DISINFECTION STERILIZATION in G.I ENDOSCOPY UNIT

By

Prof: Gamal Shiha
STERILIZATION

- Methods:
  1. Steam Sterilization
  2. Dry heat sterilization
  3. Filtration
  4. Gas sterilization
  5. Irradiation

- NOTE: End products must pass sterility tests.
Classification scheme for medical instruments

Critical instruments:
- Penetrate sterile tissue, enter the vasculature, or contact the patient’s blood.
  - Examples: cardiac catheters, biopsy forceps, and implants.

Semi-critical instruments:
- Directly or indirectly contact mucous membranes or non-intact skin.
  - Examples: rhino-laryngoscopes, naso-pharyngo-laryngoscopes, bronchoscopes, the blades and handles of rigid laryngoscopes, and GI endoscopes.

Non-critical instruments:
- Do not directly contact the patient, or only touch the patient’s intact skin.
  - Examples: blood pressure cuffs, stethoscopes, and bedpans; and environmental surfaces, such as walls, floors, and sink tops.
Endoscope Reprocessing

- Background
- Infections related to endoscopy
- Reprocessing of endoscopes and accessories
  - Cleaning
  - High-level disinfection/sterilization
  - Automated endoscope reprocessing
- Quality control
GI ENDOSCOPES

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

- Background
- Infections related to endoscopy
- Reprocessing of endoscopes and accessories
  - Cleaning
  - High-level disinfection/sterilization
  - Automated endoscope reprocessing
- Quality control
Infections related to endoscopy

- Gastrointestinal endoscopies
  1- Every kind of infectious diseases imaginable including sexually transmitted diseases.
  2- >300 Bacterial infections transmitted
  3- 70% agents Salmonella sp with colonoscopy and P. aeruginosa esp. with wet endoscopes
  4- Some viruses transmitted even cause colorectal cancer.
  5- Clinical spectrum ranged from colonization to death (~4%)
Endoscope Reprocessing

- Background
- Infections related to endoscopy
- Reprocessing of endoscopes and accessories
  - Precleaning
  - Cleaning
  - High-level disinfection/sterilization
  - Automated endoscope reprocessing
- Quality control
ENDOSCOPE CHANNELS

- Water Channel
- Suction Channel
- Biopsy/Suction Channel
- Air/CO₂ Channel
- Air Channel
- CO₂ Channel
ENDOSCOPE REPROCESSING

- Precleaning
  - After removal from patient, wipe the insertion tube with a wet cloth and alternate suctioning the enzymatic cleaner and air through the biopsy/suction channel until solution clean. The air-water channel is flushed or blown out per instructions.
  - Transport the endoscope to the reprocessing area.
  - Enzymatic cleaner should be prepared per instructions. Some data suggest enzymes are more effective cleaners than detergents. Enzymatic cleaners must be changed after use.
Endoscope Reprocessing

- Background
- Infections related to endoscopy
- Reprocessing of endoscopes and accessories
  - Precleaning
  - Cleaning
  - High-level disinfection/sterilization
  - Automated endoscope reprocessing
- Quality control
ENDOSCOPE REPROCESSING

Cleaning

- Immerse in a compatible low-sudsing, enzymatic cleaner
- Wash all debris from exterior by brushing and wiping
- Remove all removal parts of the endoscope and clean each reusable part separately
- After exterior cleaning, brush accessible channels with appropriate-sized cleaning brush (bristles contact all surfaces)
ENDOSCOPE REPROCESSING

Cleaning (continued)

- After each passage, rinse the brush, remove debris before reinserting. Continue until no visible debris on brush.
- Attach cleaning adapters for each channel per manufacturer’s instructions and flush with enzymatic cleaner to remove debris.
- After cleaning is complete, rinse the endoscope with clean water.
- Purge water from channels using forced air. Dry exterior of the endoscope with a soft, lint-free cloth.
ENDOSCOPE CHANNELS
Endoscope Reprocessing

