants
  - Label claims, maximum reuse life
  - Topping off
  - All surfaces of device in contact
  - Rinsing
  - Correct water quality (bacteria-free; AAMI TIR34)
  - Fresh water for every rinse (by immersion)
  - Correct number of rinses
- Device inspection prior to use

High Level Disinfectants

<table>
<thead>
<tr>
<th>Aldehydes</th>
<th>Oxidizing agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Glutaraldehyde</td>
<td>- Hydrogen peroxide</td>
</tr>
<tr>
<td>- OPA</td>
<td>- Peracetic acid</td>
</tr>
</tbody>
</table>

Each Product is Unique

High Level Disinfectant/Sterilants

<table>
<thead>
<tr>
<th>Chemicals</th>
<th>Sterilant</th>
<th>High Level Disinfection</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4% glutaraldehyde 20.1% isopropanol</td>
<td>8 hours at 20°C</td>
<td>10 mins at 20°C</td>
<td>Requires activation 3 rinses following exposure</td>
</tr>
<tr>
<td>2% hydrogen peroxide</td>
<td>6 hours at 20°C</td>
<td>8 mins at 20°C</td>
<td>No activation 1 rinse</td>
</tr>
<tr>
<td>0.575% OPA</td>
<td>No claim (passes sporicidal test at 32 hours at 20°C)</td>
<td>10 mins at 20°C</td>
<td>No activation 3 rinses</td>
</tr>
<tr>
<td>2.4% glutaraldehyde</td>
<td>10 hours at 25°C</td>
<td>45 mins at 25°C</td>
<td>Requires activation 3 rinses following exposure</td>
</tr>
<tr>
<td>3.4% glutaraldehyde</td>
<td>10 hours at 25°C</td>
<td>90 mins at 25°C</td>
<td>Requires activation ‘Thoroughly’ rinse following exposure</td>
</tr>
</tbody>
</table>

Concerns for Aldehydes

- Safety
- Protein binder
- Reduction in hospital use
  - Country-specific regulations
- Development of resistance
- Biofilms

Aldehydes
First marketed in 1963 as alkaline solutions
Endoscopes required low-temperature processing
- Limited reprocessing methods
- Limited inventory/quick turnover
- Decentralized reprocessing
- 1980-1990s: First reports of adverse health effects in hospitals
- Employee/patient safety concerns
  - Toxic build up
  - Dermatitis
  - Fumes
  - Aldehyde induced colitis
  - Asthma
- Closed systems

www.fda.gov
Why the Shift to Oxidative Agents?

# 1 Concern: Safety

• Safe for scopes, patients, staff, environment
• Toxicity of aldehydes
• Efficacy
• Employee health
• Aldehyde resistant organisms
• Efficiency

Oxidizing Chemistries

Advantages
• Antimicrobial activity, fast cycle times
• Low risk of resistance development
• Safety profile (staff, patients, scopes)
• Low toxicity risks
• Environmentally friendly
  – Biodegradable, no special ventilation or disposal
• Aides in removal of organic matter

Disadvantages
• Activity can vary depending on product formulation (e.g., temperature requirements)
• Variable material compatibility (product dependent)

Oxidizing Chemistries, continued

High level disinfection/sterilization:
• Formulation dependent (liquid, gas, plasma)

Reduce:
• Risk of cross-contamination
• Risk of infection with resistant bacteria

Effectiveness against:
• Biofilms
• Aldehyde resistant bacteria

Hydrogen Peroxide (H₂O₂)

• Liquid or gas
• Formulation dependent
• HLD/sterilant
  – Environmentally friendly
  – Efficacy/surface compatibility
Hydrogen Peroxide ($\text{H}_2\text{O}_2$), continued

Applications
- Antisepsis
- Cleaning/Surface disinfection
- Disinfection
  - Buildings
  - Vehicles
  - Hospital rooms
  - Laboratories

Peracetic Acid (PAA)

- Effective biocide
- High potency
- Effective in presence of organic soil
- No toxic residues
- Combined with proper buffers and anti-corrosives to safely disinfect / sterilize
  - Endoscopes
  - Heat sensitive devices

Biofilm Efficacy with PAA

- Efficacy against biofilms
  - Removes biofilms under worst case conditions
  - PAA minimizes biofilm development

Biofilm Control

Bacterial Reduction
($\log_{10}$ cfu/cm² Pseudomonas aeruginosa)

Previous Use of Aldehydes

- Aldehydes hide problems
- Leaks observed shortly after use
- Expect scope repairs

Effectiveness of Reprocessing

Contaminated  Cleaned  Disinfection  Sterilization
Sterilization Essentials

• Sterilization is dependant on adequate cleaning, rinsing and device preparation
  – Drying may also be essential
• Process claims are product specific
  – Not just the active (e.g., ‘ETO’)
  – Controlled processes
• Correct equipment installation, maintenance, use and periodic monitoring required for all systems
• Correct handling (including storage) required after the process

