High Level Disinfection and Sterilization Options for Flexible Endoscopes
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- 1 hour(s) of GI Specific content credit by ABCGN (American Board of Certification for Gastroenterology Nurses)

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  - CBRN (California Board of Registered Nursing);
  - CBSPD (Certified Board for Sterile Processing and Distribution); and
  - IAHCSMM (International Association of Healthcare Center Service Materiel Management).

- 1 AEU by BASC (provider # 1417)

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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, continued

- 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
Regulatory Agencies

- FDA U.S. Food and Drug Administration
- CMS.gov Centers for Medicare & Medicaid Services
- OSHA Occupational Safety and Health Administration
- United States Environmental Protection Agency
Agencies that Provide Accreditation Services

- Accreditation Association for Ambulatory Health Care, Inc.
- Centers for Medicare & Medicaid Services
- American Osteopathic Association
- DNV
- ASFA The Gold Standard
- The Joint Commission
Groups That Provide Standards and Guidelines
Guidelines

• CDC Guideline for Decontamination and Sterilization in Healthcare Facilities

• ASGE/SHEA/SGNA/APIC: Multi-society guideline on reprocessing flexible gastrointestinal endoscopes

• SGNA: Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes

• SGNA: Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes

• AORN Guideline for Cleaning and Processing Flexible Endoscopes and Endoscope Accessories
Association for the Advancement of Medical Instrumentation
User Standards

- ANSI/AAMI ST91 - Flexible and semi-rigid endoscope processing in health care facilities

- ANSI/AAMI ST58 - Chemical sterilization and high-level disinfection in healthcare facilities

- AAMI/ANSI ST41 - Ethylene oxide sterilization in healthcare facilities, safety and effectiveness

- AAMI TIR34 - Water for reprocessing of medical devices
ANSI/AAMI ST91

Flexible and semi-rigid endoscope reprocessing in health care facilities
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
ANSI/AAMI ST41

Ethylene oxide sterilization in health care facilities: Safety and effectiveness
AAMI TIR34 - Endoscopy Water

- Utility water:
  - Washing, rinsing soil and cleaning chemistry
  - Meets quality requirements from device and cleaning chemistry manufacturer

- Critical water:
  - Extensively treated for final rinse

- Automated Endoscope Reprocessors (AERs):
  - Incoming water does not contain excessive microbial levels
  - Filtration used for bacteria-free quality
  - Critical water
Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015


The draft of this document was issued on May 2, 2011.
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

* Reprocessing Medical Devices in Healthcare Settings: Validation Methods & Labeling, March 2015, Pg.6
# 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></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></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></td>
<td>Critical</td>
<td>Cleaning and Sterilization</td>
</tr>
</tbody>
</table>
Endoscopes and HAIs

- 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
Clostridium difficile

- $5 billion/year in healthcare costs
- Hospital costs >40% per case
- It’s all about 100% spore kill!
#2 - Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens
ERCP Scopes

Deadly superbug infected patients at Seattle hospital

'Superbug' linked to 2 deaths

Superbug outbreak extends to hospital, linked to scope

Medical scope now tied to Wisconsin superbug outbreak
Preventable Tragedies:
Superbugs and How Ineffective Monitoring of
Medical Device Safety Fails Patients

Minority Staff Report
January 13, 2016
Senate Committee: Scope Outbreak Worse Than Reported
January 15, 2016

Industry silence, hospital missteps, poor regulation cited

Senate investigations have concluded:

- The global wave of ‘superbug” infections linked to contaminated duodenoscopes was much wider than previously believed and could have been largely avoided

- At least 250 people in 25 outbreaks worldwide were sickened by the tainted instruments between 2012 and 2015

- The FDA, in turn, failed to alert hospitals, health care workers and the public for 17 months after learning of the potential hazard
Evaluation of Residual Contamination

American Journal of Infection Control

Brief Report
Assessing residual contamination and damage inside flexible endoscopes over time

Cori L. Ofstead MSPH, Harry P. Wetzler MD, MSPH, John E. Eiland MS, RN, Otis L. Heymann BA, Sarah B. Held MBA, RN, Michael J. Shaw MD

Ofstead & Associates, Inc, St Paul, MN
Fairview Maple Grove Medical Center, Maple Grove, MN
Division of Gastroenterology, Department of Medicine, University of Minnesota Medical School, Minneapolis, MN
Study: Damage and Contamination

- Rigorous reprocessing not consistently effective
- Incubation encouraged slow growing microbes
- Need routine visual inspection, and cleaning verification testing
Infections and Outbreaks
Stages of Processing

- Contaminated
- Cleaned
- High-Level Disinfection
- Sterilization
Understanding Processing Options

• High-level disinfectant
  – Kills all microorganisms except large number of bacterial spores
  – Use according to label

• 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 to provide free from viable microorganisms
Hierarchy of Resistance

- **Bacterial Spores**
  - *Clostridium difficile*
  - *Clostridium perfringens*
  - *Clostridium botulinum* – food poisoning

- **Mycobacteria**
  - *Mycobacterium tuberculosis*
  - *Mycobacterium chelonae*

- **Non-Enveloped Viruses**
  - Poliovirus
  - Rhinovirus

- **Fungi**
  - *Candida albicans* – thrush
  - *Trichophyton spp.*

- **Vegetative Bacteria**
  - *Salmonella*, ssp.
  - *Staphylococcus*, ssp.
  - *E. coli*, VRE, MRSA