- **Background**
- **Infections related to endoscopy**
- **Reprocessing of endoscopes and accessories**
  - Precleaning
  - Cleaning
  - High-level disinfection/sterilization
  - Automated endoscope reprocessing
- **Quality control**
Nosocomial Infections via GI Endoscopes

- Observations
  - Number of reported infections is small, suggesting a very low incidence
  - Endemic transmission may go unrecognized (e.g. inadequate surveillance, low frequency, asymptomatic infections)
Nosocomial Infections via GI Endoscopes

- Infections traced to deficient practices
  - Inadequate cleaning (clean all channels)
  - Inappropriate/ineffective disinfection (time exposure, perfuse channels, test concentration, ineffective disinfectant, inappropriate disinfectant)
  - Failure to follow recommended disinfection practices (tapwater rinse)
  - Failure to check Automated Endoscope Reprocesses (AERs)
Nosocomial Outbreaks via GI Endoscopes
Infections Associated with Accessories

- Infections associated with biopsy forceps
- Reusable endoscopic accessories like contaminated biopsy forceps that break the mucosal barrier should be mechanically cleaned and sterilized between patients
Minimum Effective Concentration (MEC) High Level Disinfectant (HLD)

- Dilution of HLD occurs during use
- Test strips are available for monitoring MEC
- For example, test strips for glutaraldehyde monitor 1.5%
- Test strip not used to extend the use-life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used (used daily, test at least daily)
- Record results
CHEMICAL MONITORING
CHEMICAL MONITORING
High-level disinfection (HLD):

Destroys *all* pathogenic microorganisms, including some bacterial endospores during short exposure times – Example: *Clostridium difficile*.

Destroys high numbers of bacterial endospores (sporicidal) during long exposure times.

Sporicidal (limited), tuberculocidal, virucidal, fungicidal, and bactericidal

Uses mycobacteria as indicators of effectiveness

Examples: 2% glutaraldehyde, 7.5% hydrogen peroxide, 0.55% *ortho*-phthalaldehyde

Primarily used for *semi-critical* instruments.
Endoscope Reprocessing

- Background
- Infections related to endoscopy
- Reprocessing of endoscopes and accessories
  - Precleaning
  - Cleaning
  - High-level disinfection/sterilization
  - Automated endoscope reprocessing
- Quality control
Automated Endoscope Reprocessors (AERs)

- Advantages: automate and standardize reprocessing steps, reduce personnel exposure to chemicals, filtered tap water
- Disadvantages: does not eliminate precleaning, does not monitor HLD concentration
- Problems: incompatible AER (side-viewing duodenoscope); contaminated AER; inadequate channel connectors
- Must ensure exposure of internal surfaces with HLD/sterilant
The 3 stages of effective endoscope reprocessing:

STAGE 1
Cleaning

STAGE 2
High-level disinfection

STAGE 3
Drying before storage: 70% alcohol rinse, forced air

Cleaning + high-level disinfection: $3 + 6 = 9$ log reduction of microorganisms (mycobacteria)

• Note 1: The 3 log reduction achieved during cleaning (stage 1) is used as the basis for 2% glutaraldehyde's recommended 20 minute soak at room temperature (during stage 2).

• Note 2: This diagram applies to all types of flexible endoscopes.

If STAGE 3 is skipped, waterborne microorganisms (e.g., Pseudomonas) may proliferate during storage and pose a serious risk of nosocomial infection, despite effective cleaning and high-level disinfection.

If STAGES 1, 2 and 3 are performed properly, there is virtually NO risk of nosocomial infection following endoscopy.
Source of contamination for infections (36 outbreaks) transmitted by GI endoscopes from 1974-2001:

- Cleaning-3 (12%)
- Disinfection-19 (73%)
- Rinse, Dry, Store-3 (12%)
- Etiology unknown-19
Ideal HLD/Chemical Sterilant

- Rapid HLD (< 10 min)
- No disinfectant residue after rinsing
- Excellent material compatibility
- Long shelf-life
- Nontoxic (no odor or irritation issues)
- No disposal problems
- Monitor minimum effective concentration
## List of different liquid chemical sterilants/disinfectants

