Improving the Quality Control of Flexible GI Endoscope Reprocessing

January 21, 2016
Grace Thornhill and Larry Talapa

House Keeping

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House Keeping

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• Both Grace Thornhill and Lawrence Talapa are employees of 3M Infection Prevention Division

Learning Objectives
1. Present flexible endoscope reprocessing and the risk of endoscope-associated infections (EAI)
2. Explain why cleaning verification is a necessary component of a quality control program
3. Describe the application of low temperature sterilization to endoscopes
4. Discuss implementation of a quality control program to help address EAI

The Outbreaks: In the news but not new.....
There is a well documented history of outbreaks
What is the issue?

In the past year there has been a significant increase in reports of outbreaks related to the use of Duodenoscopes for ERCP.

What is ERCP?

- Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure that combines the use of endoscopy and fluoroscopy to diagnose and treat certain problems of the biliary or pancreatic ductal systems.
- You will often see the term "ERCP scope" used. ERCP is a procedure that uses a side-view duodenoscope (an upper GI flexible endoscope).

The Outbreaks: The microbes are changing the game

- Carbapenem-resistant Enterobacteriaceae – CRE
- Limited or no treatment
- High transmission rate 6-46%
- High mortality rate ~ 50%

www.cdc.gov/drugresistance/threat-report-2013/
CRE Outbreaks – A Wake Up Call

• Tampa
• Chicago
• Pittsburgh
• Seattle
• Wisconsin
• Los Angeles (1)
• Los Angeles (2)
• Los Angeles (3)
• These events triggered a Senate Investigation; found 25 outbreaks

Preventable Tragedies:
Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients, Jan.13, 2016
United States Senate Health, Education, Labor and Pensions Committee
Patty Murray, Ranking Member

• Senator Murray’s staff investigation has demonstrated that the clusters of infections at Virginia Mason and Advocate Lutheran were not isolated incidents. Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different incidents of antibiotic-resistant infections that sickened at least 250 patients worldwide.
• Hospitals, FDA and mfr’s all failed in their responsibility to report, notify and act on knowledge that outbreaks were occurring.

What is the response?
FDA
CDC
Manufacturers Associations
The complex design of duodenoscopes may impede proper reprocessing
Meticulous manual cleaning should reduce risk of transmission of infection
Implement a comprehensive Quality Control program
Quarantine scopes suspected of association with patient infection until shown to be free of pathogens

http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm434871.htm

FDA seeking expert scientific and clinical opinion. 19 member advisory panel.
“Duodenoscopes and AERs do not provide a reasonable assurance safety and effectiveness”
“Manual Cleaning is a critical component.”
There is a need for “...development and validation of cleaning verification assays”
“Majority of the panel also believes it is necessary to reclassify duodenoscopes from semi-critical to critical and support the move from high level disinfection to sterilization.”

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm

Enhanced measures include:
- Ethylene Oxide Sterilization.
- Multiple rounds of High-Level Disinfection
- Use of a liquid chemical sterilant processing system
- Microbial surveillance

Implementation of these additional measures may not be feasible
The limitations of each of these measures must be taken into consideration.
These measures are to be considered in addition to following manufacturer's instructions for reprocessing, meticulous manual cleaning and the implementation of a comprehensive quality control program.
Are there any new recommendations?

APIC: Association for Professionals in Infection Control and Epidemiology
ASGE: American Society for Gastrointestinal Endoscopy
SGNA: Society for Gastroenterology Nurses and Associates.
SHEA: Society for Healthcare Epidemiology of America

- Follow manufacturer’s instructions for reprocessing
  - Olympus, Fujinon published new IFU
- Pay special attention to manual cleaning
  - Meticulous cleaning required
  - Elevator mechanism needs special attention
- Implement comprehensive training
- Verify competency
- Periodic review of policies and procedures
- ASGE also recommends microbial surveillance

ANSI/AAMI ST91:2015 Flexible and semi-rigid endoscope reprocessing in health care facilities

- Design of the endoscope processing area, including work flow considerations
- Personnel issues such as training, hygiene, clothing, policies, and immunizations
- Processing steps: pre-cleaning, leak-testing, manual cleaning, high-level disinfection, sterilization, storage
- Various topics including automated endoscope reprocessors (AER), sterile endoscope sheaths, and processing accessories
- Storage and transport
- Quality control
- Bibliography

Flexible GI scopes are not the only problem!!