- **Enveloped Viruses**
  - Hepatitis A, B & C
  - Herpes Simplex
  - HIV, Ebola

Disinfection Levels:
- **Sterilization**
- **High Level Disinfection**
- **Intermediate Level Disinfection**
- **Low Level Disinfection**
Manual vs. Automated
Automation

- Automate and standardize processing steps
- Reduced chemical exposure
- Specific design-dependent
- Pre-cleaning still required
Disinfection: Key Points

- Label claims vary
- Single use or multiple use
  - **Note:** Multiple use disinfectants: All surfaces of device in contact
# 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 20oC</td>
<td>10 mins at 20oC</td>
<td>Requires activation 3 rinses following exposure</td>
</tr>
<tr>
<td>2% hydrogen peroxide</td>
<td>6 hours at 20oC</td>
<td>8 mins at 20oC</td>
<td>No activation 1 rinse</td>
</tr>
<tr>
<td>0.575% OPA</td>
<td>No claim (passes sporicidal test at 32 hours at 20oC)</td>
<td>10 mins at 20oC</td>
<td>No activation 3 rinses</td>
</tr>
<tr>
<td>2.4% glutaraldehyde</td>
<td>10 hours at 25oC</td>
<td>45 mins at 25oC</td>
<td>Requires activation 3 rinses following exposure</td>
</tr>
<tr>
<td>3.4% glutaraldehyde</td>
<td>10 hours at 25oC</td>
<td>90 mins at 25oC</td>
<td>Requires activation ‘Thoroughly’ rinse following exposure</td>
</tr>
</tbody>
</table>
High Level Disinfectants

Aldehydes
- Glutaraldehyde
- Orthophthalaldehyde (OPA)

Oxidizing agents
- Hydrogen peroxide
- Peracetic acid

Each Product is Unique
Aldehydes Concerns

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

Before & After 5 Cycles of Peracetic Acid, after long term use of Aldehydes.
Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants

Jordan Meyers, Eric Ryndock, Michael J. Conway, Craig Meyers and Richard Robison

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§§Present address: Department of Foundational Sciences, Central Michigan University, Mount Pleasant, MI 48859, USA.

It was found in the rinsing water and in the drain of 1 of the 2 automated endoscope reprocessors. PFGE revealed
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

- Antimicrobial activity, fast cycle times
- Activity can vary on product formulation (e.g., temperature requirements)
- Low toxicity risks
- Effective in aiding the removal of organic matter
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
  - Aldehyde resistant bacteria
Hydrogen Peroxide (H2O2)

- Liquid or gas
- Formulation dependent
- HLD/sterilant
  - Environmentally friendly
  - Efficacy & surface compatibility
Hydrogen Peroxide (H2O2)

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
• Combines with proper buffers and anti-corrosives to safely disinfect or sterilize endoscopes and other heat sensitive devise
Gaseous & Liquid Chemical Sterilization Options
Sterilization Essentials

- Sterilization is dependent on adequate cleaning, rinsing and device preparation
- Process claims are product specific
- Correct equipment installation, maintenance, use and periodic monitoring required for all systems
- Correct handling (including storage) required after the process
Ethylene Oxide

- Ensure devices are clean and dry
- Low pressure (vacuum) systems
- Sterilization parameters should be validated by endoscope manufacturer
- Post-sterilization aeration is essential
- Endoscopes may have a limited number of cycles before requiring extensive repair
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
- Ensure devices are clean and dry before sterilization
Liquid Chemical Sterilization

- One system cleared as a liquid chemical sterilant processing system by 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
Gastrointestinal Endoscopes
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 patients were infected or colonized with the same strain of NDM-E. coli. 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 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,

“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 Procedures, pg. 40
One Liquid Chemical Sterilant Processing System that was successfully tested with Duodenoscopes at extreme worst case conditions using G. stearothermophilus.
Joint Commission HLD/Sterilization Assessment Tool – *High Risk*

- No gross cleaning – soil allowed to dry
- HLD manufacturer’s IFUs not followed
- Vaginal/rectal/TEE probes not subject to HLD
- No initial of ongoing staff competency
- Lack of leadership oversight of sterilization/HLD processes
Joint Commission HLD/Sterilization Assessment Tool – *Moderate Risk*

- Gross cleaning not completed at point of use
- HLD/sterilization logs inconsistently completed
- Instruments allowed to dry before cleaning
- Single-use brushes reused
- Multi-use brushes not cleaned between uses
Quality Control Plan

- Verification points
  - Specific for each product/process
- Standards Recommendations
- Cleaning
- Disinfection
- Sterilization
- Documentation
Quality Control

• Knowledge of standards and guidelines

• Risk analysis
  – Where are your risks/hazards?
  – What have you done to reduce these?
  – Continuous improvement

• Reprocessing policy
  – Facility/Department
  – Healthcare organizations should maintain records with traceability back to the patient

• Staff training and demonstrated competency
Action Plan

- Consider the benefits of sterilization versus high level disinfection when making decisions for reprocessing flexible endoscopes.
  - Identify the advantages and disadvantages of aldehyde and oxidative chemistries
- Develop and implement a quality control plan
References


References, continued


References, continued


References, continued


References, continued


References, continued


Handouts

To access the handouts for this presentation, go to: university.steris.com/85.
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