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Formulation</th>
<th>concentration</th>
<th>disinfection claim</th>
<th>Sporicidal claim</th>
<th>MEC</th>
<th>Maximum days of reuse</th>
<th>Activation required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cidex, Metricide</td>
<td>glutaraldehyde</td>
<td>2.4%, 2.6%</td>
<td>45 mins @ 25° C</td>
<td>10 hours @ 25° C</td>
<td>1.5%</td>
<td>14</td>
<td>Yes</td>
</tr>
<tr>
<td>Cidex 7, Metricide 28</td>
<td>glutaraldehyde</td>
<td>2.5%</td>
<td>90 mins @ 25° C</td>
<td>10 hours @ 20-25° C</td>
<td>1.8%</td>
<td>28</td>
<td>Yes</td>
</tr>
<tr>
<td>Cidex Plus</td>
<td>glutaraldehyde</td>
<td>3.4%</td>
<td>20 mins @ 25° C</td>
<td>10 hours @ 20-25° C</td>
<td>2.1%</td>
<td>28</td>
<td>Yes</td>
</tr>
<tr>
<td>Rapicide</td>
<td>glutaraldehyde</td>
<td>2.5%</td>
<td>5 mins @ 35° C</td>
<td>7 hrs 40mins @ 35°C</td>
<td>1.5%</td>
<td>28</td>
<td>No (acidic)</td>
</tr>
<tr>
<td>Steris 20</td>
<td>peracetic acid</td>
<td>0.2%</td>
<td>12 mins @ 50-56°C</td>
<td>12 mins @ 50-56° C</td>
<td>NA</td>
<td>single-use</td>
<td>No</td>
</tr>
<tr>
<td>Sporox, Sporox II</td>
<td>hydrogen peroxide</td>
<td>7.5%</td>
<td>30 mins @ 20° C</td>
<td>6 hours @ 20° C</td>
<td>6.0%</td>
<td>21</td>
<td>No</td>
</tr>
<tr>
<td>Cidex OPA</td>
<td>ortho-phthalaldehyde</td>
<td>0.55%</td>
<td>(1) 12 mins @ 20° C</td>
<td>No claim; NA</td>
<td>0.3%</td>
<td>14</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>(dual label claim)</td>
<td>0.55%</td>
<td>(2) 5 mins @ 25° C</td>
<td>No claim; NA</td>
<td>0.3%</td>
<td>14</td>
<td>No</td>
</tr>
<tr>
<td>Cidex OPA Concentrate</td>
<td>ortho-phthalaldehyde</td>
<td>0.05% (use)</td>
<td>5 mins @ 50° C</td>
<td>No claim; NA</td>
<td>NA</td>
<td>single-use</td>
<td>No</td>
</tr>
<tr>
<td>Acecide</td>
<td>peracetic acid (PA),</td>
<td>7.0%</td>
<td>5 mins @ 25° C</td>
<td>5 hours @ 25° C</td>
<td>1900 ppm</td>
<td>5</td>
<td>No (mix 2 chemicals)</td>
</tr>
<tr>
<td></td>
<td>hydrogen peroxide</td>
<td>8.3%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aldahol III</td>
<td>glutaraldehyde, isopropyl alcohol</td>
<td>3.4%</td>
<td>10 mins @ 20° C</td>
<td>10 hours @ 20° C</td>
<td>2.1%</td>
<td>14</td>
<td>Yes</td>
</tr>
<tr>
<td>Sterilox</td>
<td>hypochlorous acid</td>
<td>650 ppm AFC</td>
<td>10 mins @ 25° C</td>
<td>No claim; NA</td>
<td>NA</td>
<td>single-use</td>
<td>No</td>
</tr>
</tbody>
</table>

**Market trends:** Decreasing immersion time; Increasing temperature; No "sterilization" label claim; Use only in an automated endoscope reprocessor (AER)

PA: peracetic acid  
MEC: minimum effective concentration  
AFC: available free chlorine  
ppm: parts-per-million  
NA: not applicable  
ASP: Advanced Sterilization Products (a division of Johnson and Johnson Medical)  
20° C equals "room temperature"
Glutaraldehyde (cidex)

