



February 8, 2016

The Honorable Patty Murray
United States Senate
154 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Murray:

The Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA) applauds and supports your efforts to protect patients from device-associated infection with introduction of the Preventing Superbugs and Protecting Patients Act. APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. SHEA is a professional society representing more than 2,000 physicians and other healthcare professionals globally that have expertise in and passion for healthcare epidemiology and infection prevention. Our members are charged with the prevention of healthcare-associated infections and are usually the first to identify outbreaks.

The reprocessing of reusable patient care devices is a complex process with many steps. This is especially true in the case of duodenoscopes and endoscopic ultrasound scopes, which are highly complicated devices that are exceedingly difficult to clean effectively. Current guidelines do not address the appropriate surveillance to assess effectiveness of endoscope reprocessing. Historically, scopes have only been cultured during outbreak situations. However, according to the U.S. Centers for Disease Control and Prevention (CDC), even the suggested current culturing technique has an unknown sensitivity and specificity. Therefore, this can only be considered as part of an overall quality assurance program.

In comments to the Gastroenterology and Urology Devices Panel of the Food and Drug Administration (FDA) Medical Devices Advisory Committee in May, 2015, APIC, in collaboration with the CDC and other experts, urged FDA to develop a validation approach that determines when the process has been successful at eliminating the risk of transmission. The approach should be used for both validating the submitted reprocessing instructions, and/or use by facilities utilizing and reprocessing the scopes. We also encouraged the FDA to work toward sterilization of reusable endoscopes as the standard reprocessing approach or transition to the use of disposable scopes.

The risk to patients is great, and all stakeholders have a role to play in preventing infection. With guidance from the FDA and CDC, manufacturers must provide labeling and instructions for use regarding cleaning, disinfection, and sterilization. Additionally, manufacturers' guidelines for high level disinfection or sterilization must be successfully validated by third parties as eliminating all bacterial and viral challenges while reflecting actual practices around those processes. In addition, the manufacturer must

provide users with information on the total number of complete reprocessing cycles a scope should be expected to tolerate during its usable lifespan.

Healthcare facilities should develop and implement a comprehensive quality control program for reprocessing duodenoscopes and endoscopic ultrasound scopes; implement standardized procedures for training reprocessing personnel and maintain competency; and ensure strict adherence to all manufacturers' guidelines, endoscope reprocessing guidelines, and precautions established by the infection prevention and control community and endoscopy professionals. This can only be accomplished if the manufacturers validate those processes and provide users with clear and concise instructions for use and reprocessing. Armed with that information, healthcare facilities will work to improve the rates of compliance with the reprocessing steps, which in turn will decrease the spread of life-threatening superbugs and other antibiotic-resistant infections.

The Preventing Superbugs and Protecting Patients Act would ensure that the information healthcare facilities need to reduce and prevent infections associated with reusable medical devices is available. Please direct any questions to Laura Evans, APIC's Legislative Affairs Representative, via email at levans@apic.org or via phone at 202-454-2612. We thank you for your leadership on this important issue and look forward to working with you to advance the legislation.

Sincerely,



Susan A. Dolan RN, MS, CIC
2016 APIC President



Louise M. Dembry MD, MS, MBA
2016 SHEA President