What the IP needs to know about endoscope reprocessing......

Objectives

- Identify standards relevant to processing of flexible endoscopes
- List potential errors that can occur during both manual and automated reprocessing
- Discuss current unresolved issues relevant to flexible endoscope reprocessing

Spaulding’s Classification

In 1968 Dr. Earle Spaulding devised a rational approach to disinfection and sterilization. This is now referred to as Spaulding’s Classification and it has been refined and retained over the years because it is so clear and logical. Spaulding believed that instruments and equipment should be cleaned and reprocessed according to the level of risk associated with their intended use.

<table>
<thead>
<tr>
<th>Body Contact</th>
<th>Disinfection Requirements</th>
<th>FDA Device Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact skin</td>
<td>Low level</td>
<td>Non-critical</td>
</tr>
<tr>
<td>Mucous membranes</td>
<td>High level</td>
<td>Semi-critical</td>
</tr>
<tr>
<td>Sterile body cavity</td>
<td>Sterilization</td>
<td>Critical</td>
</tr>
</tbody>
</table>
Spaulding Classification/Medical Instrument Classification

CRITICAL
- Penetrates skin or mucous membranes
  - Sterilization
    - Sterilization kills all microorganisms including HIGH numbers of bacterial spores
      - Heat (Steam or Dry)
      - Chemical Gas, Vapor, or Plasma
      - Radiation
      - Liquid Chemical
  - Examples: Biopsy forceps, angioscope

SEMI-CRITICAL
- Comes in contact with mucous membranes
  - High-level disinfection – minimum requirement
    - Kills all microorganisms except HIGH numbers of bacterial spores
  - Example: flexible bronchoscope

NON-CRITICAL
- Comes in contact with only intact skin; environmental surfaces
  - Intermediate- to low-level disinfection to soap and water cleaning
  - Tuberculocidal chemicals (phenolics, iodophors, chlorine, alcohols)
  - Hospital-type germicides (quats)
  - Examples: blood pressure cuff, OR table
Multisociety Guideline

- Purpose is to provide evidence-based guidelines for reprocessing GI scopes (colonoscopes and gastroscopes)
- Focuses on high-level disinfection
- Does not address reprocessing of flexible, rigid or semi-rigid endoscopes used in other procedures, such as cystoscopy and bronchoscopy
- Originally published in 2003, revised in 2011
- 39 key points

Endorsing Organizations

American Society for Gastrointestinal Endoscopy (ASGE)
Society for Healthcare Epidemiology (SHEA)
American College of Gastroenterology (ACG)
American Gastroenterological Association (AGA)
American Society of Colon and Rectal Surgeons (ASCRS)
Accreditation Association for Ambulatory Health Care (AAAHC)

Endorsing Organizations (cont’d)

Association of periOperative Registered Nurses (AORN)
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)
Association of Professionals in Infection Control and Epidemiology (APIC)
Gastroenterology Nurses and Associates (SGNA)
The Joint Commission (TJC)
**Reprocessing Steps**

<table>
<thead>
<tr>
<th>Step</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-cleaning</td>
<td>Rinse and flush endoscope in examination room and wipe outer surface.</td>
</tr>
<tr>
<td>Leak testing</td>
<td>Detect damage on the inside and outside of the endoscope.</td>
</tr>
<tr>
<td>Cleaning</td>
<td>As a manual cleaning procedure, brush off inside and outside of endoscope.</td>
</tr>
<tr>
<td>Disinfecting or sterilizing</td>
<td>Immerse in a high-level disinfectant or sterilant; list of approved sterilant and disinfectants has been provided by the FDA. Can be automated.</td>
</tr>
<tr>
<td>Rinsing</td>
<td>Rinse with sterile water, filtered water or tap water. Can be automated.</td>
</tr>
<tr>
<td>Drying</td>
<td>Rinse with alcohol and dry with forced air. Can be automated.</td>
</tr>
<tr>
<td>Storing</td>
<td>Avoid recontamination and facilitate drying.</td>
</tr>
</tbody>
</table>

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**CDC (Centers for Disease Control and Prevention) system for categorizing recommendations**

- **Category IA**: strongly recommended – supported by well designed studies
- **Category IB**: strongly recommended – supported by some studies & a strong theoretical rationale
- **Category IC**: required by state or federal
- **Category II**: recommended for implementation and supported by suggestive studies or theoretical rationale
- **No recommendation**: unresolved issue – insufficient evidence or no consensus

