It's Time to Reevaluate the Safety of Reusable Devices

The Healthcare Industry Needs to Stop Overlooking Reusable Devices as Potential Conduits of Dangerous Infections

The rise of healthcare-associated infections (HAIs), many of which are caused by antibiotic-resistant bacteria, are taking a toll on the U.S. healthcare system. More than two million people become infected with resistant bacteria each year, and 23,000 of them die from the infections. While the overuse and misuse of antibiotics is to blame (some estimates claim that more than half of all prescriptions written are unnecessary or inappropriate), the healthcare community has taken steps to combat the crisis – but they haven't been enough.

Why is Infection Prevention Still Failing?

The U.S. Food & Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) and other world health organization have come out with guidelines for infection prevention and proper disinfection techniques. These have certainly helped curb the spread of some dangerous bacteria, but healthcare is still far away from being at absolute zero for HAIs.

Some of the most forward-thinking healthcare systems have adopted a vigilant, three-pronged approach to infection prevention – implementing federal guidelines, changing long-standing staff behaviors and adopting antimicrobial-treated medical devices. This strategy has helped make real progress, but unless there is adherence across the board, it will never reach its ultimate goal. Plus, there is a large, high-risk area that many healthcare organizations are not actively addressing with their broader infection prevention plans: reusable devices.

Reusable devices, including endoscopes, surgical instruments, ultrasound wands, leads and cables, have been subject to traditional disinfection techniques for decades. There is the common perception that these types of devices are "safe" as long as they are cleaned. And even if they are not completely disinfected, they are typically not too invasive and therefore don't pose a very high risk. This type of thinking is wrong – very wrong – particularly in the context of antibiotic-resistant bacteria.

The healthcare industry has overlooked reusable devices as major sources of infection and recent events have brought to light just how dangerous they can be.

Infection Outbreaks Caused by Reusable Devices

Before we discuss recent outbreaks, it's important to understand *why* reusable devices can pose such dangers. The answer to that is in the name – reusable. Simply put, these devices are used over and over again to treat and diagnose patients. They can include more invasive devices like endoscopes and surgical instruments, to things that may not even come into direct

contact with a patient like monitor cords. While some of these devices might have been considered “harmless” in the past, given the aggressive and highly infectious antibiotic-resistant strains of today, they are acting as gateways to disease.

In the last four years, there have been six major CRE outbreaks due to duoendoscopes, fiber-optic tubes that are threaded through the body into the small intestines to perform lifesaving procedures. One of the most common reusable devices, accounting for 500,000 procedures a year, duodenoscopes caused antibiotic-resistant infection crises at hospitals in Washington, Illinois, Pennsylvania and California.

And endoscopic tools are not the only reusable devices causing infections. A recent study found the presence of HPV on ultrasound wands, contaminated dental instruments caused Hepatitis B and C infections in Virginia and The Methodist Hospital in Houston had to close ORs and cancel orthopedic procedures to investigate an outbreak in joint patients. The culprits were arthroscopic shavers and inflow/outflow cannulas that were not sufficiently decontaminated. These are just a few examples of documented cases, however, any reusable device has the potential to cause infection if not adequately reprocessed.

The FDA caught on to the dangers of reusable devices in this era of multi-drug resistant bacteria in 2011. It started to update reprocessing guidelines (for the first time since 1996) to try and minimize patient exposure to infectious agents. The guidelines include:

- Cleaning, high-level disinfection and sterilization methods
- Premarket validation data to support labeling claims and instructions
- Use of risk mitigation strategies, including surveillance cultures
- The need to consider the impact of design

As noted above, these guidelines are a step in the right direction, but ensuring proper decontamination is a complex challenge. Some of the deadly CRE outbreaks were found to be due to the improper cleaning of scopes and breaches in protocol, while others, including the most recent one in California, occurred following approved protocols. As these devices evolve, they are becoming smaller and more intricate, which also makes them more difficult to clean.

What Can Be Done?

With the rising concern around reusable devices acting as gateways to antibiotic-resistant infection – and the challenge to properly cleaning them – what can the industry do to help reduce the risk of infection?

- **Leverage Antimicrobials:** Other healthcare devices, including catheters and wound-care products, have leveraged the use of antimicrobials for years. Now’s the time for the reusable device market to do the same. Embedded antimicrobials are proven to have high-

kill rates against some of the most dangerous strains of bacteria, in addition to having effectiveness that can last through rigorous reprocessing cycles. Antimicrobials can act as a second-line of defense against the growth of microbes.

With some healthcare personnel struggling to adequately decontaminate devices and hospitals being financially accountable for infection rates, the time is now to consider embedded antimicrobials for all reusable devices.

- **Go Back to the Design Drawing Board:** Certain med-device manufacturers are playing their part in the fight against infection by revisiting the design of reusable devices. Some are looking at easier-to-clean designs without rough surfaces, deep groves, hard angles or multiple parts that can hold on to bacteria. Others are considering active surfaces that that discourage bacterial attachment. This is done through the use of embedded, controlled-release antimicrobials or the use of low-attachment hydrophilic surfaces, making it hard for organisms and bodily fluids to adhere to the product.

  Manufacturers are even looking at disposable options, rendering some reusable devices, no longer reusable. In this instance, there are a lot of things to consider, including cost and use time, to determine whether it makes sense to have a disposable device. For some reusable devices, manufacturers are even weighing the option of disposable components – parts that can be thrown away after each use.

- **Think Differently About Education:** While healthcare professionals – whether a clinician, administrator or med-device engineer – are familiar with infection-prevention guidelines, the industry has to go back to the start in terms of education. From the manufacturers designing the devices, to the clinicians using them, to the technicians reprocessing them, it is critical to understand the risks associated with medical products. Time and resources need to go into educating professionals on how the product will be used, the risks associated with it and where the path of infection typically starts.