2016 Sterilization Standards Update
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IAHCSMM Representative to AAMI
Thank you to Onesourcedocs for your sponsorship.
Objectives

• Discuss the FDA Panel on Gastroenterology and Urology Devices
• Review the CDC & FDA Health Advisory Recommendations
• Present new Standards & Guidelines
• Introduce SGNA 2015 Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes
• Introduce AORN 2016 Guideline for Processing Flexible Endoscopes
Flexible Endoscopes

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

Gastroenterology and Urology Devices Panel May 14-15, 2015
Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication

To raise awareness among health care professionals, including those working in reprocessing units in health care facilities, that the complex design of ERCP may impede effective reprocessing.
Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication

- Challenging to clean and high-level disinfect due to complex design
- Transmission of infectious agents, ie CRE.
ERCP Scopes

Approximately 135 infections relating to possible microbial transmission from reprocessed ERCP scopes from January 2013 through December 2014,

- Infectious agents includes multidrug-resistant bacterial infections caused by Carbapenem-Resistant Enterobacteriaceae (CRE)
ERCP

- The moving parts of the elevator mechanism contain microscopic crevices that may not be reached with a brush.
- Residual body fluids and organic debris may remain in these crevices after cleaning and disinfection.
- If these fluids contain microbial contamination, subsequent patients may be exposed to serious infections.
IAHCSMM presented human factors issues

- Constant interruptions
- Complex IFUs
- Staff turnover
- Pressure to turn scopes
<table>
<thead>
<tr>
<th>Frequency</th>
<th>Response Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Every day</td>
<td>28.9%</td>
</tr>
<tr>
<td>Occasionally</td>
<td>53.7%</td>
</tr>
<tr>
<td>Never</td>
<td>19.4%</td>
</tr>
</tbody>
</table>

**Answered Question**

**Skipped Question**
11. How is training on scope reprocessing performed at your facility?

<table>
<thead>
<tr>
<th>Training Method</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formal training with competency completion</td>
<td>63.3%</td>
<td>635</td>
</tr>
<tr>
<td>Formal training</td>
<td>19.4%</td>
<td>195</td>
</tr>
<tr>
<td>Observation</td>
<td>12.3%</td>
<td>123</td>
</tr>
<tr>
<td>No formal training provided</td>
<td>5.0%</td>
<td>50</td>
</tr>
</tbody>
</table>

Answered question: 1,003
Skipped question: 334
12. Does your department receive education on flexible scope reprocessing when new scopes arrive at your facility?

<table>
<thead>
<tr>
<th></th>
<th>Response Count</th>
<th>Response Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>897</td>
<td>89.7%</td>
</tr>
<tr>
<td>No</td>
<td>103</td>
<td>10.3%</td>
</tr>
</tbody>
</table>

answered question: 1,000
skipped question: 337

13. In the past 12 months, have you received continuing education on flexible scope processing?

<table>
<thead>
<tr>
<th></th>
<th>Response Count</th>
<th>Response Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>738</td>
<td>73.5%</td>
</tr>
<tr>
<td>No</td>
<td>266</td>
<td>26.5%</td>
</tr>
</tbody>
</table>

answered question: 1,004
skipped question: 333
Hospitals performing ERCPs should do one of the following (priority ranked); doing nothing is not an option:

- Ethylene oxide sterilization after high level disinfection with periodic microbiologic surveillance
- Double high-level disinfection with periodic microbiologic surveillance
- High-level disinfection with scope quarantine until negative culture
- Liquid chemical sterilant processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance
- High-level disinfection with periodic microbial testing
Additional Recommendations

- Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism
- Implement a comprehensive quality control program with written procedures for monitoring:
  - training
  - adherence to the program,
  - documentation of equipment tests,
  - processes,
  - quality monitors used during the reprocessing procedure.
The Joint Commission BoosterPak

- Leadership
- Risk Assessment
- Sterilization
- Environment of Care
- High-level Disinfection
- Competency & Training
CDC & FDA Health Alert