FDA analysis to date has identified two recurrent themes:
- Failure to meticulously follow manufacturer instructions for reprocessing
  - Continued use of devices despite integrity, maintenance and mechanical issues.”

FDA Recommendation: “Implement a comprehensive reprocessing quality control program. Your reprocessing program should include written procedures for monitoring, training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.”
CDC Interim Duodenoscope Protocol 3/12/15

• Still working on protocol so is subject to change
• Sensitivity of this method is unknown
• Look for pathogens and elevated levels of non-pathogens
• Frequency of testing not defined
  o Weekly, monthly, every time, every 60 procedures
• Pay Special attention to
  o Inspection and Manual Cleaning
  o Drying
http://www.cdc.gov/hai/outbreaks/index.html

CDC Interim Protocol: The Jury is Still OUT……

• “…Not sufficient in the current form to be implemented by healthcare facilities as best practice”  FDA Panel on Gastroenterology and Urology, May 14-15, 2015
• Sensitivity unknown  CDC Interim Protocol for Duodenoscope Surveillance
• “…clinical microbiology labs should not perform routine cultures of reprocessed duodenoscopes due to lack of data on utility of such culturing”  American Society for Microbiology statement on CDC Interim Protocol.

Culturing Scopes: What are the limitations?

Current methods are not sensitive enough to detect low-levels of bacteria, limitations of these methods not being discussed

Current methods:
  o Do not detect all bacteria
  o Do not detect viruses or parasites
  o Do not substantiate cleanliness
  o Do not substantiate any level of sterilization or disinfection

Current methods not sufficient for sampling duodenoscopes
  o Biofilm bacteria must be cultured differently
  o Bacteria exposed to disinfectants need special culture conditions
Why Cleaning Verification is a Necessary Component of a Quality Control Program

We do not understand basic definitions

<table>
<thead>
<tr>
<th>Cleaning</th>
<th>High-Level Disinfection (HLD)</th>
<th>Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Removal of organic soil</td>
<td>• Microbial kill under defined conditions</td>
<td>• Kills all living organisms including spores</td>
</tr>
<tr>
<td>• Microbes and soil can still be present</td>
<td>• Spores are not killed</td>
<td>• Effectiveness dependent on meticulous cleaning</td>
</tr>
<tr>
<td>• Device can still be infectious</td>
<td>• Effectiveness dependent on meticulous cleaning</td>
<td></td>
</tr>
</tbody>
</table>

Flexible Endoscope Reprocessing What are we doing wrong?

Cleaning
- Removal of organic soil
- Microbes and soil can still be present
- Device can still be infectious

High-Level Disinfection (HLD)
- Microbial kill under defined conditions
- Spores are not killed
- Effectiveness dependent on meticulous cleaning

Sterilization
- Kills all living organisms including spores
- Effectiveness dependent on meticulous cleaning
The Outbreaks: No consistent root cause

How did the duodenoscopes become contaminated?
- Occult defects in the flexible endoscope
- Inadequate cleaning
  - Elevator Guidewire Channel, Elevator Mechanism, Suction/Biopsy Channel
- Complex design of duodenoscope
- Current Reprocessing Guidelines are not adequate
  - Residual contamination found after scopes have been reprocessed, overhauled by mfr, subjected to enhanced cleaning.
- Staff training inadequate, Questions on competency

Overview of Flexible Endoscope Reprocessing

Pre-Cleaning: Occurs in procedure room. Wipe down and flush scope. Prepare for transport to reprocessing.
Leak testing: Followed by complete disassembly of scope
Manual Cleaning: Flushing, brushing all parts and channels of the scope, purge with air
Visual Inspection: Inspect for conditions that might affect HLD
High-Level Disinfection: Automated in AER or can be performed manually
Drying: Air and Alcohol flush, Wipe down external surfaces
Storage: Vertical Hang

Implementation of a Quality Control (QC) Program

"Implement a comprehensive quality control program for reprocessing duodenoscopes. Your reprocessing program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure."

Design of Endoscopic Retrograde Cholangiopancreatography (ERCP)
Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication

What to consider? Quality Control through the implementation of rapid cleanliness indicators, ethylene oxide sterilization to replace HLD and appropriate use of microbial monitoring audits.
Common responses to the current outbreak information

- Wait for new guidelines, new scope designs, definitive research
- Don’t do anything because you believe you don’t have transmission issues.
- Don’t worry because you don’t use duodenoscopes.
- We’ve never had a problem so there is nothing to fix.

What can you do now? What does everyone agree on?