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**Precleaning**

2. "Precleaning should be performed at the point of use, before bioburden has an opportunity to dry and before complete decontamination. Point-of-use precleaning should remove visible debris by wiping the exterior of the endoscope with appropriate detergent solution and aspiration of a large volume of detergent solution through the air/water and biopsy channels".
Transporting Soiled Endoscopes

3. "An open container can suffice for transport to immediately adjacent processing rooms, but fully enclosed and labeled containers or bags should be used for transportation to distant reprocessing areas."¹

Medical equipment inventory

"In 2010, The Joint Commission required flexible and rigid endoscopes to be included in the medical equipment inventory of clinical engineering departments – even though only flexible endoscopes had been identified in the cross contamination warning." p. 176 ¹²

Appropriate Brushes

6. "Use brushes appropriate for the size of the endoscope channel, parts, connectors and orifices (e.g., bristles should contact all surfaces) for cleaning. Cleaning items should be disposable or thoroughly cleaned and disinfected/sterilized between uses."¹

- Ofstead study describes discrepancies
- FDA looking at the requirements of accessories that could reduce the breaches in cleaning

Category II – recommended for implementation and supported by suggestive studies

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Cleaning Studies

Study on the Impact of Human Factors

Manual high-level disinfection (MHLD)  Endoscope cleaning and reprocessing machine (ECR)

Summary of Results: Types of Nonadherence with Guidelines

- **MHLD**
  - 57% Did not brush all channels & components
  - 55% Did not dry with forced air
  - 22% Tested for leaks using sudsy water
  - 16% Skipped air purge after detergent flush
  - 14% Did not flush with alcohol
  - 10% Skipped final wipe down

- **ECR**
  - 25% Skipped final wipe down

Endoscope Channels and Capacity

<table>
<thead>
<tr>
<th>Channel</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air channel</td>
<td>∅ 0.7 mm</td>
</tr>
<tr>
<td>Water channel</td>
<td>∅ 0.7 mm</td>
</tr>
<tr>
<td>Biopsy channel</td>
<td>∅ 4.2 mm</td>
</tr>
<tr>
<td>Suction channel</td>
<td>∅ 4.2 mm</td>
</tr>
<tr>
<td>CO₂ channel</td>
<td>∅ 0.7 mm</td>
</tr>
<tr>
<td>Water jet channel</td>
<td>∅ 0.7 mm</td>
</tr>
<tr>
<td>Elevator channel</td>
<td>∅ 0.15 mm</td>
</tr>
</tbody>
</table>
Other studies referenced in Multisociety guideline

2009 – CDC piloted an audit tool at 68 ambulatory surgery centers to assess adherence to recommended practices.

- Following recommendations for reprocessing of endoscopic equipment was not uniform in 28.4% of the centers.
- Sample area covered 3 states.

Enzymatic detergents

7. "Discard enzymatic detergents after each use because these products are not microbicidal and will not retard microbial growth."

- Enzymatics denature protein.

Washing the Endoscope

Criteria in selecting a cleaner:

- Contains one or more enzymes
  * Breaks down complex proteins, carbohydrates, and fats
- Low foaming
- Works at room temperature
- Has a mild/neutral pH
- Rinses easily
- Acts rapidly
Use of Enzymatic Detergents

Common Misuses:
• Failure to dilute the enzymatic detergent
• Overdilution of detergent
• Use of expired enzymatic
• Inadequate exposure time
• Failure to adequately rinse
• Failure to change after each use

High-Level Disinfectants

11. "There are new high-level disinfectants and agent-specific machines on the market. Information regarding these technologies should be obtained from the FDA Web site and independent peer-reviewed publications. Use a high-level disinfectant cleared by the FDA for high-level disinfection."

Category IA – strongly recommended for implementation and strongly supported by studies

Routine Testing (MEC)

27. "Perform routine testing of the liquid high-level disinfectant to ensure at least the minimum effective concentration of the active ingredient. Check the solution at the beginning of each day of use (or more frequently) and document the results. If the chemical indicator shows that the concentration is less than the MEC, the solution should be discarded."

