

PROFESSION

New products pitched to improve injection safety

Injection-related outbreaks have proved difficult to eliminate. Syringes that prevent reuse and systems that simplify injections involving multiple medications are being pushed as potential fixes.

By KEVIN B. O'REILLY, amednews staff. Posted Oct. 1, 2012.

Despite repeated warnings from the Centers for Disease Control and Prevention and others, unsafe injection practices continue to lead to disease outbreaks. Though rare in the U.S., safety experts say these mishaps should never happen.

Health industry companies say they have a solution: injection systems they say are designed to make it easier for physicians, nurses and other health professionals to deliver shots safely.

From 2001 to 2006, nine outbreaks infected nearly 300 patients with bloodborne diseases such as hepatitis C at ambulatory care clinics, the U.S. Government Accountability Office said in a July report. The CDC issued guidelines on injection safety in 2007. In 2008, the CDC and many physician and health-professional organizations formed the Safe Injection Practices Coalition and launched the One and Only Campaign to spread the word on preventing injection-related disease transmission.

Yet problems continue. From 2007 to 2011, another nine outbreaks infected 66 patients with bloodborne diseases. The culprits are unsafe injection practices, such as the reuse of syringes and single-dose vials, and improper aseptic technique when using multidose vials. Nearly 100,000 patients had to be notified for follow-up testing related to these outbreaks.

In spring 2012, the CDC traced injection-related outbreaks of *Staphylococcus aureus* infections that hospitalized 10 patients to clinics in Arizona and Delaware. Studies have found that safety lapses in injection practices happen at 30% of ambulatory surgery centers and among 6% of nurses. CDC officials remain flummoxed on how to eliminate the problem.

"If I had an answer for why it keeps happening, we would have fixed it by now," said Melissa Schaefer, MD, a medical officer in the CDC's Division of Healthcare Quality Promotion. "It's rare, but it's not rare enough. I don't know why they continue to occur. It's completely unacceptable. Health care should not be a mechanism for these kinds of infections."

Drug shortages have exacerbated the problem, experts say, with smaller sizes for some single-dose packages becoming costlier or harder to find.

Whatever is contributing to unsafe injection practices, some product manufacturers see a market opportunity in safety. One innovation is the syringe that is automatically disabled after one use. If a health professional attempts to draw back the locked plunger after use, it breaks off and is rendered unusable. Franklin Lakes, N.J.-based Becton, Dickinson and Co., is the world's largest manufacturer of syringes and launched a line of safety syringes in 2011.

But the company, known as BD, only sells its auto-disabled syringes in developing countries, where unsafe injections kill an estimated 1.3 million people a year, according to the World Health Organization. The United Nation's Children's Fund says auto-disable syringes cost developing nations about six cents each, while traditional syringes cost four cents each.

In the U.S., BD markets several other products aimed at making injections safer. Its prefilled heparin and saline syringes remove the additional infection risk of drawing the fluid into the syringe. Another injection device is called Integra and features a needle that, after use, retracts into the barrel of the syringe to prevent needlesticks and syringe reuse. Little Elm, Texas-based Retractable Technologies markets a similar line of retractable-needle syringes. The products are "designed to be nonresusable," according to the company's website.

Simplifying injection technique

Although much of the safety focus has been on preventing the reuse of single-dose vials with multiple patients, multidose vials also can pose a danger to patients.

CDC guidelines call for using only sterile needles to access the multidose vial, keeping the vials away from patient treatment areas and storing them according to manufacturer's recommendations. Drawing the medications for an injection involving multiple drugs can increase the risk for slipups. An injection to treat joint pain that involves anesthetics and a steroid can take as long as 15 minutes to prepare, said John S. Reach Jr., MD, assistant professor of orthopedics and rehabilitation at Yale University School of Medicine in Connecticut.



John S. Reach, MD, uses the Navigator Delivery System to deliver a pain-relief injection. The system allows doctors to draw drugs without needles, using disposable cassettes.

[Photo courtesy of Carticept Medical Inc.]



"You're taking three different vials, and you have to swab the vials on the top," said Dr. Reach, director of Yale's Foot and Ankle Section. "Then you take a bigger needle and stick it through the rubber gasket on the top of it, suck up each of those fluids, and you have to maintain sterility through all that. There are a lot of different places to make a mistake."

Dr. Reach is a paid consultant for Carticept Medical Inc. of Alpharetta, Ga., which in 2011 launched a product designed to automate the process of delivering intra-articular pain-relief injections. Its product, the Navigator Delivery System, allows health professionals to draw the drugs without needles, using disposable cassettes. The physician preparing the injection determines how much medication to draw from each vial using a computer interface that is part of the device.

The system, which costs \$12,000, is being marketed to orthopedic and sports medicine practices that do 10 or more ultrasound-guided injections daily. The product was cleared for marketing by the Food and Drug Administration in 2011, but its efficacy in reducing injection-related disease transmission has not yet been tested. Fewer than 20 clinics are using the product, but company officials say they expect a revised version to gain more traction in the marketplace.

The CDC's Dr. Schaefer declined to comment on the potential for these products to help improve injection safety. A May 2010 meeting of pharmacists, nurses, industry companies and others hosted by the CDC and the FDA said new equipment designs such as auto-disable syringes and vials and tamper-evident packaging could help improve injection safety.

The American Academy of Orthopaedic Surgeons also did not comment directly on how new products might prevent injection-related disease outbreaks. The organization's Patient Safety Committee is examining injection safety and "will continue to monitor developments on this issue as more information becomes available to help ensure best practices of orthopedic care are maintained," the academy said in a statement.

ADDITIONAL INFORMATION:

WEBLINK

"HHS Has Taken Steps to Address Unsafe Injection Practices, but More Action is Needed," U.S. Government Accountability Office, July 13 (www.gao.gov/products/GAO-12-712)

Centers for Disease Control and Prevention on preventing unsafe injection practices (www.cdc.gov/injectionsafety/unsafepractices.html)

"Infection Control Assessment of Ambulatory Surgical Centers," *The Journal of the American Medical Association*, June 9, 2010 (jama.jamanetwork.com/article.aspx?articleid=186038)

"Injection practices among clinicians in United States health care settings," *American Journal of Infection Control*, December 2010 (www.ncbi.nlm.nih.gov/pubmed/21093696)

"Invasive *Staphylococcus aureus* Infections Associated with Pain Injections and Reuse of Single-Dose Vials — Arizona and Delaware, 2012," *Morbidity and Mortality Weekly Report*, July 13 (www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm)

Auto-disabled syringe, Star Syringe Ltd. (www.starsyringe.com/KST.html)

BD Emerald PRO Reuse Prevention Syringe (www.bd.com/emerald/en/#/product/pro/)

Navigator Delivery System, Carticept Medical Inc. (www.carticept.com/navigator-delivery-system.html)

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Navigator Delivery System

[Photo courtesy of Carticept Medical Inc.]

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