



When all else fails

hospitals are switching to the reliability of EO sterilization



What changed?

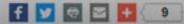
The Superbug Era changed everything



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Olympus Updates Scope Cleaning Procedures After Superbug Deaths



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Medical Devices

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

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Probe of superbug-tainted medical scopes grows to include cleaning machines

Peter Eisler, USA TODAY | Published 5:41 p.m. ET Sept. 15, 2015 | Updated 5:53 p.m. ET Sept. 15, 2015



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Deadly bacteria on medical scopes trigger infections

Peter Eisler, USA TODAY | Published 6:21 p.m. ET Jan. 21, 2015 | Updated 3:06 p.m. ET March 19, 2015



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CBS NEWS | January 22, 2015, 12:29 PM

Deadly superbug infected patients at Seattle hospital



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 E0



Hospitals opt for gas sterilization, surveillance cultures to combat duodenoscope-caused infections

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.

Citation: Epstein, L. (2015, May 7). Hospitals opt for gas sterilization, surveillance cultures to combat duodenoscope-caused infections. Retrieved April 4, 2017, from <http://www.mayoclinic.org/medical-professionals/clinical-updates/digestive-diseases/hospitals-opt-for-gas-sterilization-surveillance-cultures-to-combat-duodenoscope-caused-infections?p=1>



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going forward. "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.

Douglas O. Faigel, M.D., says the current practice at Mayo Clinic's campus in Arizona is to perform

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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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New Delhi metallo- β -lactamase-producing
carbapenem-resistant *Escherichia coli*
associated with exposure to duodenoscopes.

Summary: This article discusses the Advocate Lutheran General Hospital's CRE outbreak, reporting that 35 out of the 39 cases had duodenoscope exposure in one hospital.

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MAIN OUTCOMES AND MEASURES: Association between exposure and acquisition of NDM-producing CRE; results of environmental cultures and organism typing.

RESULTS: In total, 39 case patients were identified from January 2013 through December 2013, 35 with duodenoscope exposure in 1 hospital. No lapses in duodenoscope reprocessing were identified; however, NDM-producing *Escherichia coli* was recovered from a reprocessed duodenoscope and shared more than 92% similarity to all case patient isolates by PFGE. Based on the case-control study, case patients had significantly higher odds of being exposed to a duodenoscope (odds ratio [OR], 78 [95% CI, 6.0-1008], $P < .001$). After the hospital changed its reprocessing procedure from automated high-level disinfection with orthophthalaldehyde to gas sterilization with ethylene oxide, no additional case patients were identified.

CONCLUSIONS AND RELEVANCE: In this investigation, exposure to duodenoscopes with bacterial contamination was associated with apparent transmission of NDM-producing *E coli*

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.

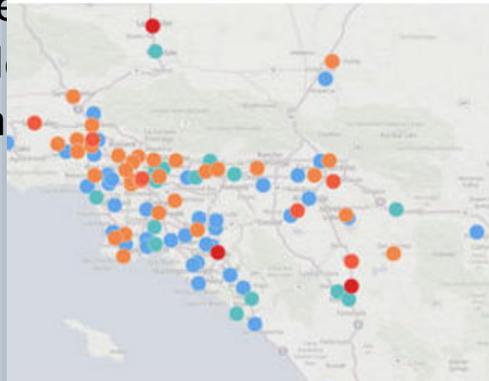
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CONCLUSIONS: Proper use of high-level disinfection alone may not eliminate multidrug-resistant organisms from duodenoscopes. In this single-center study, the addition of ETO sterilization and frequent monitoring with cultures reduced duodenoscope contamination and eliminated clinical infections. As such, ETO gas sterilization may provide benefit in further decontamination of 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.

Summary: A February 23, 2015, article in the Los Angeles Times reported that UCLA Ronald Reagan Medical Center began sterilizing its duodenoscopes using FO gas. According to this Times article, the hospital defended the technology, saying that the new method "can damage the scopes themselves. And so we are not, at this time, recommending routine ethylene oxide sterilization." The article also mentioned that the hospital's safety score was high.



hospital's safety score

using gas "can damage the scopes themselves. And so we are not, at this time, recommending routine ethylene oxide sterilization."

In response to the FDA comments, UCLA defended its new cleaning protocol and said no new infections have occurred since it made the change.

Also Monday, Rep. Ted Lieu (D-

Summary: A February 23, 2015, article in the Los Angeles Times reported that UCLA Ronald Reagan Medical Center began sterilizing its

duodenoscopes using FO gas. According to this Times article, the hospital including the two deaths, and 179 others may have been exposed to the bacteria from October to January.

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Dale Tate, a spokeswoman for UCLA, said Olympus Corp., which manufactures the scopes used at the hospital, recommends ethylene-oxide gas as an alternative for sterilization and "it is not harmful to the scopes that UCLA is using."

She added that the hospital allows time for the gas to wear off to reduce toxicity to patients and employees. Some other U.S. hospitals have also adopted the gas method in response to the bacterial outbreaks.

Other institutions are cleaning the duodenoscopes as they did before but also putting them aside for some period of time, say 48 hours, so they can test them for bacterial growth.



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

Summary: An article in the October 13, 2014 issue of Pittsburgh-Tribune Review reported that, according to Dr. Carlene Muto, director of infection prevention at UPMC Presbyterian, all UPMC hospitals replaced the use of an AER that achieves high-level disinfection with EO sterilization. According to this article, Dr. Muto recommends that duodenoscopes be sterilized using EO gas.

Citation: Fabregas, L. (2014, October 13). *Scope disinfection failure suspected in superbug cluster, leads UPMC to alter methods.* Retrieved April 4, 2017, from <http://triblive.com/news/healthnews/6955957-74/scopes-infection-upmc>

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

Summary: An article in the October 13, 2014 issue of Pittsburgh-Tribune

investigation and adopted a new disinfection technique to replace a high-level disinfection.

Muto called for new guidelines to disinfect the scopes with a gas sterilization method that uses ethylene oxide. It is now used to clean all scopes used in gastrointestinal procedures across UPMC and has not led to new cases of CRE, Muto said.

"I feel comfortable now that we're doing all the right things and doing everything we can to prevent transmission of this and other bacteria," said Tami Minnier, UPMC's chief quality officer.

No patients died as a direct result of the CRE infection, Muto said. Some had heart

FDA recommends EO for
duodenoscope endoscopes

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THE INSIDE WORD

*"Instrument processing
is a team sport."*

Terri Goodman
See story page 13

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 called 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.

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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"

which 55 professionals from various backgrounds and across the globe engaged one another on how best to achieve the vision of effective training for BMETs in countries that need their services desperately.

"Without technology that supports diagnosis

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Exposure Limits

Compound	Ethylene Oxide	Hydrogen Peroxide	Peracetic Acid
OSHA ¹ 8hr/15min PEL ²	1 ppm / 5 ppm	1 ppm / -	- / -
ACGIH ³ 8hr/15min TLV ⁴	1 ppm / -	1 ppm / -	- / 0.4 ppm
HSE ⁵ 8hr/15 WEL ⁶	5 ppm / -	1 ppm / 2 ppm	- / -
NIOSH ⁷ IDHL ⁸	800 ppm	75 ppm	n/a
Odor Threshold	400 to 700 ppm	Almost no odor	50 ppb

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

Source: Chemdaq <http://www.chemdaq.com/resources/health-risks/>