DISINFECTS Study: Duodenoscope Infection Surveillance in Functioning AERs in Conjunction with ETO Sterilization

The Problem
- Recent outbreaks of infections due to highly resistant bacteria have been attributed to contaminated duodenoscopes, possibly secondary to inadequate reprocessing
- Limited data suggests gas sterilization with ethylene oxide may reduce the risk of contamination, though this method is a limited expensive resource
- The Centers for Disease Control and Prevention has recommended institutions routinely culture duodenoscopes to surveil for antimicrobial-resistant bacteria; the optimal frequency of culture surveillance is not known

Aim/Goal
This is a prospective randomized trial comparing three methods of disinfecting duodenoscopes. The primary objective is to identify the optimal method of high-level disinfection/sterilization of duodenoscopes in a non-outbreak setting. Additionally, the frequency of duodenoscope contamination with antimicrobial-resistant bacteria will help BIDMC determine a duodenoscope surveillance strategy.

The Method
- Duodenoscopes were randomized to one of three study arms: standard HLD with ortho-phthalaldehyde (sHLD), HLD with repeated disinfectant cycle (dHLD), and standard HLD followed by ethylene oxide gas sterilization (HLD/ETO).
- All procedures requiring duodenoscopes were included; BIDMC performs approximately 1,500 of these procedures annually.
- After disinfection and prior to each procedure, duodenoscopes were cultured for the presence or the absence of ≥1 MDRO pathogen and for any anaerobic bacteria
- Cultures were obtained from the elevator mechanism and from the working channel.

The Results/Progress to Date
Data presented are from the first 2 months of the anticipated 3.5-6 month study
- Of 298 duodenoscopes used, 98% (293) were cultured and 95% (284) were randomized
- Of these 284 samples, 96, 94, and 94 included duodenoscopes from the sHLD, dHLD, and HLD/ETO study arms respectively
- None of the 284 sampled duodenoscopes were positive for MDRO from either culture site when using sHLD, dHLD, or HLD/ETO

Lessons Learned
- Adherence to manufacturers’ guidelines including diligent manual cleaning and reprocessing of duodenoscopes appears critical in preventing duodenoscope contamination
- Preliminary data suggests sHLD may be adequate to prevent MDRO contamination of duodenoscopes

Next Steps/What Should Happen Next
- Continue diligence in maintaining strict adherence to manufacturer guidelines surrounding duodenoscope high-level disinfection
- Complete study and re-evaluate with complete data (N = 525 duodenoscope procedures)
- Determine the frequency of duodenoscope culturing for surveillance of antimicrobial-resistant bacteria at the conclusion of the study

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