BD Global Public Policy Position
Preventing Infections from Reuse of Single-Use Medical Devices

ISSUE: Reuse of Single-Use Medical Devices Poses a Serious Health Risk to Patients

Single-use medical devices for injection, infusion, and blood collection are intended to be used on one patient during a single procedure in order to protect the sterility of the device and prevent cross-contamination among patients. Regulatory bodies that are responsible for the approval of these devices, as well as entities that provide guidance on their appropriate use, have made clear that these single-use products are not intended to be reprocessed (cleaned, disinfected, sterilized) or reused, but must be discarded as medical waste after a procedure. Nonetheless, the World Health Organization (WHO) estimates that 40 percent of the 16 billion injections administered worldwide each year are given with syringes and needles that are reused. This has led to the transmission of dangerous pathogens. Reuse specifically accounts for the transmission of 32% of hepatitis B cases, 40% of hepatitis C cases and 5% of HIV infections in ten geographical sub-regions in 2000. While the reasons for reuse of these devices may vary by region, this practice is dangerous to patients in any setting.

POSITION: BD supports comprehensive reuse prevention measures to prevent patient exposure to bloodborne pathogens.

BD supports comprehensive reuse prevention efforts that:

1. **Educate and train healthcare workers on infection prevention and control, including the appropriate use of single-use medical devices**
   In order to address inconsistent compliance to infection prevention and control guidelines, BD supports the development of infection prevention education and training programs that include the proper use, handling and disposal of single-use medical devices.

2. **Provide effective oversight of healthcare facilities to enforce compliance with established infection prevention and control guidelines**
   The transmission of infectious disease through the reuse of single-use medical devices can be prevented when healthcare personnel adhere to basic infection prevention principles. Governments around the world should develop and enforce laws and regulations that prohibit reuse to protect patients.

3. **Require the use of products designed to prevent reuse in certain regions and healthcare settings where reuse has posed the highest risk to patients and healthcare workers**
   Products with features to prevent reuse have been designed to meet the needs of a variety of healthcare delivery models, including auto-disable syringes for immunization, retracting devices for blood collection, and similar technologies. Reuse prevention products should be required in 1) regions with a high rate of reuse, and 2) healthcare settings that have historically been the site of product reuse such as private physician offices, oncology clinics, hemodialysis centers, endoscopy clinics, nursing homes and assisted living facilities.
4. **Increase oversight of healthcare facilities and enhance surveillance of infectious disease outbreaks**

   It is essential that oversight of healthcare facilities is sufficient to enforce compliance with laws and regulations designed to prevent reuse. Enhanced surveillance is also needed to monitor potential infectious disease outbreaks that occur as a result of the reuse of single-use devices.

5. **Advance patient awareness of the appropriate use of single-use devices**

   BD supports initiatives that educate and empower patients regarding the appropriate use of needles, syringes and other single-use medical devices.

**BACKGROUND: Reuse of Single-Use Medical Devices Can Lead to Transmission of Infectious Diseases**

The reuse of single-use devices for injection, infusion, and blood collection is a global public health problem. The motivations for reuse may vary in different parts of the world, but the practice is inappropriate in any geographic setting.

In nations with developed healthcare systems, the reuse of syringes and other single-use medical devices has led to a growing number of outbreaks of HBV and HCV. The purported mechanism of patient-to-patient transmission in these cases has primarily been syringe reuse that contaminated injectable medications or flush solutions. The reasons behind reuse in these instances appear to be a failure to adhere to basic infection prevention and control practices and lack of awareness of the implications of reusing single-use medical devices.

The public health impact of these unsafe reuse practices is enormous. A recent review of viral hepatitis in the US revealed that over 30 outbreaks of HBV and HCV occurred in the past decade. As a result of these and subsequent outbreaks, more than 125,000 patients had to be notified that they were at-risk for bloodborne infections because of improper practices at their healthcare facilities. It is important to note that symptoms of HBV and HCV sometimes do not appear until ten or more years after infection, so many more patients may have been infected but are not yet aware of their condition.

National health authorities and other groups have published best-practice guidance to prevent healthcare-associated infections and to help facilities assess risk and investigate identified breaches in infection control. However, lack of adherence to these guidelines and basic infection prevention and control principles is a significant problem. For example, a survey of US healthcare workers who provide medication through injection found that 1%-3% reused the same needle and/or syringe on multiple patients. In addition, studies have shown that nearly 30% of healthcare facilities have been cited for deficiencies related to medication administration, including use of single-dose medications for multiple patients. These data demonstrate that awareness, understanding and implementation of best practices as well as the use of available engineering controls remain suboptimal.

In the developing world the reasons for reuse of single-use medical devices include lack of resources, insufficient training of healthcare providers in safe injection and infection control practices and lack of patient awareness regarding the risks associated with needle-sharing among family members. Risks are also underappreciated because bloodborne pathogens often take years for symptoms to develop.

In the late 1980s, the WHO and other nongovernmental organizations involved in childhood immunization programs began to recognize that disease was being spread among children during mass immunization campaigns through reuse of conventional syringes. WHO reached out to manufacturers to develop technology solutions for this problem. In response, auto-disabled
syringes, which automatically lock after a single use, were developed for immunizations. However, while the use of reuse prevention products is common in many immunization programs, immunizations represent only a small portion of overall injections and there are still significant gaps in their utilization and in healthcare worker training and awareness. In some regions the rate of unsafe injections practices is alarmingly high. For example, an assessment of injection practices in India found that nearly one third of all injections carried a potential risk of transmitting a bloodborne pathogen. That study found that the type of injection equipment had a profound effect on the safety of injections and recommended policies to encourage universal use of reuse prevention technologies.12

10 Infection Control Assessment of Ambulatory Surgical Centers. Melissa K. Schaefer; Michael Jhung; Marilyn Dahl; Sarah Schillie; Crystal Simpson; Eloisa Llata; Ruth Link-Gelles; Ronda Sinkowitz-Cochran; Priti Patel; Elizabeth Bolyard; Lynne Sehulster; Arjun Srinivasan; Joseph F. Perz. JAMA. 2010; 303(22):2273-2279.

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