

Office of Evidence Based Practice – Specific Care Question: Endoscope Disinfection

Specific Care Question:

When cleaning endoscopes, is ReSert XL HDL (2.0%) vs. OPA Cidex more efficacious in terms of residual bacteria?

Question Originator: Brenda Wilzbach RN and Wendy Morgan, MHA, BSN, RN

Literature Review:

High-Level Disinfection (HLD) is defined by the Food and Drug Administration (FDA) as a minimum of 6-log reduction of mycobacterium. HLD solutions are recommended, by the FDA as cleaning agent for endoscopes (FDA, 2009).

There is no current literature that compares ReSert XL HDL (2.0%) vs. OPA Cidex. Both products are FDA approved HLDs. Despite lack of evidence comparing specific HLDs, the topic of reprocessing of endoscopes and surgical instruments is important. Inadequate reprocessing of endoscopes and surgical instruments is reported as a Top 10 Health Technology Hazard for 2015 by ECRI Institute (ECRI, 2014).

Information on proper HLDs used in healthcare was synthesized. William A Rutala, Weber, and Control (2008) and the Healthcare Infection Control Practices Advisory Committee (CDC) report hydrogen peroxide, glutaraldehyde, ortho-phthalaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable HLDs provided the factors influencing germicidal procedures are met.

Omidbakhsh (2006) studied a 2% accelerated hydrogen peroxide. Testing found it to be a fast-acting and broad-spectrum microbicide in addition to being biodegradable, virtually nontoxic, and free from volatile organic compounds and alkyl phenol ethoxylates. Disadvantages of hydrogen peroxide 2.0% HLD (W. A. Rutala & Weber, 2011) include: material compatibility concerns due to limited clinical experience, antimicrobial claims not independently verified, organic material resistance concerns due to limited data.

Bordas et al. (2005) and Foliente et al. (2001) compared similar products but the hydrogen peroxide concentrations were different, 13% and 7.5% respectively. Data was not provided to show a comparison between the products. Bordas et al. (2005) compared the efficacy of different disinfectants on the market including a 13% hydrogen peroxide. Hydrogen peroxide was found to be just as effective as other products on the market. Foliente et al. (2001) compared the relative efficacies of different HLDs against mycobacteria when used in conjunction with a standardized, validated manual cleaning protocol. Although ReSert XL HDL and/or Cidex were not specifically studied, they found that commercially available HLDs are equally efficacious for reprocessing flexible GI endoscopes.

Petersen et al. (2011) released a multisociety (The American Society for Gastrointestinal Endoscopy [ASGE] and The Society for Healthcare Epidemiology of America [SHEA]) guideline on repossessing flexible GI endoscopes. No recommendations are given on product to use, other than to use FDA approved products and independent peer-reviewed publications. The guideline established that most pathogen transmissions were associated with a breach in currently accepted cleaning and disinfection guidelines.

Care should be taken in rinsing the endoscopies as two case reports (Coriat, Chaput, Ismaili, & Chaussade, 2008; Kara, Turan, Polat, Dogru, & Bagci, 2010) described possible chemical colitis caused by hydrogen peroxide that was used as HLD. Both articles reported the cause could have been attributed to peracetic acid. Peracetic acid with hydrogen peroxide were used to reprocess endoscopes in both case reports. If hydrogen peroxide is used as a HLD, monitoring the endoscopic population for post procedure colitis should be considered as a balancing measure.

EBP Team Member Responsible for Reviewing, Synthesizing, and Developing this Literature: Jarrod Dusin, MS, RD, LD, CNSC, EBP Program Manager



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Plain Language Summary from the Office of Evidence Based Practice:

A recommendation between ReSert XL HDL or OPA Cidex cannot be made due to the lack of studies comparing these current high-level disinfectants. While no studies compared the efficacy of ReSert XL HDL vs OPA Cidex, the ASGE and SHEA report failures to adhere to reprocessing endoscope procedures is a major factor in pathogen transmission. A program to identify breaches in Endoscope reprocessing is recommended.