Focus on Manual Cleaning

- It is a problem
- It is critical to success of HLD and Sterilization
- Lack of proper manual cleaning contributed to outbreaks
- It can be improved by monitoring cleaning efficacy
  - AORN, AAMI and SGNA all recommend implementation of cleaning verification
- Use validated, real-time indicators of cleaning efficacy
  - Commercially available kits that test for ATP, protein, hemoglobin, carbohydrate

Why are flexible endoscopes difficult to reprocess?

- Complex design
- Multiple, long, narrow, channels that are difficult to clean
- Lack of consistent effective training
- Lack of time and resources for adequate reprocessing
- Visual inspection not adequate to monitor efficacy of reprocessing.
  - > 120 step involved in reprocessing!!
ANSI/AAMI ST91 Section 12: Quality Control

- QC is critical to successful reprocessing
- All facilities should have a comprehensive QC program
  - Product identification and traceability
  - Documentation and record-keeping
  - Verification and monitoring of the cleaning process
  - Monitoring of high-level disinfection and sterilization processes
  - Product recalls
  - Quality process improvement

ST91 – Cleaning Verification: What do the Pass/Fail benchmarks mean?

- The Pass/Fail benchmarks were developed to assess if a scope was cleaned according to manufacturer’s instructions.
- Pass/Fail benchmarks for cleaning verification are not a measure of the risk of pathogen transmission
- Patient Safety claims are based on the successful performance of the entire reprocessing procedure
- Only the disinfection or sterilization step has any claim on microbial kill

What do we do now?

We can no longer assume that GI endoscopy is a low risk procedure.

Implement QA programs
- Written policies
- Training/Competencies
- Regular Audits and continued oversight
- Make sure IFUs are up to date, they are changing!
- Informed consent for patients

Implement a monitoring program for manual cleaning
- Multiple sampling sites
- Multiple methods
- Every scope, Every time
Application of low temperature sterilization to flexible endoscopes

Biocidal Practices for Flexible Endoscopes

High level disinfection (HLD) options in ANSI/AAMI ST58:2013
- Glutaraldehyde solutions
- Hydrogen peroxide solutions
- Ortho-phthalaldehyde (OPA) solutions
- Peracetic acid solutions
- Sodium hypochlorite–hypochlorous acid

All have advantages and disadvantages
All have toxicity limits to consider

HLD used for faster reprocessing and device turnaround times
HLD designed with less margin of safety vs. terminal sterilization

Definition of disinfection
Demonstrate ability to kill 6 Logs of organisms
Various test organisms (not all spores)

"Process that kills pathogenic and other microorganisms by physical or chemical means"

"Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms such as bacterial spores" (ANSI/AAMI ST58: 2013)
Biocidal Practices for Flexible Endoscopes

- Sterilization is designed for a higher margin of safety
- Demonstrate ability to kill 12 Logs
- Sterilization Assurance Level (SAL 10⁻⁶)
- Validation includes testing the processes most resistant bacterial spores

“Required to kill all types of microorganisms including bacterial spores”

(a validated process used to render product free from viable microorganisms) (ISO/TS 11139:2006)

HLD designed with a less margin of safety vs. terminal sterilization

HLD - 6 Logs

\[1,000,000 = 10 \times 10 \times 10 \times 10 \times 10 \times 10 = 10^6\]

“Disinfection processes do not ensure the margin of safety associated with sterilization processes”

AAMI and FDA Documents

Sterilization - 12 Logs

\[1,000,000,000,000 = 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 = 10^{12}\]

Sterilization increases the margin of safety compared to HLD!
Sterilization of Flexible Endoscopes

**Terminal Sterilization:**
FDA cleared to demonstrate 12 logs of bacterial spore kill to a validated sterility assurance level (SAL) of 10^-6.

Because log linear kinetics have not been demonstrated for most liquid chemicals, other methods are used to evaluate the efficacy of those products.

ANSI/AAMI ST58:2013

Biocidal Practices for Flexible Endoscopes

Ask yourself
Ask your vendor
Does your automated endoscope reprocessor (AER) provide 12 logs of bacterial spore kill?
Effectiveness - Ethylene Oxide Sterilization

Foliente et al. ethylene oxide sterilization eliminate all organisms from duodenoscopes and colonoscopes in simulated use testing. Several methods of high level disinfection did not result in complete activation.

