

For Immediate Release
September 3, 2014



Media Contact: Anne Brownsey
(630) 570-5635
abrownsey@asge.org

American Society for Gastrointestinal Endoscopy
3300 Woodcreek Drive
Downers Grove, IL 60515

P (630) 573-0600
F (630) 963-8332
www.asge.org
www.screen4coloncancer.org

REPORT EXAMINES TECHNOLOGIES FOR MONITORING THE QUALITY OF ENDOSCOPE REPROCESSING

DOWNERS GROVE, Ill. – September 3, 2014 – The American Society for Gastrointestinal Endoscopy (ASGE) has issued a report on technologies for monitoring the quality of endoscope reprocessing. Emerging technologies offer the ability to perform rapid surveillance of the quality of reprocessing, which may potentially help reinforce adherence to the many steps in reprocessing. The report, developed by ASGE's Technology Committee, appears in the September issue of *GIE: Gastrointestinal Endoscopy*, the monthly peer-reviewed scientific journal of ASGE.

It is estimated that more than 20 million endoscopies are performed in the United States annually. Despite the large number of procedures performed, transmission of infection via endoscopes is very rare. Reported infections have usually been associated with a failure to follow established multisociety guidelines for reprocessing or attributed to defective equipment. The manual component of reprocessing appears most prone to error. Periodic surveillance may potentially help reduce such errors by reinforcing adherence to the many steps in reprocessing. However, further studies are needed to determine whether surveillance strategies can effectively identify failures of cleaning, disinfection or storage that are not detected by process monitoring and that create a risk of transmission of infection. Currently, there are no recommendations for monitoring the efficacy of reprocessing of flexible endoscopes in the United States. This report highlights the status of current technology for monitoring the efficacy of flexible endoscope reprocessing.

About Endoscope Reprocessing

Endoscope reprocessing comprises manual cleaning steps followed by high-level disinfection (HLD), then by rinsing and drying steps. Meticulous manual cleaning is imperative to achieve subsequent HLD. HLD is defined as the destruction of all vegetative microorganisms, mycobacteria, small and medium viruses (lipid or nonlipid), fungal spores, and some bacterial spores. This usually comprises bedside cleaning and suctioning of enzymatic detergent followed by manual washing, flushing and brushing of accessible channels to remove all residues. These processes were detailed in the 2011 Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes. HLD may be performed manually or by automated endoscope reprocessors (AERs). AERs allow for automation and standardization of several reprocessing steps and thereby minimize the risk and impact of human error.

Emerging Technologies for Monitoring Endoscope Reprocessing

Effective surveillance of flexible endoscope reprocessing ideally requires testing methods that allow for rapid assessment of compliance with current reprocessing standards. However, the lack of both widely accepted bioburden/microbial benchmarks and widely validated means of assessing these has limited implementation of such strategies. Potential methods for surveillance include:

- Microbial culture - Culturing for bacterial load
 - The European Society of Gastrointestinal Endoscopy (ESGE) recommends surveillance cultures of reprocessed endoscopes at intervals of not more than three months. However, culturing for bacterial load is impractical for many endoscopy centers that may not have easy access to microbiology laboratories. In addition, the slow turnaround time (minimum 24 hours) for results does not allow for rapid reuse of the tested endoscope. Furthermore, viruses such as hepatitis B and C and HIV cannot be cultured by using standard methods.
- Bioburden assays - Evaluation of residual bioburden and organic matter
 - Currently available methods allow rapid evaluation of residual bioburden and organic matter from the endoscope channels. Methods include a test for protein residue on the surface of endoscopes, a test able to detect protein and blood residues within the biopsy channel of endoscopes and a test to detect protein, blood and carbohydrate residues within the biopsy channel of endoscopes.
- Adenosine triphosphate (ATP) bioluminescence testing - ATP bioluminescence is present in microorganisms and human cells and therefore offers a means of testing for microbial and biological residue.
 - ATP bioluminescence testing provides results within a few minutes. ATP bioluminescence was first used for measuring the cleanliness of surfaces in hospitals. Recent studies have demonstrated the measurement of ATP to be effective in monitoring HLD of flexible endoscopes. The ability to obtain immediate results is a significant advantage of ATP bioluminescence over standard microbial cultures. Currently, there are multiple ATP measurement tools available on the market.

Areas for Future Research

These technologies offer endoscopy units the ability to implement surveillance strategies, which may potentially improve the quality of endoscope reprocessing. The available data regarding technology for monitoring the efficacy of endoscope reprocessing are limited. The efficacy data for available techniques to measure residual organic material or ATP are noncomparative and small in sample size. Areas for future research include the following:

- Establishment and validation of standardized bioburden/microbial benchmarks and ATP bioluminescence thresholds after reprocessing of flexible endoscopes.
- Assessment of cost-effectiveness of implementing surveillance strategies for monitoring the quality of endoscope reprocessing.
- Large prospective studies to assess the relative clinical and cost-effectiveness of different available surveillance technologies as well as their impact on reducing the transmission of clinically significant infections.
- Potential for incorporating bioburden/microbial assessments into AERs.

###

About the American Society for Gastrointestinal Endoscopy

Since its founding in 1941, the American Society for Gastrointestinal Endoscopy (ASGE) has been dedicated to advancing patient care and digestive health by promoting excellence and innovation in gastrointestinal endoscopy. ASGE, with more than 13,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education. Visit www.asge.org and www.screen4coloncancer.org for more information and to find a qualified doctor in your area.

About Endoscopy

Endoscopy is performed by specially-trained physicians called endoscopists using the most current

technology to diagnose and treat diseases of the gastrointestinal tract. Using flexible, thin tubes called endoscopes, endoscopists are able to access the human digestive tract without incisions via natural orifices. Endoscopes are designed with high-intensity lighting and fitted with precision devices that allow viewing and treatment of the gastrointestinal system.