INFECTIOUS RISKS OF GASTROINTESTINAL ENDOSCOPY

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Introduction

• Beneficial role of GI endoscopy for the prevention, diagnosis, and treatment of many digestive diseases and cancer is well established.
Introduction

• Concern about the best methods for disinfection or sterilization of GI devices between patient uses to prevent bacterial and viral outbreaks following GI endoscopy

• 1 in 1.8 million procedure: Estimated risk of iatrogenic infection during gastrointestinal endoscopy
Disinfection classification

• The classification system first proposed by Dr. E.H. Spaulding divides medical devices into categories based on the risk of infection involved with their use.

Disinfection classification

Critical:

- A device that enters normally sterile tissue or the vascular system. Such devices should be **STERILIZED**, defined as the destruction of all microbial life.

- Biopsy forceps and sphincterotomes.
Disinfection classification

Semicritical:

• A device that comes in contact with intact mucous membranes and does not ordinarily penetrate sterile tissue.

• These devices (eg, endoscopes) should receive at least **HIGH-LEVEL DISINFECTION (HLD)**, defined as the destruction of all vegetative microorganisms, mycobacteria, small or nonlipid viruses, medium or lipid viruses, fungal spores and some, but not all, bacterial spores.
Disinfection classification

• HLD has been defined by the FDA as a 6-log reduction of mycobacteria and is recognized as appropriate for gastrointestinal endoscopes by the Center for Disease Control and Prevention (CDC)
Disinfection classification

Noncritical:

• Devices that do not ordinarily touch the patient or touch only intact skin, such as stethoscopes, electrodes or cautery plates. These items may be cleaned by low level disinfection.
Nosocomial transmission of microorganisms, can be categorized as:

• Nonendoscopic

Or

• Endoscopic
Nonendoscopic transmission of infection

Related to improper handling of intravenous sedation tubing, multidose vials and/or reuse of needles

Endoscopic transmission of infection

1. Transmission from patient to patient by contaminated endoscopic or accessory equipments
2. From the GI tract through the bloodstream during endoscopy to susceptible organs or prostheses
3. Or spread to adjacent tissues that are breached as a result of the endoscopy procedure
4. From patients to endoscopy personnel
5. From endoscopy personnel to patients
Management of Contaminated Mobile Surfaces

(Procedure Stretcher, Linens, Equipment, Patients)
Reprocessing endoscopic or accessory equipments

• Most guidelines for endoscope reprocessing prescribe the following six steps:
  Precleaning → Cleaning → Rinsing →
  Disinfection → Rinsing → Drying → Storage

N.B.: Follow manufacturers’ instructions
Reprocessing endoscopic or accessory equipments

• Accessories that penetrate the mucosal barrier (biopsy forceps, guide wires, cytology brushes,..):
  — Use once only
  — Or clean ultrasonically/mechanically and then sterilize/autoclave between each patient use.

• Accessories that are not passed through the working channel (bougies) should be autoclaved for 20 minutes at 134 °C
Pathogens that are difficult to eliminate, in decreasing order of resistance to disinfectants/sterilization:

- Prions * (e.g. CJD, BSE)
- Coccidia (e.g. Cryptosporidium spp)
- Bacterial spores (e.g. Bacillus spp, Clostridium difficile)
- Mycobacteria (e.g. M. tuberculosis)
- Cysts (e.g. Giardia spp)
- Small non-enveloped viruses (e.g. poliovirus)
- Gram-negative Bacteria (e.g. P. aeruginosa, Enterobacteriaceae)
- Fungi (e.g. Candida spp)
- Vegetative bacteria (e.g. S. aureus, Enterococcus, Streptococcus)
- Lipid enveloped viruses (e.g. CMV, RSV, HIV, HBV)

Disinfection levels:
- Sterilant: Disinfectant with prolonged exposure time
- High level
- Intermediate level
- Low level

Hospitals
Contaminated endoscopic or accessory equipments

- Infections and outbreaks due to contaminated GI endoscopes had been reported

Gastmeier P, Vonberg RP. Klebsiella spp. in endoscopy associated infections: we may only be seeing the tip of the iceberg. Infection 2014

Hong KH. Recent Update of Gastrointestinal Endoscope Reprocessing. Clin Endosc 2013
# Reported Pathogen Transmission