- **Advantages**
  - Numerous use studies published
  - Relatively inexpensive
  - Excellent materials compatibility

- **Disadvantages**
  - Respiratory irritation from vapor
  - Pungent and irritating odor
  - Relatively slow mycobactericidal activity
  - Coagulate blood and fix tissues to surfaces
  - Allergic contact dermatitis
Ortho-phthalaldehyde (cidex OPA)

**Advantages**
- Fast acting HLD
- Excellent materials compatibility
- Not a known irritant to eyes and nasal passages
- Weak odor

**Disadvantages**
- Stains protein gray
- Cost ($30/gal); but lower reprocessing costs-soak time, devices per gal
- Slow sporicidal activity
- Hypersensitivity in some patients with a history of bladder cancer
<table>
<thead>
<tr>
<th>Glutaraldehyde</th>
<th>OPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0% Glutaraldehyde</td>
<td>0.55% Ortho-phthalaldehyde</td>
</tr>
<tr>
<td>HLD: 45 min at 25°C</td>
<td>HLD: 12 min at 20°C</td>
</tr>
<tr>
<td>Needs activator</td>
<td>No activator needed</td>
</tr>
<tr>
<td>14 day use life</td>
<td>14 day use life</td>
</tr>
<tr>
<td>2 year shelf life</td>
<td>2 year shelf life</td>
</tr>
<tr>
<td>Strong odor</td>
<td>Weak odor</td>
</tr>
<tr>
<td>Cost - $12/gallon</td>
<td>Cost - $30/gallon</td>
</tr>
</tbody>
</table>
Hydrogen Peroxide

**Advantages**
- No activation required
- Enhanced removal of organisms
- No disposal issues
- No odor or irritation issues
- Does not coagulate blood or fix tissues to surfaces

**Disadvantages**
- Material compatibility concerns for brass, zinc, copper, and nickel/silver plating (cosmetic and functional damage)
- Eye damage with contact
Peracetic Acid/Hydrogen Peroxide

Advantages

✓ No activation required
✓ No odor or irritation issues
✓ Effective in the presence of organic matter

Disadvantages

✓ Material compatibility issues for lead, brass, copper, zinc (both cosmetic and functional damage for 1% HP with 0.08% PA)
✓ Limited clinical use
Endoscope Reprocessing

- Background
- Infections related to endoscopy
- Reprocessing of endoscopes and accessories
  - Precleaning
  - Cleaning
  - High-level disinfection/sterilization
  - Automated endoscope reprocessing
- Quality control
ENDOSCOPE REPROCESSING

Staff Safety

- Personal protective equipment (e.g., gloves, gowns, eyewear, respiratory protection devices) should be available and used, as appropriate, to protect workers

- Reprocessing Room
  - Area designated for this function with: adequate space, proper airflow and ventilation, work flow patterns
infection of Emerging Pathogens
Disinfection and Sterilization of Emerging Pathogens

- Hepatitis C virus
- Clostridium difficile
- Cryptosporidium
- Helicobacter pylori
- E.coli 0157:H7
- SARS coronavirus
- Noroviruses
- Antibiotic-resistant microbes (MDR-TB, VRE, MRSA)
- Creutzfeldt-Jakob disease (no brain, eye, spinal cord contact)
Disinfection and Sterilization of Emerging Pathogens

Standard disinfection and sterilization procedures for patient care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood and other body fluids from persons infected with emerging pathogens.
ENDOSCOPE SAFETY
Quality Control

- Ensure protocols equivalent to guidelines from professional organizations
- Are the staff who reprocess the endoscope specifically trained in that job?
- Are the staff competency tested at least annually?
- Conduct IC rounds to ensure compliance with policy
- Consider microbiologic sampling of the endoscope
Conclusions

- Endoscopes represent a nosocomial hazard
- Proper cleaning and disinfection will prevent nosocomial transmission
- Current guidelines should be strictly followed
- Compliance must be monitored
- Safety and efficacy of new technologies must be validated