When all else fails

hospitals are switching to the reliability of EO sterilization
What changed?
The Superbug Era changed everything
FDA orders postmarket studies from trio of duodenoscope makers as 'superbug' scare continues

by Stacy Lawrence | Oct 6, 2015 7:15am

The three manufacturers that market duodenoscopes in the U.S.—Olympus America, Fujifilm Medical Systems and Hoya through its Pentax division—have all been required by the FDA to submit postmarket surveillance plans to the agency.
2015 CRE Outbreak

• Investigations revealed:
  • No breaches in protocols
  • No equipment malfunctions
  • No operator error
  • Confirmed by DNA analysis
Going back to the basics

Only EO proves reliable enough to stop the outbreaks
These hospitals are leading the switch to EO
Summary: One of the largest CRE infections ever reported took place in the Chicago area involving 44 patients. The outbreak was investigated by the CDC and traced back to a contaminated endoscope used in ERCP. In the hospitals where high-level disinfection was replaced by ethylene oxide (EO) sterilization or post-reprocessing quarantine and testing, there have been no additional cases of multidrug-resistant infections.
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"The sites that have released data on their CRE outbreaks have adopted measures beyond the FDA guidelines," Dr. Petersen explains. "At least four are using ethylene oxide sterilization; one or more are culturing the instrument after each high-level reprocessing cycle and quarantining it from use until results return negative. Both methods are cumbersome and neither is perfect, but it's what centers are opting for."

He says the first step across all Mayo sites was to culture and sterilize every duodenoscope in the inventory to ensure no problems exist. Mayo Clinic's campus in Rochester, Minnesota, is using weekly EtO sterilization, with the intention of moving to per-procedure gas sterilization as capabilities are ramped up.

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Douglas O. Faigel, M.D., says the current practice at Mayo Clinic's campus in Arizona is to perform CRE screening on all patients undergoing a procedure with a duodenoscope.

"That scope is not used again until the result is negative," he says. "We are double reprocessing all our duodenoscopes between uses. If a duodenoscope is used on a patient with CRE or a positive CRE screen, then we will send that scope for gas sterilization. All these steps go well beyond manufacturer and FDA recommendations."

At Mayo Clinic's campus in Florida, all duodenoscopes are double reprocessed between uses, and patients undergoing duodenoscope procedures will soon be screened for CRE, according to

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Summary: This article discusses Advocate Lutheran General Hospital's use of EO sterilization to stop its 2013 CRE outbreak, reporting that: "Proper use of high level disinfection alone may not eliminate multidrug resistant organisms from duodenoscopes. In this single center study, the addition of EO sterilization and frequent monitoring with cultures reduced duodenoscope contamination and eliminated clinical infections. As such, EO gas sterilization may provide benefit in further decontamination of the duodenoscopes but further investigation is necessary.

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Summary: A February 23, 2015, article in the Los Angeles Times reported that UCLA Ronald Reagan Medical Center began sterilizing its duodenoscopes using EO gas. According to this Times article, the hospital defended its decision to use EO gas, finding that since implementing this technology for the sterilization of its duodenoscopes, no new infections of the deadly CRE were identified following ERCP.

FDA official casts doubt on new method to clean scopes linked to infections

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Scope disinfection failure suspected in superbug cluster, leads UPMC to alter methods

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FDA recommends EO for duodenoscope endoscopes
FDA Beefs Up Reprocessing Guidance

Responding to contamination and infection concerns, the U.S. Food and Drug Administration has released new recommendations on how to enhance the reprocessing of a complex type of endoscope.

The list of supplemental measures, as the FDA calls the recommendations, applies to duodenoscopes, which are used in endoscopic retrograde cholangiopancreatography (ERCP) procedures. The devices, which are flexible, lighted tubes, are threaded through the mouth, throat, and stomach to examine the top of the small intestine or duodenum.

Supplemental Measures For Duodenoscopes
1. Microbiological culturing of duodenoscopes to identify possible bacterial contamination on the devices after they have been reprocessed
2. Ethylene oxide (EtO) sterilization following cleaning and high-level disinfection
3. Use of a liquid chemical sterilant processing system following cleaning and high-level disinfection
4. Repeat high-level disinfection

Report Highlights Training Needs Of BMETs in Low-Resource Countries

Skilled biomedical equipment technicians (BMETs) are crucial to advancing healthcare in low-resource countries, according to a new report, which calls on a wide variety of stakeholders to come together to support the development of "scalable, replicable, and sustainable" training initiatives.

"Without technology that supports diagnosis and treatment of disease, low-resource countries may struggle to improve care and productivity," the report states. "It is time that stakeholders come together to address the training needs of BMETs in their area of interest."
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2. Ethylene oxide (EtO) sterilization following cleaning and high-level disinfection

3. Use of a liquid chemical sterilant processing system following cleaning

The Inside Word

"Instrument processing is a team sport."

Toni Goodman
See story page 13

Reporting Meeting Needs Of BMETS in Low-Resource Countries

Skilled biomedical equipment technicians (BMETS) are crucial to advancing healthcare in low-resource countries, according to a new report, which calls on a wide variety of stakeholders to come together to support the development of “scalable, replicable, and sustainable” training programs for these professionals from various backgrounds and across the globe. The report highlights the need to ensure that these programs align with the needs of stakeholders, who identified three key areas: training, technology, and career development.

Without technology that supports diagnoses and interventions, BMETS are limited in their ability to provide accurate and timely information to healthcare providers. The report emphasizes the importance of investing in technology that is accessible and user-friendly, and that can be adapted to meet the unique needs of each country.

The report also advocates for the establishment of a global network of BMETS, which will enable professionals to share best practices, resources, and experiences. This network will facilitate collaboration and knowledge exchange, allowing for the development of more effective and sustainable solutions.

In conclusion, the report calls for a multi-faceted approach to address the needs of BMETS in low-resource countries, combining training, technology, and career development. By working together, stakeholders can create a more equitable and sustainable healthcare system for all.
# Exposure Limits

<table>
<thead>
<tr>
<th>Compound</th>
<th>Ethylene Oxide</th>
<th>Hydrogen Peroxide</th>
<th>Peractic Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA¹ 8hr/15min PEL²</td>
<td>1 ppm / 5 ppm</td>
<td>1 ppm / -</td>
<td>- / -</td>
</tr>
<tr>
<td>ACGIH³ 8hr/15min TLV⁴</td>
<td>1 ppm / -</td>
<td>1 ppm / -</td>
<td>- / 0.4 ppm</td>
</tr>
<tr>
<td>HSE⁵ 8hr/15 WEL⁶</td>
<td>5 ppm / -</td>
<td>1 ppm / 2 ppm</td>
<td>- / -</td>
</tr>
<tr>
<td>NIOSH⁷ IDHL⁸</td>
<td>800 ppm</td>
<td>75 ppm</td>
<td>n/a</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>400 to 700 ppm</td>
<td>Almost no odor</td>
<td>50 ppb</td>
</tr>
</tbody>
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¹ OSHA Occupational Safety and Health Administration  
² PEL Permissible Exposure Limit  
³ ACGIH American Conference of Governmental Industrial Hygenists  
⁴ TLV Threshold Limit Value  
⁵ HSE Health, Safety, and the Environment, UK  
⁶ WEL Workplace Exposure Limit  
⁷ NIOSH National Institute for Occupational Safety and Health  
⁸ IDLH Immediately Dangerous to Life and Health