Two Sterilization Options for most Semi-Critical Flexible Endoscopes used in GI Reprocessing Modality

<table>
<thead>
<tr>
<th>Type</th>
<th>Unit</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Traditional Sterilization  | ETO    | Uses Toxic gas.  
  Large Inventory Required.  
  60 minute Cycle, 12 hour aeration. Known for leaving residuals. May damage devices after long term use. |
| Liquid Chemical Sterilization | SYSTEM 1E | 23 minute cycle.  
  Less inventory needed.  
  Oxidative, non fixative chemistry that is safe for the user and patient.  
  No toxic residuals |

Ethylene Oxide

• Ensure devices are clean and dry
  – ETO is sensitive to the presence of residual soil and water
• Low pressure (vacuum) systems
  – Venting cap required
• Sterilization parameters should be validated by endoscope manufacturer
  – Conditioning, sterilization and aeration
• Post-sterilization aeration is essential
  – Processing time typically >15 hours
• Endoscopes may have a limited number of cycles before requiring extensive repair

EPA EtO National Emission Standards

• March 2008
  – Sterilize full loads
  – Demonstrate, submit compliance status with management practice standard
  – Record keeping
    • Compliance status
    • Sterilizers not equipped with air pollution control devices
• March 2010
  – Single chamber process – no separate aerator

Recent FDA statement on EtO

Dr. William Maisel, FDA Deputy Director and Chief Scientist:
• EtO sterilization is “not something that we routinely recommend”
• “…There can be ethylene oxide residual levels on the products that can be harmful to patients.”
• “[EtO] can damage the scopes themselves. And so we are not, at this time, recommending routine ethylene oxide sterilization.”

Hydrogen Peroxide Gas

- Processes with and without 'plasma'
  - Vacuum processes require device venting
- Claims (lumen length and diameter restrictions) are product specific
  - Generally critical flexible endoscopes
  - Some systems include claims for single/multiple lumened devices
  - No GI endoscope claims
- Typical sterilization time ~30 minutes
- Ensure devices are clean and dry before sterilization

Liquid Chemical Sterilization

- One system cleared as a liquid chemical sterilant processing system cleared through the FDA
  - Liquid chemical sterilization with peracetic acid sterilant
  - Rinsing with extensively treated water
  - Removal of bacteria, viruses, protozoa and fungi
  - Controlled rinsing (non-toxic)
- Cycle time (23 minutes)
- Validated flexible endoscope models including ERCP scopes
  - Includes specially designed connectors

GI Endoscopes: Shift from Disinfection to Sterilization


Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?


Unresolved Issue

Endoscope Shelf Life prior to reprocessing:

- AAMI ST 91: perform risk assessment
- AORN: recommends up to 5 days currently under review
- APIC: up to 7 days
- SGNA: up to 7 days
- CDC: not addressed
- FDA: not addressed
- Refer to AAMI ST91, ST58

“To protect the public health we must shift endoscope reprocessing from HLD to sterilization. FDA should mandate that GI endoscopes used in healthcare facilities be sterile by 2018”

Dr. Bill Rutala, 2015
Quality Control Plan

• Know your standards and guidelines
• Risk analysis
  – Where are your risks/hazards?
  – What have you done to reduce these?
  – Continuous improvement
• Reprocessing policy
  – Facility
  – Department
• Staff training and demonstrated competency

Conclusion

• Review current documents and standards to ensure policies and procedures are consistent with best practices
• Identify the advantages and disadvantages of aldehyde and oxidative chemistries
• Consider the benefits of sterilization versus high level disinfection when making decisions for reprocessing flexible endoscopes

Refer to scope manufacturer’s instructions for proper use and handling

Action Plan

• Review current documents and standards to ensure policies and procedures are consistent with best practices
• Provide continuing education to staff based on updated information, new endoscope models, equipment and reprocessing methods
• Perform risk assessment as part of quality improvement

Useful References

• AAMI/ANSI ST 58. Chemical sterilization and high-level disinfection. 3rd edition (2013)
• AAMI/ANSI ST91. Flexible and semi-rigid endoscope processing in health care facilities (2015)
• AAMI TIR34 Water for the reprocessing of medical devices (2014)
• ASGE/SHEA/SGNA/APIC: Multi-society guideline on reprocessing flexible gastrointestinal endoscopes (2011)
• Anne Marie Noronha, Steve BrozakA 21st century nosocomial issue with endoscopes , BMJ 2014;348:g3947
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• Ribiero, M., A. Cristina de Oliveira, Analysis of the air/water channels of gastrointestinal endoscopies as a risk factor for the transmission of microorganisms among patients, AJIC, May 2012


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