<table>
<thead>
<tr>
<th>Organism</th>
<th>No. of reported cases</th>
<th>Years of episodes</th>
<th>Reason for failure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteria</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>216</td>
<td>1974-2005</td>
<td>Inadequate cleaning</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inadequate disinfectant</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>AER or the water supply with its predilection for a moist environment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Failure to disinfect the elevator channel of duodenoscope</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Failure to completely dry channels of the endoscope</td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>48</td>
<td>1976-1987, no reported case since 1988</td>
<td>Failure to mechanically clean the internal instrument channel</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inadequate disinfectant</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inadequate disinfectant time</td>
</tr>
<tr>
<td><em>Helicobacter pylori</em></td>
<td>12</td>
<td>1988-2000</td>
<td>Suboptimal cleaning and disinfection</td>
</tr>
<tr>
<td><em>Enterobacteriacea</em> including <em>E. coli, Klebsiella, Enterobacter, and Serratiamarcescens</em></td>
<td>5</td>
<td>1975-1995</td>
<td>Flaws in the cleaning and disinfection process</td>
</tr>
<tr>
<td><strong>Viruses</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Hepatitis C virus</em></td>
<td>8</td>
<td>1993-2005</td>
<td>Contamination of syringe or multi-dose vials</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inadequate disinfection</td>
</tr>
<tr>
<td><em>Hepatitis B virus</em></td>
<td>5</td>
<td>1975-1999</td>
<td>Inadequate disinfection</td>
</tr>
<tr>
<td><strong>Parasites</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Strongyloides</em></td>
<td>1</td>
<td>1976</td>
<td>Unknown</td>
</tr>
</tbody>
</table>
Carbapenem-resistant Enterobacteriaceae (CRE)

• Several reports of outbreaks infections and colonizations in the US and Europe due to a GI endoscope, most often to an ERCP endoscope, contaminated with CRE.

• ERCP endoscope’s “forceps elevator” or “elevator area” is a recognized challenge for disinfection and has been implicated as the potential source of biofilm formation, bacterial growth, and persistent contamination.

CRE

Non-standardized practices for duodenoscope reprocessing:

• Quarantine procedures
• Routine or randomized culturing, using bioburden/adenosine triphosphate bioluminescence assays
• Alternative sterilization measures, such as ethylene oxide (ETO) gas
• Repeat HLD
## Compliance of Established Guidelines

<table>
<thead>
<tr>
<th>Investigator (reported time in year)</th>
<th>Object</th>
<th>Compliance, %</th>
<th>Culture positive, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gorse et al. (1991)</td>
<td>2,030 Members of SGNA in USA</td>
<td>67-93</td>
<td>-</td>
</tr>
<tr>
<td>Kaczmarek et al. (1992)</td>
<td>26 Health care facilities in USA</td>
<td>-</td>
<td>24</td>
</tr>
<tr>
<td>Jackson et al. (1997)</td>
<td>19 Family practice and internal medicine offices in USA</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Brullet et al. (2001)</td>
<td>144 Centers in Spain</td>
<td>79</td>
<td>-</td>
</tr>
<tr>
<td>Moses et al. (2004)</td>
<td>230 Members of SGNA in USA</td>
<td>50-85</td>
<td>-</td>
</tr>
<tr>
<td>Heudorf et al. (2006)</td>
<td>23 Private practices in Germany</td>
<td>52-74 (in 2003)</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>90 (in 2004)</td>
<td>-</td>
</tr>
<tr>
<td>Rățilă et al. (2006)</td>
<td>29 Centers in Romania</td>
<td>17.2-96.5</td>
<td>-</td>
</tr>
<tr>
<td>Schaefer et al. (2010)</td>
<td>67 Ambulatory surgical centers in USA</td>
<td>28.4</td>
<td>-</td>
</tr>
<tr>
<td>Barbosa et al. (2010)</td>
<td>60 Endoscopes in 20 medical services in Brazil</td>
<td>10-35</td>
<td>-</td>
</tr>
<tr>
<td>Zhang et al. (2011)</td>
<td>122 Endoscopy units in China</td>
<td>29.5</td>
<td>-</td>
</tr>
<tr>
<td>Soares et al. (2011)</td>
<td>25 Units in Portugal</td>
<td>48-88</td>
<td>-</td>
</tr>
</tbody>
</table>
Transmission of infection from endoscopy personnel to patients

