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Important information for infection preventionists regarding media attention on an outbreak involving reusable surgical instruments.

Background

The Center for Public Integrity (CPI) issued a recent report titled "[Filthy surgical instruments: The hidden threat in America's operating rooms](#)," which has received much press attention. The report discusses the results of an investigation into a series of surgical site infections (SSIs) at a hospital in Texas. Investigators discovered that infections were caused by the use of dirty surgical instruments (arthroscopic shavers, which surgeons use to shave away bone and tissue during surgery; and cannulas, long narrow metal tubes used to irrigate and suction the surgical site). The result of this investigation, led by Tosh and colleagues, was published in an article titled "Outbreak of *Pseudomonas aeruginosa* Surgical Site Infections after Arthroscopic Procedures: Texas, 2009," in the December 2011 issue of *Infection Control and Hospital Epidemiology*.¹

Although the hospital had followed the instructions for use (IFU) and reprocessing provided by the manufacturer of the shavers, the CPI report alleges evidence of a larger problem of dirty hospital instruments, beyond this recent report. CPI noted that the Food and Drug Administration (FDA) was aware of potential problems with reprocessing some surgical instruments. The FDA convened a workshop last summer to an audience including government, providers and industry representatives. During the meeting, a clinical engineer at the University of Michigan Health System presented findings from his investigation that almost all surgery-ready suction tips (a tool for suctioning blood and fluids during surgery) still contained debris after they had been cleaned per the manufacturer's instructions. Please note, to date APIC is not able to confirm if this study has been published in the peer reviewed literature.

The CPI report is critical of the device manufacturing industry, as well as the FDA, and cites improper cleaning and sterilization related to poor manufacturer design, proliferation of highly complex surgical instruments, and inadequate device testing by manufacturers. The report also cites inadequate pay and stressful working conditions in healthcare settings for sterile processing technicians who are charged with cleaning and sterilizing instruments used in surgical procedures. According to the report, only the state of New Jersey requires professional certification for sterile processing employees.

Important considerations for infection preventionists

Infection preventionists can play an important role in collaboration with the perioperative team and the facility's sterile processing department (SPD)/surgical reprocessing professionals to



ensure the proper cleaning and sterilization of surgical instruments. Given this outbreak investigation, APIC recommends that, infection preventionists (IPs) work with their perioperative colleagues at their affiliated facilities to:

- Encourage the perioperative and SPD team members to assure the adequacy of reprocessing reusable surgical instruments that considers the following:
 - Review the manufacturer's IFU before purchasing or finalizing loaner agreements to review the following: (1) complexity of the device relative to key elements for effective reprocessing (2) availability of correct equipment and tools to reprocess the medical device, and (3) assess inventory to allow for adequate turn-around time to effectively reprocess the device.
 - Ensure SPD personnel responsible for device reprocessing are aware of and comply with all steps in the device manufacturer's IFU. Refer to the specific instructions provided in the labeling or user manual for each brand and/or model that is in use. Other aspects of reprocessing that should be addressed include transportation, sorting, disassembling, cleaning, inspecting, packaging, loading, sterilizing, storing, and distribution of reprocessed items.
 - Inspect thoroughly devices after cleaning to ensure removal of organic and inorganic material. Depending on the complexity of the device additional equipment may be needed to facilitate this inspection, e.g. magnification.
 - Apply practices and procedures that are consistent with evidence-based and/or professional guidelines that include but are not limited to:
 - ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
 - Annex D, User verification of cleaning processes since bioburden and microorganisms cannot be detected by visual inspection
 - Section 7.5.3.3 and 7.5.5 and Recommendation XXII in AORN Care of Instruments in the *AORN Perioperative Standards and Recommended Practices (2012)* Healthcare Infection Control Practices Advisory Committee (HICPAC), Centers for Disease Control & Prevention (CDC). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
- Encourage SPD and perioperative personnel to investigate instances of retained tissue or other debris in surgical instruments. If this remains after performing the manufacturer-recommended reprocessing IFU, contact the manufacturer and, if appropriate, file a [voluntary report](#) with MedWatch, the FDA Safety Information and Adverse Event Reporting program either by phone (1-800-FDA-1088), via [fillable form online](#), fax (1-800-FDA-0178), or mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787).

IPs play an important role in patient safety, and should support a coordinated, systematic approach to effective device reprocessing. Surveillance for unusual clusters of infection that may result from ineffective surgical instrument reprocessing must be maintained.



Cleaning, disinfection and/or sterilization are included under Conditions of Participation and Conditions for Coverage issued by Centers for Medicare & Medicaid Services (CMS) and accreditation requirements issued by the Joint Commission related to infection prevention and control. IPs should be sure these resources are included in risk assessment and IPC plan development. IPs are encouraged to work with key stakeholders such as SPD/CSR and Surgical Services departments when addressing reprocessing of surgical instruments in a facility's IPC Plan. Other key sources of information include the manufacturer representatives for the surgical instrument who can provide up-to-date IFU.

Assist APIC in supporting initiatives that actively promote certification of sterile processing personnel at the state level. APIC provides a course on ["Disinfection and Sterilization: Best Practices in Reprocessing Surgical Instruments,"](#) which helps healthcare professionals in all settings ensure compliance with regulatory standards for sterile processing and adhere to recommended best practices. APIC is reaching out to the audience of sterile processing personnel with information about its course. The FDA is actively working with the manufacturers of these devices to gather more data about this situation and to understand its potential public health impact. APIC is closely following the investigation by the FDA. We will keep you informed of any new developments.

1. Tosh PK, Disbot M, Duffy JM, Boom ML, Heseltine G, Srinivasan A, Gould CV, Berríos-Torres SI. Outbreak of *Pseudomonas aeruginosa* Surgical Site Infections after Arthroscopic Procedures: Texas, 2009. *Infection Control and Hospital Epidemiology*, Vol. 32, No. 12, December 2011, pp.1179-1186.

