DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

Brief Summary of the Gastroenterology and Urology Devices Panel Meeting May 14-15, 2015

Introduction:

The Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on May 14 and 15, 2015 to discuss recent reports and epidemiologic investigations of the transmission of infections associated with the use of duodenoscopes in endoscopic retrograde cholangiopancreatography (ERCP) procedures in hospitals in the United States. The panel provided scientific and clinical opinion related to reprocessing of duodenoscopes and automated endoscope reprocessors based on available scientific information.

Day 1:

Dr. Stephen Ostroff, FDA Commissioner (Acting), provided introductory remarks emphasizing the importance of the meeting and the Agency's commitment to ensuring patient safety in procedures involving reprocessed duodenoscopes and other endoscopes.

The FDA provided an overview presentation on FDA's timeline of events associated with ERCP infections as well as a broader perspective on the Agency's long term efforts related to challenges in reprocessing of medical devices, an introduction to ERCP, an overview of duodenoscopes and reprocessing procedures as well as automated endoscope reprocessors and sterilization and medical device adverse event reports. The FDA also presented in the afternoon on the phases involved in responding to an outbreak or other public health concern in addition to different communication methods.

Medivators, Advanced Sterilization Products and Steris Corporation each provided presentations on automated endoscopic reprocessors.

The open public hearing session included presentations from the following professional societies: American Society for Gastrointestinal Endoscopy, Association of perioperative Registered Nurses, Gastroenterological Society of Australia, International Association of Healthcare Central Service Material Management, Society of Gastroenterology Nurses and Associates and Society for Healthcare Epidemiology of America. In addition to the professional societies, the panel heard testimony provided by a widower whose husband passed away from a bacterial infection acquired during ERCP.

FDA invited speakers from two U.S. hospitals, an international hospital and the Centers for Disease Control and Prevention to present to the panel. The invited speakers on day one

included: Margreet Vos, M.D., Ph.D. of Erasmus Medical Center (Netherlands), Zachary Rubin, M.D. of UCLA Medical Center, and Andrew Ross, M.D. of Virginia Mason Medical Center. Each hospital provided their perspective on current methods implemented to mitigate the risk of patient exposure to bacteria from a reprocessed duodenoscope. In addition, Alexander Kallen, M.D., M.P.H. discussed CDC's outbreak investigation on duodenoscopes. Finally, day one concluded with a presentation by Michelle Alfa, Ph.D., a researcher from University of Manitoba (Canada) discussing her research on reprocessed duodenoscopes.

Day 2:

FDA invited speakers on day two included: Matthew Arduino, M.S., Dr.P.H., William Rutala, Ph.D., M.P.H. and Timothy Leighton. Dr. Arduino presented CDC's interim protocol for surveillance of duodenoscopes after reprocessing. Dr. Rutala discussed his experience in shifting from disinfection to sterilization for gastrointestinal endoscopes. Finally, Mr. Leighton presented on behalf of the U.S. Environmental Protection Agency and discussed worker exposure and associated risks of ethylene oxide.

The open public hearing session included industry presentations from Nelson Laboratories, Inc. and 3M.

FDA Questions:

The panel was asked to consider six FDA discussion questions and the panel provided the following recommendations:

1. Based on the methodology and criteria for acceptance of cleaning, high-level disinfection, and sterilization validation testing for both manual and automated processes, the panel concluded that duodenoscopes and AERs do not provide a reasonable assurance of safety and effectiveness. The panel believes that manual cleaning is a critical component in the process, thus needs to continue. Majority of the panel also believes it is necessary to reclassify duodenoscopes based on the Spaulding Classification from semi-critical to critical and support the move from high level disinfection towards sterilization. Although, some panelists maintained that high level disinfection is adequate, if done properly.

The panel unanimously agreed that ERCP is an important procedure and the use of duodenoscopes during this procedure is safe and should continue from a public health perspective. The benefits of the procedure for the population outweigh the potential risks associated with the use of duodenoscopes.

2. The panel discussed the role of pre-market human factors testing in reprocessing instructions and concluded human factors testing is important and therefore, should be a part of the pre-market assessment. The panel supported a guide of best practices and competency assessments for ensuring user adherence with manufacturer's reprocessing instructions.

3. The panel discussed cleaning agents and brushes differing from the duodenoscope manufacturer's instructions and concluded that brushes or other cleaning agents should meet the manufacturer's specifications. The panel also agreed it is necessary to receive data from the

manufacturer on the efficacy of brushes or other cleaning agents as well as the need for development and validation of cleaning verification assays

4. The panel discussed CDC's interim guidance for surveillance for bacterial contamination of duodenoscopes after reprocessing and concluded the guidance is not sufficient in the current form to be implemented by healthcare facilities as a best practice. The panel believes more data and validation testing is needed before a surveillance program should be implemented by healthcare facilities. Despite its limitations, the panel agreed the guidance provides a well-documented outline for healthcare facilities.

5. The panel's recommended approach for ensuring patient safety for ERCP is to discuss the informed consent with patients and to provide information on the risk of infection from the procedure and to disclose if the health facility has had an issue with infections. Patient selection is also critical for ensuring patient safety. Patients should also be informed of the effects of foregoing the procedure and provided alternatives to the procedure.

6. The panel discussed temporizing measures the FDA should consider when the FDA has a medical device concern but not enough information to determine the most appropriate action towards a resolution. The panel urged the FDA to provide early communication of the facts to the public. The panel also stated the FDA should work with professional societies in an effort to disseminate a consistent message to healthcare providers.

Contact:
Natasha Facey, Designated Federal Officer
301-796-5290, Natasha.Facey@fda.hhs.gov

Transcripts may be purchased from: (written requests only)
Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
410-974-0947 or 1 800-231-8973 Ext. 103
410-974-0297 fax
Or
Food and Drug Administration
Freedom of Information Staff (FOI)
5600 Fishers Lane, HFI-35
Rockville, MD 20851
(301) 827-6500 (voice), (301) 443-1726