<table>
<thead>
<tr>
<th>Type of procedure</th>
<th>Physical damage</th>
<th>Chemical damage</th>
<th>Bacteria (CFU)</th>
<th>Bacteria (CFU)</th>
<th>ETO sterilized</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Alcohol</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>High level disinfection</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ethylene oxide sterilization</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Effectiveness - Ethylene Oxide Sterilization**

- Epstein et al. JAMA 2014; 312:1447-1455
- Northeastern Illinois Hospital
- First reported in CDC Morbidity and Mortality January 2014
- No breach in reprocessing with HLD identified

Ethylene oxide sterilization of endoscopes

*...*gas sterilization contributed to controlling this outbreak...*

**Effectiveness - Ethylene Oxide Sterilization**

- Zachary L. Smith, et al. GASTROINTESTINAL ENDOSCOPY Volume 81, No. 4 : 2015
- Milwaukee, Wisconsin
- Review of the disinfection procedure revealed that all standard recommendations and guidelines with regard to endoscope reprocessing were followed

*...*after ETO sterilization of all duodenoscopes, no additional cases of CRE infection were diagnosed...*
Effectiveness - Ethylene Oxide Sterilization

University of Pittsburg Medical Center
No breach in reprocessing with HLD identified

"...no additional healthcare-associated infections have been noted since ERCP/EUS scope reprocessing included ETO..."

Effectiveness - Ethylene Oxide Sterilization

FDA Gastroenterology and Urology Devices Advisory Panel
Key Invited Speakers

Zachary A. Rubin M.D.
UCLA Clinical Epidemiology & Infection Prevention Los Angeles, CA
Carbapenem-resistant Klebsiella pneumoniae following ERCP at RRUMC, December 2014 to January 2015
No new infections after starting ethylene oxide sterilization

William A. Rutala PhD, M.P.H (University of North Carolina, School of Medicine, Chapel Hill, NC)
"Doing Nothing is Not An Option"
Hospitals performing ERCP should do one of the following (5 options ranked in priority)
1. Ethylene oxide sterilization after HLD with periodic microbiologic surveillance (currently performed at UNC, Chapel Hill)
Ethylene oxide (EtO) sterilization following cleaning and high-level disinfection...

“Implementing EtO gas sterilization is costly and the process may not be readily available in or accessible to all health care facilities.”

- EO sterilization is a commercially available technology for use in a hospital
- Over 600 U.S. health care facilities (49 states except Alaska) have ethylene oxide sterilization capability, total number of ethylene oxide sterilizers in the U.S. is greater than 1000 sterilizers
- The two newest EO sterilizers on the U.S. market received FDA 510(k) clearance this year in January 2015

Ethylene oxide (EtO) sterilization following cleaning and high-level disinfection...

“EtO may affect the material and mechanical properties of the duodenoscope.”

- No published references to support this statement
- 3M has customers that have successfully used ethylene oxide sterilization for their endoscopes for many years
- CDC 2008 “[EO] Can sterilize heat or moisture-sensitive medical equipment without deleterious effects on the materials used in medical devices”
- It is possible that this presumption is based on confusing ethylene oxide with hydrogen peroxide which has known (published) material compatibility limitations

Ethylene oxide (EtO) sterilization following cleaning and high-level disinfection...

“It is critical that devices are meticulously cleaned and disinfected prior to EtO sterilization. Gas sterilization with ethylene oxide may fail in the presence of viable microorganisms after inadequate cleaning and disinfection.”

- Meticulous cleaning is always important for all sterilization methods
- All methods of sterilization and high level disinfection would be challenged by microorganisms embedded in clinical soil inside an endoscope channel
- Alfa et al. Zentral Sterilization Central Service 2005;13 “…prevacuum steam, ethylene oxide, and peracetic acid fails in the presence of organic material...”
FDA Safety Communication August 4th 2015

Ethylene oxide (EtO) sterilization following cleaning and high-level disinfection...

“EtO may be toxic to reprocessing personnel, and to patients if residual EtO remains on the device after sterilization.”

• EO has been safely used in health care for over 50 years! If in doubt, monitor your employees and procedures to demonstrate safety!
• EO is safe when used per medical device manufacturer’s (MDM) instructions for use (IFU) and sterilizer manufacturer’s operators manual cleared by the FDA.
• Medical device manufacturer’s (MDM) validates the device is safe for patient use; FDA reviews MDM’s device safety testing before clearance to market in U.S.

FDA Safety Communication August 4th 2015

Ethylene oxide (EO) sterilization following cleaning and high-level disinfection...