Category IA – strongly recommended for implementation and strongly supported by studies
**High Level Disinfectants**

Test Strips
- Used to test MEC (minimum effective concentration)
- Solution can typically be used if it meets the MEC or up to 14 days
- Requires a check prior to each use
- Log
- Control check – quality assurance procedure
- Storage of bottle

**Quality Control Procedure**
- Facilities known to be sited by TJC for failure to perform quality control checks on test strip bottles
- Need to follow the manufacturer’s specific instructions on how to perform quality checks
- Temperature of the solution should be monitored according to the manufacturer’s instructions

**Alcohol and forced air**

20. "After high-level disinfection, rinse the endoscope and flush the channels with sterile, filtered or tap water to remove the disinfectant solution.”
- Discard rinse water after each cycle
- Use 70 to 90% isopropyl alcohol and forced air
- Reduces risk of remaining pathogens and possibility of recontamination of water-borne microorganisms

*Category IA – strongly recommended for implementation and strongly supported by studies*
**Storing the Endoscope**

22. "When storing the endoscope, hang it in a vertical position to facilitate drying (with caps, valves and other detachable components removed, per manufacturer's instructions)." 

23. “Endoscopes should be stored in a manner that will protect them from contamination.”

Both Category II – recommended for implementation and supported by suggestive studies

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**Reuse of Endoscope After Processing**

24. "Although reuse of endoscopes within 10 to 14 days of high-level disinfection appears to be safe, the data are insufficient to provide a maximal duration for use of appropriately cleaned, reprocessed, dried and stored flexible endoscopes.”

- Needs further studies, several organizations have shorter storage intervals
- OR Manager article "What’s new in endoscopy guidelines?"

No recommendation – unresolved issue – insufficient evidence or no consensus

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**Bioburden Benchmark – Dr. Alfa 2012**

Study by Dr Alfa & associates looked at residuals found in reprocessed scopes over a 7-month period in an endoscopy center

99.5% of scope channels consistently demonstrated <100 cfu/mL of microbial growth

Looked at 20 flexible gastrointestinal endoscopes for the presence of bacteria and fungi early Monday morning

Periodic monitoring of scope channels (4-6 times per scope each year) could provide a check for compliance.
Water bottles

25. "High-level disinfect or sterilize the water bottle (used for cleaning the lens and irrigation during the procedure) and its connecting tube at least daily." \(^1\)

**Category IB – strongly recommended – supported by some studies & a strong theoretical rationale**

Maintaining a Log

26. "Maintain a log for each procedure indicating the patient’s name and medical record number (if available), the procedure, and the serial number or other identifier of the endoscope (and AER, if used) to assist in an outbreak investigation". \(^1\)

**Category II – recommended for implementation and supported by suggestive studies**

Discarding the liquid high-level disinfectant

28. "Discard the liquid high-level disinfectant at the end of its reuse life (which may be a single use), regardless of the minimal effective concentration. If additional liquid is added to an AER (or basin, if manually disinfected) the reuse life should be determined by the first use/activation." \(^1\)

-topping off does not extend its reuse life

**Category IB – strongly recommended – supported by some studies & a strong theoretical rationale**
Identifying when Endoscope has been processed

33. “Healthcare facilities should ensure that users can readily identify whether and when an endoscope has been processed.”

- Using a tag or sticker system

Category II – recommended for implementation and supported by suggestive studies

Transmission of Infection

More than 15 million flexible endoscopic procedures a year

American Society for Gastrointestinal Endoscopy (ASGE) estimate

- Chance of a serious infection being transmitted by an endoscope is 1 in 1.8 million

Actual number is unknown

- Infections difficult to recognize
- Increase in ambulatory procedures
- Fear of litigation and bad press

Importance of disinfection in reprocessing flexible endoscopes:

- Mycobacteria remaining in inadequately cleaned flexible bronchoscopes persisted after a full 60 min disinfection in 2% glutaraldehyde.
- Transmission of Serratia marcescens by an inadequately cleaned flexible bronchoscope, after 24 hr ethylene oxide “sterilization” process - causing several deaths. 2
Infection and Endoscope Reprocessing

Source of contamination for infections transmitted by GI endoscopes from 1974-2001:

- Cleaning - 3 (12%)
- Disinfection - 19 (73%)
- Rinsing, Drying, Storage - 3 (12%)
- Etiology unknown - 11 (3%)

Identified factors:

- Improper use/connection with AER
- Faulty filters leading to waterborne contamination
- Endoscope design
- Inadequate cleaning and/or processing

What Can Go Wrong?

