EO gold standard for endoscope reprocessing

Complex Devices that cannot be dependably disinfected:

Duodenoscopes are a type of upper gastrointestinal endoscope used during endoscopic retrograde cholangiopancreatography, or ERCP, to diagnose and treat disorders of the bile and pancreatic ducts.

Urological endoscopes are used for viewing and accessing the urinary tract.

Bronchoscopes may be used to examine, diagnose and treat disorders and diseases of the throat, larynx, trachea, and lower airways.

Which device will be next?

COMPLEX DEVICE REPROCESSING, SUPERBUGS AND EO

According to the U.S. Centers for Disease Control (CDC), on any given day one in 31 hospital patients has at least one healthcare-associated infection.[1] More healthcare-associated outbreaks have been linked to flexible endoscopes than to any other type of medical device.[2]

The mortality rates for patients infected with certain multidrug-resistant organisms (MDRO) can be as high as 50%.[4,3]

To date, ethylene oxide (EO or EtO) sterilization has proven to be the most effective tool in combating MDRO.

Setting the stage

"**Superbugs**" are strains of bacteria, viruses, parasites and fungi that are resistant to most antibiotics and other medications commonly used to treat the infections they cause. These classes of antibiotics can include carbapenems – which are "last resort" antibiotics used to treat many types of serious infections caused by multidrug-resistant bacteria.[3]

Carbapenem-resistant *Enterobacteriaceae* – or CRE – are a particularly pernicious family of gram-negative bacteria resistant to these antibiotics. CRE and related superbugs have become a global public health scourge. The mortality rates for patients infected with CRE and certain other superbugs, particularly bloodstream infections, can be as high as 50% – or higher, in some patient subgroups.[4,3]

In February 2015, the U.S. Food and Drug Association (FDA) acknowledged for the first time, that duodenoscopes could remain persistently contaminated with life-threatening superbugs and related multidrug-resistant organisms.[5] Examples of these potentially deadly microorganisms include CRE and carbapenem-resistant Pseudomonas aeruginosa.

During its subsequent review of several duodenoscope-related outbreaks, the FDA found that many of the superbug infections occurred despite staffers cleaning and disinfecting the duodenoscope in accordance with manufacturer's instructions.

According to the FDA, the complex physical design of duodenoscopes "may impede effective reprocessing," ominously stressing that "meticulously cleaning duodenoscopes prior to high-level disinfection should reduce the risk of transmitting infection but may not entirely eliminate it."[5]

(Deadly) Alphabet Soup

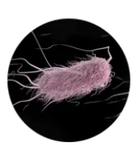
MDRO: Multidrug-resistant microorganisms. Strains of bacteria, viruses, parasites and fungi that are resistant to most antibiotics and other medications commonly used to treat the infections they cause. Also known as superbugs.

CRE: Carbapenem-resistant *Enterobacteriaceae*, a particularly pernicious superbug.

HAI: Hospital acquired infection or nosocomial infection. Most superbugs are acquired in a healthcare setting.

Common Superbugs

Carbapenem-resistant Enterobacteriaceae (CRE)



E. Coli

This was a watershed finding because, previously, virtually every infection associated with a contaminated duodenoscope, or other type of flexible endoscope, had been attributed to a reprocessing breach – more specifically, to failure to clean and disinfect the device as instructed in its labeling. Reprocessing a flexible endoscope as prescribed by the manufacturer had always prevented cross-infection (with few exceptions) until that time first recognized in 2015.[5]

To combat the infection risk, enhance reprocessing and improve the safety of duodenoscopes, FDA advised healthcare facilities, in a safety communication published a few months later, in August 2015, to consider implementing one or more of four enhanced, or "supplemental," measures, which included ethylene oxide sterilization.[6]

Drawing a distinction between disinfection and sterilization, FDA stated in August 2015 that "duodenoscopes should be subjected to high-level disinfection following manual cleaning after each use. When possible and practical, duodenoscopes should be sterilized due to the greater margin of safety provided by sterilization."[6]

MRSA

C. Diff

Indeed, subsequent field surveillance later confirmed ethylene oxide (EO) sterilization was the most effective of the supplemental measures, and validation studies showed that it was the only measure that assures the complete inactivation of highly resistant microorganisms.[7]

A rising infection risk?

Some data suggest that the incidence of a duodenoscope transmitting microorganisms, including CRE and other potentially deadly superbugs, during ERCP decreased, at least for a time, following the FDA's alerts in 2015 informing healthcare facilities and device manufactures about this public health risk.[8]

However, reports submitted to the FDA's adverse event database for medical devices, or "MAUDE," since 2015 indicate that, while the number of FDA reports linking a duodenoscope to an infection apparently decreased in 2016 and even more so in 2017 compared to the relatively high number of cases reported to the FDA in 2015.[8] But 2018 reversed the trend and in 2019 the FDA received twice as many reports.

Ratcheting up the stakes, a report published in 2019 linked a duodenoscope to the possible transmission of a superbug carrying the mcr-1 gene, which can confer colistin antibiotic-resistance to the microorganism.[9] Like carbapenems, colistin may be used as a "last line of defense" for treating some types of multidrug-resistant infections. Notably, some colistin-resistant infections may be untreatable.

Several factors may explain these troubling trends, but one clear point warrants particular attention: The risk of infection associated with use of a duodenoscope remains a concern today.

FDA published alerts in 2019 and 2020 recommending that healthcare facilities and manufacturers "begin transitioning to duodenoscopes with disposable components" and, in the later alert, stressed "sterilization, particularly terminal (e.g., gas) sterilization, provides a greater margin of safety than high level disinfection."[10]

Andersen solves problem

In 2015, Andersen Sterilizers had a duodenoscope clearance underway with the FDA. Because of the CRE outbreak, Andersen was forced to withdraw its claim. At the time, the agency wasn't sure of the source of infections or how to test these complicated instruments post-sterilization.

Andersen spent the next two years negotiating testing protocols with the FDA. During this time duodenoscopes were redefined as a "collection of instruments." A new validation and simulated use testing protocol was chosen: The duodenoscope is inoculated at **seven of the hardest-to-reach sites in the scope with 10^6 bacterial spores**.

This is a significantly higher bar than any previous FDA requirement. Andersen is very proud to have achieved it.

Andersen validated duodenoscopes from all three major endoscope manufacturers and a colonoscope with an 11'6" channel x 1.2mm.

Article Continues: [EO gold standard for endoscope reprocessing - Andersen Sterilizers (sterility.com)]

Further topics:

- Bronchoscopes & urological endoscopes pose a risk, too
- Growing support
- Hospitals fell out of love with EO
- Modality in-fighting
- EO: Gentle, mighty & compatible
- Game changer
- Conclusions
- Recap