- Endoscopy may be considered a low-risk task for transmission of serious infection from hospital personnel to patients
Transmission of infection from patients to endoscopy personnel

Potential modes of transmission may include:

- Needlestick injury
- Blood splashes to the conjunctiva
- Inhalation of aerosolized microorganisms
- Transfer from direct handling of patients
- Higher prevalence of H pylori infection in endoscopy personnel

Personnel training

- Training health care personnel in the endoscopy unit
- Protective equipments for protection against exposure to chemicals or potentially infectious materials
- Competency testing
Quality assurance

• Iatrogenic infection is related
  1. to the number of biofilm growth inside the endoscope
  2. in addition to mucosa damage during endoscopic service especially in case with immune compromise
• Microbiological surveillance is an instrument for detecting deficiencies in reprocessing process

## Microbiological surveillance test

<table>
<thead>
<tr>
<th>Guidelines or investigators (reported time in year)</th>
<th>Method</th>
<th>Sampling site</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>APIC (2000)\textsuperscript{26}</td>
<td>Rinse samples culture</td>
<td>Suction/biopsy, air/water, elevator, and carbon dioxide channels</td>
<td>Routine test not recommended</td>
</tr>
<tr>
<td>GESA (2003)\textsuperscript{37}</td>
<td>Rinse samples culture for channels Sample from manufactures’ guideline culture for AER</td>
<td>All channels AER</td>
<td>Every 4 weeks</td>
</tr>
<tr>
<td>German (2004)\textsuperscript{39}</td>
<td>Rinse samples culture</td>
<td>All channels</td>
<td>No longer than 3 months</td>
</tr>
<tr>
<td>ESGE-ESGENA (2008)\textsuperscript{40}</td>
<td>Rinse samples culture for channels and water bottle Swab culture from outer surface</td>
<td>All channels The outer surfaces The connected water bottle</td>
<td></td>
</tr>
<tr>
<td>BSG (2008)\textsuperscript{26}</td>
<td>Culture for atypical mycobacteria</td>
<td>AER</td>
<td>Annual testing</td>
</tr>
<tr>
<td>Canada (2010)\textsuperscript{41}</td>
<td>Rinse sample culture</td>
<td>Suction/biopsy and air/water channel</td>
<td>Routine test not recommended</td>
</tr>
<tr>
<td>ASGE-SHEA (2011)\textsuperscript{2}</td>
<td>Rinse sample culture</td>
<td>Suction/biopsy and air/water channel AER channel</td>
<td>Routine test not recommended</td>
</tr>
<tr>
<td>Gillespie et al. (2007)\textsuperscript{38}</td>
<td>Rinse sample culture</td>
<td>Suction/biopsy and air/water channel AER channel</td>
<td>Annually</td>
</tr>
<tr>
<td>Chiu et al. (2010)\textsuperscript{42}</td>
<td>Rinse sample culture</td>
<td>Internal channel</td>
<td></td>
</tr>
<tr>
<td>Alfa et al. (2012)\textsuperscript{43}</td>
<td>Rapid use scope test</td>
<td>Suction/biopsy channel</td>
<td></td>
</tr>
<tr>
<td>Chiu et al. (2012)\textsuperscript{44}</td>
<td>Rinse sample culture</td>
<td>Biopsy channel</td>
<td></td>
</tr>
<tr>
<td>Lu et al. (2012)\textsuperscript{45}</td>
<td>Swab culture</td>
<td>AER</td>
<td></td>
</tr>
</tbody>
</table>
Unresolved issues

SHELF LIFE

• Unclear. Reuse within 10 to 14 days appears to be safe

• If reprocessing process is appropriately done according to the established guidelines, endoscopes remain free from pathogenic organisms for at least 120 hours

Unresolved issues

PROPER FREQUENCIES FOR REPLACEMENT of clean water bottles, tubing for insufflation of air and lens wash water, waste vacuum canisters and suction tubing

• Concern relates to the possibility of backflow
Unresolved issues

ENDOSCOPE DURABILITY AND LONGEVITY

• The potential for reduced function or reduced ability to reach high level disinfection after a certain number of years or procedures need to be investigated
“The entire environment must be considered when developing infection control processes”
Infection Control gaps along the continuum of care in GI endoscopy can impact patient safety

Guidelines for safety in the GI endoscopy unit (ASGE 2014)