“Health care facilities should assess their supply and clinical demand for duodenoscopes when considering EO sterilization.”

• Implement a tiered approach to the frequency of ethylene oxide sterilization of endoscopes
• Purchase new or rent additional endoscopes
• Surgery / procedure schedules can be optimized to accommodate reprocessing times
• Purchase new or additional EO Sterilizers
FDA Safety Communication August 4th 2015

Ethylene oxide (EtO) sterilization following cleaning and high-level disinfection...

"Users should follow duodenoscope manufacturer reprocessing instructions pertaining to EtO concentration, sterilization temperature, exposure time, and relative humidity."

- These are the four critical parameters for EO sterilization
- Other process variables listed in the endoscope manufacturer’s IFU typically are not the critical process variables routinely verified for the safe and effective use of ethylene oxide sterilization

Overview Ethylene Oxide Sterilization
Flexible Endoscopes

<table>
<thead>
<tr>
<th>Package*</th>
<th>Sterilize* in Locked Chamber Under Vacuum</th>
<th>Aerate* in Chamber</th>
<th>Store DRY Sterile in Package</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>Estimated 4 - 5 hours</td>
<td>Estimated 12* hours</td>
<td>&quot;Follow device manufacturers IFU&quot;</td>
</tr>
</tbody>
</table>

What is ethylene oxide (EO)?

EO is a simple molecule
- 1) Oxygen
- 2) Carbons
- 4) Hydrogens
EO is natural and organic
- EO is a byproduct of microbial ethylene catabolism
- Formed through several metabolic pathways with ethylene
Endogenous to some plants and humans
- Formed through several metabolic pathways with ethylene
Sustained higher levels are toxic

EO Molecule

*Follow device manufacturers IFU
Safety Documentation Ethylene Oxide Sterilization

- 50 years of use in U.S. Healthcare facilities
- Collective knowledge of global experts
- Documented in National and International Standards
- Recognized U.S. Food and Drug Administration Consensus Standards
- American National Standards Institute (ANSI) / Association Advancement
  Medical Instrumentation (AAMI)
- Environmental Protection Agency (EPA)
- Occupational Safety and Health Administration (OSHA)
- International Standard Organization (ISO)
- International Association of Healthcare Central Service
  Materials Management (IAHCSMM) Central Service
  Technical Manual (7th ed)

Packaging, Preparation, and Loading

Preparation for Terminal Sterilization with EO

- Some endoscopes require connecting a ventilation adapter (ventilation cap)
- Some endoscopes are vented by the REMOVEAL of the water resistant cap
  (soaking cap)
- Some brands and models of endoscopes require BOTH and the removal of
  subparts.
- Always follow the manufacturer's instructions for use!

Terminal Sterilization Packaging for EO

- Rigid containers
- Plastic trays, metal baskets with disposable sterilization wraps or (woven) muslin
- Pouches (paper / plastic or spun-bonded olefin / plastic)
- Must be cleared for use in EO by U.S. FDA for use in the U.S.
Quality Control - Ethylene Oxide Sterilization


Association of periOperative Registered Nurses (AORN) Recommended Practices section on EO processing

Quality Control - AAMI ST41:2008/(R)2012

Physical monitoring of cycle

- Exposure time
- Exposure temperature
- Relative humidity
- Aeration time and temperature
- Follow sterilizer manufacturer’s instruction’s for use

Chemical Indicators for EO

- External chemical indicator distinguish between processed and unprocessed
- Internal chemical indicator for equipment malfunctions and can assist in certain procedural errors

Biological Indicators for EO

- BIs are the only sterilization process monitoring device that provide a direct measure of the lethality of the process

Biological Indicators in PCDs for EO - providing a challenge to the process that is equal or greater than the challenge posed by the most difficult item routinely processed
7 Levels Quality Control - AAMI ST41:2008/(R)2012

1. Routine load release  
   Routine sterilization efficacy monitoring
   - Testing of each non-implant and implant load

2. Sterilizer testing after sterilization process failures
   Sterilizer qualification testing after malfunctions, major repairs
   - Routine BI test pack or a commercially available BI PCD

3. Sterilizer testing after sterilization process failures
   Sterilizer qualification testing after installation, relocation
   - Monitoring one cycle with routine BI test pack or commercial equivalent.

4. Sterilizer qualification testing after sterilization process failures
   Sterilizer qualification testing after major redesign
   - Testing of the sterilizer after any monitoring device suggests that the process was inadequate.
   - Testing consists of monitoring one cycle with routine BI test pack or commercial equivalent.