Joint Alert Issued September 11, 2015

Alert issued due to identified lapses in healthcare reprocessing practices resulting in a critical gap in patient safety.
CDC & FDA Health Advisory

Recommendations

Have an expert/consultant assess reprocessing procedures to assure:

- Reprocessing is performed correctly
- Adequate time is allowed/taken
- All steps from the IFU are followed
CDC & FDA Alert
Recommendations

Training

- Through training upon hire, annually and with new instrumentation
- Provide demonstrated competency
- Maintain documentation of training and competency
- Have IFUs available
CDC & FDA Alert
Recommendations

Audit & Feedback

Perform regular reprocessing documented audits

- Prompt cleaning
- Use disinfectants according to IFUs
- Monitor sterilizer performance
- Monitor AER performance
- Conduct audits & feedback in all areas performing reprocessing
CDC & FDA Alert

Recommendations

Infection Control Policies & Procedures

• Ensure adequate time for all reprocessing steps

• Ability to identify patient ready items

• Have policies & procedures for processing errors;
  • Assess the error for risk of infection
  • Identification & notification of patients
  • Follow patients
CDC & FDA Alert
Recommendations

Infection Control Policies & Procedures

- Personnel responsible for re-processing & infection prevention consulted for new products
- Maintain documentation of all re-processing activities
- Follow manufacturers recommendations for maintenance & repair of their medical devices
Barrier Gown Protection

Minimal or Low Barrier protection:

- ANSI/AAMI PB70 Level 1 protection
- ANSI/AAMI PB70 Level 2 protection

Moderate or High Barrier protection:

- ANSI/AAMI PB70 Level 3 protection
- ANSI/AAMI PB70 Level 4 protection or equivalent
Class I Isolation Gown

Statements relating to barrier protection, statements are for only minimal or low barrier protection

- Not labeled as surgical gown
- Exempt from FDA 510k clearance
Class II Surgical Gown

Intended for use during sterile procedures

- Examples:
  - masks
  - gowns

- Requires FDA 510k clearance
Amendment to Containment devices for reusable medical device sterilization

ANSI/AAMI ST77/Amendment A.1/CDV-1
Container Cleaning

inappropriate for use due to interactions with the reprocessing steps (i.e., cleaning, disinfection and/or sterilization) appropriate cautions should be included in the container manufacturers accompanying validated written instructions for use.
# Chemical Indicator Terminology Change

## Table 1 — Categories according to intended use

<table>
<thead>
<tr>
<th>Intended use</th>
<th>Type</th>
<th>Category</th>
<th>Description (intended use)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicate exposure to a process to allow differentiation between unprocessed and processed items, and/or indicate gross failure of a sterilization process.</td>
<td>1</td>
<td>e1</td>
<td>&quot;Exposure&quot; or process indicator Requirements according to Type 1</td>
</tr>
<tr>
<td>Indicators for use in special applications, e.g. Bowie and Dick-type test.</td>
<td>2</td>
<td>s2</td>
<td>&quot;Special&quot; indicator (e.g. Bowie-Dick) Requirements in accordance with ISO 11140-3, ISO 11140-4, and ISO 11140-5.</td>
</tr>
<tr>
<td>Indicators to be placed inside individual load items and to assess attainment of the critical process variables at the point of placement.</td>
<td>3</td>
<td>i3</td>
<td>&quot;Internal&quot; indicator Single variable indicator Requirements according to Type 3</td>
</tr>
<tr>
<td>This indicator only reacts to one critical process variable.</td>
<td>4</td>
<td>i4</td>
<td>&quot;Internal&quot; indicator Multivariable indicator Requirements according to Type 4</td>
</tr>
<tr>
<td>This indicator reacts to more than one critical process variable.</td>
<td>5</td>
<td>i5</td>
<td>&quot;Internal&quot; indicator Integrating indicator Requirements according to Type 5</td>
</tr>
<tr>
<td>This indicator reacts to all critical process variables.</td>
<td>6</td>
<td>i6</td>
<td>&quot;Internal&quot; indicator Emulating indicator Requirements according to Type 6</td>
</tr>
</tbody>
</table>

