Rx: Health Care FYI #57

Subject: *Eliminating Infections from Medical Devices*
From: *Rep. Tim Murphy (PA-18)*
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The problem: At least half of all cases of nosocomial (hospital-acquired) infections are associated with medical devices.[1] Bacteria, viruses, fungi, or parasites can cause hospital-acquired infections. Even after rigorous cleaning and sterilization, viruses and bacteria can still exist on medical device which increases the risk of infection. Preventable infections affect 2 million patients and end up costing 90,000 lives and over $50 billion annually.[2]

What are Medical Devices?

- Medical devices are a medical instrument or machine "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease." [3] This includes a wide variety of devices from tongue depressers to catheters.
- A few commonly reused medical devices designed for single use include surgical saw blades, surgical drills, surgical staplers, laparoscopy scissors, orthodontic (metal) braces, electrophysiology catheters, electrosurgical electrodes and pencils, endotracheal tube, balloon angioplasty catheter, biopsy forceps, umbilical scissors, gas masks, ophthalmic knifes, irrigating syringes and surgical gowns.[4]

Rates of Infection from Medical Devices:

- Central Venous Catheter (tubes placed in the patient's vein near the heart to deliver drugs or fluids). Approximately 80,000 related bloodstream infections annually in intensive care units (ICUs) with up to 20,000 deaths.[5]
- Peritoneal dialysis catheters (tubes placed in the patient's abdomen to deliver fluid) used for dialysis: 23% infection rate.[6]
- Pacemakers: 7% infection rate.[7]
- Implantable Cardioverter Defibrillators (ICDs): 7.2% infection rate. [8]
- Ventricular Assist Devices: Up to 50% infection rate.[9]
- Bladder catheters (tubes placed to empty a patient's bladder): 30% infection rate.[10]

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[1] Richards, M. Et. al. Nosocomial infections in medical intensive care units in the United States. National Nosocomial Infections Surveillance System. Crit. Care Med. 27**:**887-892. 1999.
[2] Centers for Disease Control. CDC Advisory Committee Offers Guidance to States on Developing Systems for Public Reporting of Healthcare-Associated Infections. February 2005.
[3] Federal Food, Drug, and Cosmetic Act, 21 United States Code [321] (h).
[4] FDA Consumer Magazine. Reusing Medical Devices: Ensuring Safety The Second Time Around. October 2000.
[5] Mermel, L. Et. al. Guidelines for the management of intravascular catheter-related infections. Infect. Control Hosp. Epidemiol. 22: 222-242. 2001.
[6] Kerr, C. M. Et. al. Fungal peritonitis in patients on continuous ambulatory peritoneal dialysis. Ann. Intern. Med. 99:334-336. 1983.
[7] Giamarellou, H. Nosocomial cardiac infections. J. Hosp. Infect. 50:91-105. 2002.
[8] Lai, K. K., and S. A. Fontecchio. Infections associated with implantable cardioverter defibrillators placed transvenously and via thoracotomies: epidemiology, infection control, and management. Clin. Infect. Dis. 27:265-269. 1998.
[9] Myers, T. J. Et. al. 2000. Infectious complications associated with ventricular assist systems. Asaio J. 46:S28-S36.
[10] Darouiche, R. O. Device-associated infections: a macroproblem that starts with microadherence. Clin. Infect. Dis**.** 33:1567-1572. 2001.

Reprocessed (or reused) Medical Devices increase the risk for infection:

- When reusing any device, extreme caution should be used. Studies have found that even after rigorous cleaning and sterilization, viruses were still present on reprocessed catheters.[11]

The Federal Government's role:

- Medical devices, including, reprocessed or reused devices are regulated for safety by the Food and Drug Administration.
- In 2002, with enactment of the Medical Device User Fee and Modernization Act (MDUFMA), Congress mandated a number of new requirements for single use device reprocessors including the pre-market submission of data to the Agency that exceeded the requirements for original manufacturers.
- Under medical device reporting regulations, hospitals are subject to the same reporting requirements as manufacturers to report adverse events to the FDA of reused single use devices which may have caused or contributed to a serious injury to a patient at the facility.

Recommendations:

- Pass the reauthorization of the Medical Device User Fee Act, which contains legislative language for the federal government to study and report the number of nosocomial infections attributable to new or reused medical devices. This study will also examine the possible causes of these infections, including: if infections were acquired from reprocessed medical devices designed for single-use, the handling of medical devices, in-hospital sterilization of medical devices, health care professional practices for patient examination and treatment, hospital based policies and procedures for infection control and prevention, and hospital based practices for handling medical waste. This information can help health care providers and medical providers to take steps to eliminate the risk for infections.
- Pass H.R.1174, the Healthy Hospitals Act, for hospitals to publicly report their infection rates. The reporting give patients an informed choice when selecting hospitals for care. H.R. 1174 also provides grants to hospitals from the savings from reducing infection rates to zero.
- The Food and Drug Administration (FDA) should implement a system to determine the number of infections from reused single-use medical devices and eliminate reuse in medical devices with increased infection risk.
- Health care providers should work with medical devices companies to provide patients with information if a medical device has been reused. Patients have the right to know whether or not a medical device designed for single use has already been used on another patient before a device is used on them. Otherwise, patients will be exposed to an unnecessary risk for hospital-acquired infections and medical device failures.

[11] Luijt DS. Et. al. Risk of infection by reprocessed and resterilized virus-contaminated catheters; an in-vitro study. Eur Heart J. 22(5): 378-84. 2001.