When the evidence reported in the healthcare literature does not aid in decision making, clinical expertise and preference are the next steps for decision making. Hydrogen peroxide HLDs have environmental advantages of being biodegradable and virtually nontoxic. However, OPA Cidex has been the product used in our hospital. Changing to a hydrogen peroxide product will require a quality program to assess:

- adherence to reprocessing procedures
- patient's outcomes such as infection
- balancing measures such as colitis.
- FDA Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication
General Recommendations for Healthcare Facilities
- Establish an institutional program for endoscope processing, along with written procedures for monitoring adherence to the program and a chain of accountability. Ensure that those responsible for endoscope processing understand the importance of this job and that they maintain proficiency in performing it for each type of endoscope they handle.
- Train employees to set-up, clean, disinfect or sterilize, and store endoscopy equipment properly. Periodically retrain and assess competence. Endoscopy is a constantly evolving technology, so it is essential to stay up to date with the specifics of each device your institution uses.
- Instruct staff to read and follow the endoscope manufacturer's instructions for use. People responsible for reprocessing endoscopes must have the manufacturer's instructions available for each endoscope and its accessories, because various endoscopes and their accessories often must be processed differently (e.g., most flexible endoscopic equipment cannot tolerate steam sterilization).
- Be sure staff members understand that the cleaning and disinfecting of endoscopes are **two separate processes**. Thorough cleaning of the endoscope must be done first, in order to remove gross contamination and debris. Without this step, the endoscope cannot be effectively disinfected or sterilized. Cleaning should begin immediately after use by thoroughly flushing the channels and rinsing/wiping the outside of the endoscope. This must be followed by a very thorough cleaning with brushes, concentrating especially on the channels. Only then is the endoscope ready for high level disinfection, which can be done manually or in an automatic endoscope reprocessor (AER). During disinfection, the high level disinfectant must contact **every** contaminated surface/channel for the time recommended by the disinfectant manufacturer.
- Be sure that the AER or sterilizer is compatible with the endoscope. Before using an AER, confirm that it properly fits the endoscope. Adhere to the AER or sterilizer instructions that specify which endoscope makes and models it can process. And be sure that the instructions for endoscopes, AERs and germicides do not contradict one another. If you become aware that instructions are contradictory, inform the endoscope and AER manufacturers as well as FDA.
- Be sure that endoscopes or accessories that contact sterile tissue are sterilized before each use, and that endoscopes that contact intact mucous membranes (e.g., the respiratory and gastrointestinal tracts) undergo at least high-level disinfection before each use (FDA, 2009).



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References:

- Bordas, J. M., Marcos-Maeso, M. A., Perez, M. J., Llach, J., Gines, A., & Pique, J. M. (2005). GI flexible endoscope disinfection: "in use" test comparative study. *Hepatogastroenterology*, 52(63), 800-807.
- Coriat, R., Chaput, U., Ismaili, Z., & Chaussade, S. (2008). What induces colitis? Hydrogen peroxide or peracetic acid. *Endoscopy*, 40(3), 231. doi: 10.1055/s-2007-995417
- ECRI Institut. (2014, November). Top 10 health technology hazards for 2015. *Health Devices*. Retrieved from <https://www.ecri.org/Pages/2015-Hazards.aspx>
- Foliente, R. L., Kovacs, B. J., Aprecio, R. M., Bains, H. J., Kettering, J. D., & Chen, Y. K. (2001). Efficacy of high-level disinfectants for reprocessing GI endoscopes in simulated-use testing. *Gastrointest Endosc*, 53(4), 456-462. doi: 10.1067/mge.2001.113380
- Kara, M., Turan, I., Polat, Z., Dogru, T., & Bagci, S. (2010). Chemical colitis caused by peracetic acid or hydrogen peroxide: a challenging dilemma. *Endoscopy*, 42(S 02), E3-E4.
- Omidbakhsh, N. (2006). A new peroxide-based flexible endoscope-compatible high-level disinfectant. *American journal of infection control*, 34(9), 571-577.
- Petersen, B. T., Chennat, J., Cohen, J., Cotton, P. B., Greenwald, D. A., Kowalski, T. E., . . . Romagnuolo, J. (2011). Multisociety guideline on reprocessing flexible GI endoscopes: 2011. *infection control and hospital epidemiology*, 32(6), 527-537.
- Rutala, W. A., & Weber, D. J. (2011). Sterilization, high-level disinfection, and environmental cleaning. *Infect Dis Clin North Am*, 25(1), 45-76. doi: 10.1016/j.idc.2010.11.009
- Rutala, W. A., Weber, D. J., & Control, C. f. D. (2008). Guideline for disinfection and sterilization in healthcare facilities, 2008: Centers for Disease Control (US).
- U.S. Department of Health and Human Services, Food and Drug Administration. (2009, November). Preventing cross-contamination in endoscope processing: FDA safety communication. Retrieved from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm>
- U.S. Department of Helath and Human Services, Food and Drug Administration. (2009, March). FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices. Retrieved from <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm>