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## HVAC Design Parameters

<table>
<thead>
<tr>
<th>Location</th>
<th>Air Changes</th>
<th>Air Flow</th>
<th>Humidity</th>
<th>Temp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decontam</td>
<td>10</td>
<td>Negative</td>
<td>Max 60%</td>
<td>60° F to 73°F</td>
</tr>
<tr>
<td>Prep &amp; Pkg</td>
<td>10</td>
<td>Positive</td>
<td>Max 60%</td>
<td>68° F to 73°F</td>
</tr>
<tr>
<td>Sterile Stores</td>
<td>4</td>
<td>Positive</td>
<td>Max 60%</td>
<td>≤ 75°F</td>
</tr>
<tr>
<td>Str Access Rm</td>
<td>10</td>
<td>Negative</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Environmental</td>
<td>10</td>
<td>Negative</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Satellite CSS</td>
<td>10</td>
<td>NR</td>
<td>Max 60%</td>
<td>60° F to 73°F</td>
</tr>
</tbody>
</table>

ASHREA American Society of Heating, Refrigerating and Air Conditioning Engineers
Decontam Considerations

- Lower temperatures can increase humidity resulting in growth of molds, bacteria….
- Impervious gowns do not release heat, based on thermodynamics
- Low temperature ranges extremely expensive & difficult to maintain
- Regulatory considerations
Instrument Air

A medical gas that falls under the general requirements for medical gases as defined by the NFPA 99: Health Care Facilities Code, is not respired, is compliant with the ANSI/ISA S-7.0.01, Quality Standard for Instrument Air, and is filtered to 0.01 micron, free of liquids and hydrocarbon vapors, and dry to a dew point of -40o F (-40o C).
Cleaning Implants

Implants should be free of all contaminates and residues that could result in adverse effects to the patient.
Cleaning Implants

- Implants should **not** be processed through a washer/disinfector with a lubrication cycle.
- Manufacturers of implants do not recommend using lubricants/instrument milk.
Cleaning Implants

- The use of lubricants can have an effect on implants.
- Cytotoxicity is a concern, since the sterile tissue will have prolonged contact with lubricant residue.
- Several implant manufacturers recommend using critical water as a final rinse to remove all residues.
Cleaning Implants

- Most washer/disinfectors can be programmed for customized cycles that exclude the lubrication cycle.
- Implants are critical devices, thus the final rinse should be with critical water to prevent water contaminates from being deposited on them.
ST 91 Flexible Endoscope Standard
Additional Recommended Practices & Guidelines
Intersocietal Accreditation Commission (IAC)

Association of periOperative Registered Nurses (AORN)

Society of Gastroenterology Nurses and Associates, Inc (SGNA)
Intersocietal Accreditation Commission (IAC) requires the TEE probes to be tested for electrical current leaks or damage between each use and to have this testing documented.
Required documentation for routine processing. TEE probe cleaning log.

- Document TEE leak test probe “pass” or “fail” the ultrasound transducer leakage tester.
- What actions were taken if the test “failed”
AORN Dress Code Clarification

The perioperative or sterile processing team member should wear scrub attire that covers the arms while preparing and packaging items in the clean assembly section of the sterile processing area.

Recommendation I.c.2
Recommendation 1.c.4

- When a long-sleeved jacket is worn, it should be snapped closed or buttoned up the front.
- Wearing the jacket snapped or buttoned closed helps prevent the edges of the front of the jacket from contaminating sterile areas.
AORN Dress Code Clarification

Recommendation III

III.a1 Personnel wearing scrub attire should not remove the surgical head covering when leaving the perioperative area
2015 SGNA

Society of Gastroenterology Nurses and Associates, Inc.

Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes
Personnel

- Annual demonstrate competency for all steps of endoscope reprocessing, including:
  - automatic endoscope reprocessing systems
  - other equipment
- Undergo more frequent validation of competency for specialty endoscopes that are used infrequently;
- Temporary personnel should not be allowed to clean or disinfect instruments in either a manual or an automated reprocessing system until competency has been established
Management

- Allow adequate time to follow all steps in the IFU
- Have adequate staff for meticulous and timely reprocessing;
- Observe staff for adherence to policies and protocols, possibly using an environmental tour checklist for endoscope reprocessing areas
Spill Containment Plan

Each endoscopy setting should have a spill containment plan for the chemicals that includes:

- Safety Data Sheet (SDS)
- Written procedures for actions to contain the spill and deactivate the chemical;
- Communication plan for both intra- and inter-departmental
- An evacuation plan.
- Personnel must be trained in the safe handling of high-level disinfectants or sterilants and spill containment procedures.
Quality Assurance

- Health care facilities must have policies and procedures detailing the response to any suspected or identified breaches in reprocessing (CDC, 2015).

- The procedure should indicate how the potentially affected patients should be identified, notified, and followed.
2016 AORN Guideline for Processing Flexible Endoscopes
Record the times that the endoscopy procedure is completed and the cleaning is initiated

- Biofilm begins to form within minutes
- Processing personnel need to know how long the endoscope has been waiting before processing
- May need to implement “delayed processing”

Recommendation IV.d.3
Mechanically clean and mechanically process flexible endoscopes by exposure to a high-level disinfectant or a liquid chemical sterilant or mechanically clean and sterilize

- Evidence shows that mechanical processing improves cleaning effectiveness
- Minimizes personnel exposure to biohazardous materials
- Can be monitored for quality and consistency
- Provides better rinsing of disinfectants
- Reduces the potential for breaches in recommended processing protocols associated with human error and noncompliance

Recommendation VIII.b
Use cleaning verification tests

- Cleaning verification reduce errors in manual cleaning
- Improve effectiveness.
- Cleaning verification testing
  - new endoscopes are purchased
  - established intervals, such as after each use.

*Recommendation XIII.f*
2016 AORN Guideline for Processing Flexible Endoscopes

Use a drying cabinet for storage

- Optimal storage of flexible endoscopes facilitates drying, decreases the potential for contamination
- Provides protection from environmental contaminants
- Internal and external surfaces should be continuously dried to suppress bacterial growth

Recommendation IX.b.1
Endoscope Storage

HEPA-filtered air

Drying cabinet
2016 AORN Guideline for Processing Flexible Endoscopes

Use a team to determine maximum storage time

- AORN no longer recommends a 5 day storage
- Evidence has shown there are unique storage variables that effect storage such as patient population, scope use, etc.
- To determine storage time assemble a multidisciplinary team including infection preventionists, endoscopy RNs, endoscopy processing personnel, endoscopists, etc to review the process

Recommendation IX.h
2016 AORN Guideline for Processing Flexible Endoscopes

Ensure cleaning and processing is conducted by individuals who have received education and completed competency verification activities related to endoscope processing.

Flexible endoscopes and accessories processed by techs who have received education and completed competency verification related to endoscope processing.

Recommendation II.k
Future Trends
Cleaning Verification

- Visual
- Visual with magnification
- Boroscope
- ATP Testing
- Protein Testing
- Residual protein detection system
Quality Systems

Processing Health Care Products
Quality Systems

• Quality Manual
  • Documentation

• Planning

• Communication

• Needed Resources
  • Equipment
  • Human Resources
Quality Systems

- Purchasing
  - CSS input
- Processing requirements
  - Cleaning implements
  - Decontam equipment
  - Sterilization requirements
  - Competency
Quality Systems

• Traceability
  • Product traceability
  • Loaner traceability

• Measurement, analysis, and improvement
QUESTIONS
References

• FDA Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication

• ANSI/AAMI ST77/Amendment A.1/CDV-1 Containment devices for reusable medical device sterilization

• The Joint Commission BoosterPak 2015

• AORN 2016 Guideline for Cleaning and Processing Flexible Endoscopes and Endoscope Accessory
References

- CDC Health Alert Network September 11, 2015, CDCHAN-00382
- SGNA 2015 Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes
- Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *Guideline for disinfection and sterilization in healthcare facilities*
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