Failure to:

- Leak test or test correctly
- Clean all channels
- Flush all channels with disinfectant
- Fully immerse endoscope
- Time disinfectant contact (no clock in processing area)
- Perform MEC test
- Discard outdated disinfectant
- Maintain standard for reprocessing
Endoscope Cleaning and Reprocessing (ECR) Technology

- Received FDA clearance for cleaning claims for manual cleaning prior to High-Level Disinfection
- SGNA – alerted users in 2007, 2009 and 2012, manual cleaning should be continued until clinical testing data is available
- Study by Dr Alfa et al. demonstrated that the cleaning cycle provided bioburden removal and was superior to optimal manual cleaning 7

What is Clean?

No specific standard

Recommendations for washing the endoscope:
- Meticulous cleaning immediately after use with an approved enzymatic detergent
- Use a validated cleaning protocol
- Do not let debris dry on endoscope

Bioburden on Flexible Endoscopes

- Cleaning removes all visible soil and significantly reduces the bioburden in order to facilitate the biocidal process.
- Devices should be cleaned promptly following the procedure to prevent bioburden from drying, which makes it more difficult to remove.
- Retained debris may inactivate or interfere with the capability of the active ingredient of the chemical solution to effectively kill and/or inactivate microorganisms.
Automated Reprocessing

- Timed cleaning
- Consistent exposure to cleaning agent
- Timed contact with liquid chemical germicide
- Air flush to remove moisture

Filtered rinse water
Copious and consistent rinse
Validated and consistent process
Minimizes personnel exposure to chemicals

Note: Not all automated reprocessors have all of the features

Do We Have Two Levels of Care?

Can say YES:
- If procedure driven
- If inconsistent practice
  - Disinfect throughout the day, sterilize at end of day
- If variation between departments
- If sterilize semi-critical items in OR and disinfect in Endoscopy

Two Levels of Care?

Can argue NO according to:

- **Joint Commission**
  Sterilizing some endoscopes while disinfecting others “creates no problem in the survey process” - there is no significant difference in nosocomial infection rate

- **APIC**
  “…not a double standard of patient care to sterilize endoscopes in one area and disinfect in another because the outcome is equivalent…”
Question...

An endoscope has been processed and hung overnight to dry...

*Does it need to be processed in the morning just before use?*

Reasons to Reprocess

- Could minimize likelihood of patient contamination if environmental bacteria proliferated overnight in scope channels
- No proof scope was properly processed/dried previously
- Media inferences

Reasons Not to Reprocess

- Increases processing costs
- Time consuming
- No data demonstrating clinical benefit to the patient
**Decision Criteria**

**Consider reprocessing if:**
- Endoscope channels are not routinely flushed with alcohol
- Moisture is noted when endoscope is removed from storage
- Potentially pathogenic bacteria have been noted in tap rinse water

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**Microbiological testing of endoscopes**

34. "The use of routine environmental microbiological testing of endoscopes for quality assurance has not been established but warrants further study."¹

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**Periodic Surveillance?**

- Defined as monitoring during a specific time period
- Periodic microbiologic sampling not generally recommended

➢ Not enough data to relate number of microorganisms on a surface with nosocomial infection rates
If You Decide To Sample

• Consult microbiology lab and infection prevention practitioner to develop protocol

• Culture the rinse water

• Process endoscope then use sterile brush to obtain sample from internal channels

What Can We Do?

• Proper training
• Performing procedure to maintain competency
• Understanding and compliance with national standards
• Time-saving measures (cutting corners)
• Cost savings
• Mixed messages from different manufacturers
• Quality improvement initiatives

Quality Improvement Steps

• Monitoring program in place to track compliance
• Provide feedback results to team
• Identify and reduce high-risk events
• Confidence reprocessing standards are followed EVERY TIME
• Understand the consequences of an improperly processed scope
Let's Review!

- Precleaning
- Transport of contaminated scopes
- Leak testing
- Manual cleaning process
- High-level disinfection
- Use of alcohol and air to promote drying
- Storage

References


Questions/Slides: www.disinfectionandsterilization.org (WA Rutala)


References

References