5. Sterilizer qualification testing after malfunctions, major repairs
   Sterilizer qualification testing after major redesign
   - Malfunctions identified after sterilization process must be corrected. Major repair: repair outside the scope of normal maintenance.
   - Qualification consists of three consecutive cycles with routine BI test pack or commercial equivalent.

6. Sterilizer qualification testing after installation, relocation
   Sterilizer qualification testing after major redesign
   - Malfunctions identified after sterilization process failures must be corrected. Major repair: repair outside the scope of normal maintenance.
   - Qualification consists of three consecutive cycles with commercial equivalent.

7. Periodic product testing
   Testing of the sterilizer after installation or relocation using one or more challenge BI test pack(s). Three consecutive cycles using simulated load.
   - Testing of the sterilizer after installation or relocation using one or more challenge BI test pack(s).
   - Three consecutive full cycles with challenge BI test pack(s) in simulated load.
   - Three consecutive half-cycles with challenge BI test pack(s) in an otherwise empty chamber.
   - Testing of the sterilizer after installation or relocation using one or more challenge BI test pack(s).
   - Three consecutive full cycles with challenge BI test pack(s) in an otherwise empty chamber.

Quality Control - AAMI ST41:2008/(R)2012

Routine Load Release / Sterilizer Efficacy Monitoring
- Physical monitoring of cycle (sterilizer cycle report)
- External and internal monitoring of packages with chemical indicators
- Monitoring of every load with a PCD (routine test pack) containing a BI and a CI or equivalent, commercially available BI PCD

Device Use or Storage
- EO sterilization is a terminal sterilization method
- The device can be stored and remain safe for patient use in the primary package in sterile storage area
- ‘Hang-time’ is not a consideration following terminal sterilization when device remains in primary package

Quality Control Comparison

<table>
<thead>
<tr>
<th>Quality Control Measure</th>
<th>EO Sterilization</th>
<th>HLD or LCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packaged for Terminal Sterilization</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Critical Physical Parameters in Cycle Report</td>
<td>YES</td>
<td>Manual – No AER – Yes (if w/ printout)</td>
</tr>
<tr>
<td>External Chemical Indicators on Device Package</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Internal Chemical Indicators inside Device Package</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Biological Indicator Designed per International Standards</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Process Challenge Device Representing Worst Case Device</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>
Quality Control Measure Comparison

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<tr>
<th>Quality Control Measure</th>
<th>EO Sterilization</th>
<th>HLD or LCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum Effectiveness Concentration of HLD</td>
<td>N/A</td>
<td>YES (solution test strip)</td>
</tr>
<tr>
<td>Spore Test Strip HLD</td>
<td>N/A</td>
<td>For one system only</td>
</tr>
<tr>
<td>Allows for Recognized Method Product Testing</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Acceptable Method for Implants</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Endoscope is Dry for Storage after Processing</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Endoscope is Packaged in Sterile Packaging?</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

Conclusions

1. The effectiveness and quality of endoscope reprocessing is inconsistent. Implement a Quality Control Program that includes the use of validated, real-time cleaning verification monitors (ATP, protein, hemoglobin, carbohydrate) for routine QC of manual cleaning effectiveness.
2. Microbial surveillance should be used as an audit tool. Limitations of methods and data should be thoroughly understood.
3. Ethylene Oxide sterilization of endoscopes will provide a higher standard of care with an increased margin of safety over high level disinfection.
4. Ethylene oxide sterilization processes have established and rigorous control testing programs that includes test of equipment and physical, chemical, and biological monitoring of every load and cycle.

Next Live Webinar

Date: Thursday February 18th
Title: It's Survey Time! Preparing for TJC or CMS Accreditation Survey.
References

  [http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm434871.htm](http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm434871.htm)
  [http://www.fda.gov/medicaldevices/safety/AlertsandNotices/ucm54766.htm](http://www.fda.gov/medicaldevices/safety/AlertsandNotices/ucm54766.htm)
- Gastroenterology and Urology Devices Panel Meeting May 14-15, 2015
  [http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevice/AMedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/ucm445590.htm](http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevice/AMedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/ucm445590.htm)
- AAMI ST91 Flexible and semi-rigid endoscope reprocessing in health care facilities
- CDC Interim Duodenoscope Protocol Mar. 12, 2015

References (2)

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How to Purchase AAMI Standards for Your Reference Library

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