Unsafe Injection Practices Plague US Outpatient Facilities, Harm Patients

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When an astute staff member at a county public health department in New York noticed that 2 patients who had been newly diagnosed with hepatitis C virus (HCV) had recently received epidural injections from the same pain management clinic, it sparked a visit by state public health officials to the clinic. During the visit, they observed the physician who treated both patients withdrawing medication from a multiple-dose vial with a previously used syringe topped with a new needle, a breach of safe injection practices that may have contaminated the vial and exposed subsequent patients to potential blood-borne infections.

The physician was not aware of the risk posed by this practice, explained Guthrie Birkhead, MD, MPH, deputy commissioner of the New York State Department of Health’s Office of Public Health, during the US Centers for Disease Control and Prevention (CDC) Public Health Grand Rounds in November (http://www.cdc.gov/about/grand-rounds/archives/2012/November2012.htm). But further investigation and testing of some of the more than 8000 patients who were notified of potential exposure identified 8 more patients with HCV infection, and molecular testing found an identical strain of the virus in 2 patients treated on the same day, Birkhead noted. The case garnered media attention and lawsuits and prompted the state medical board to place conditions on the physician’s practice.

Far from being an isolated case, Birkhead and officials from the CDC and the Center for Medicare & Medicaid Services (CMS) presented evidence suggesting that such lapses are a common occurrence in US health care, particularly at outpatient facilities. Thomas Hamilton, MD, director of the survey and certification group in CMS’s Center for Clinical Standards and Quality, noted that a 3-state pilot survey published in 2010 found 46 of 68 facilities (67.6%) had at least 1 lapse of infection control (Schafer MK et al. JAMA. 2010; 303[22]:2273-2279). The survey, part of the CMS’s effort to audit whether ambulatory surgery centers were following the CDC’s recommended infection control practices, found that reuse of single-dose vials for multiple patients was a common lapse, occurring at one-third of facilities surveyed. Results of a follow-up survey involving all states found similarly high rates of infection control violations, reported Hamilton, with 51.3% of facilities having such a failure in 2010. Small declines in infection control slipups have been documented at ambulatory surgical centers in the most recent national surveys, with such lapses found at 43.5% of centers in 2011 and 42.1% in 2012.

Michael Bell, MD, associate director for infection control in the CDC’s division of health care quality promotion, was frank in his assessment of the data, saying US patients deserve better than a “coin toss” chance of being exposed to infection at a surgical center.

“It is not cutting-edge science,” Bell said. “It is, in fact, appalling.”

COMMON MISTAKES

In the last decade, there have been at least 48 US outbreaks of infectious diseases traced back to unsafe injection practices, not including cases involving medications contaminated at the site of production, such as those implicated in the ongoing outbreak of fungal meningitis, said Joseph Perz, DrPH, of the CDC. Of these outbreaks, 21 involved patients infected with hepatitis B or C and 27 resulted in patients developing bacterial infections, often invasive blood infections, said Perz, team leader of the ambulatory and long-term care prevention and response branch in the CDC’s division of health care quality promotion. Most of the affected patients were infected during treatment at an outpatient facility, particularly pain clinics and outpatient oncology centers, he noted.

During these outbreaks, more than 150 000 patients were notified of potential exposure to infection. In addition to causing potential distress to patients and imposing costs related to

To prevent the spread of blood-borne infections, the US Centers for Disease Control and Prevention has launched a campaign reminding clinicians not to reuse needles or syringes.
testing and follow-up care, such notifications may erode public trust in the health care system, Perz said. For example, Birkhead noted that high-profile episodes involving patients placed at risk during colonoscopy procedures in Nevada or during influenza vaccinations in New York may lead patients to forgo such preventive interventions.

Perz said that certain unsafe practices have been implicated in multiple outbreaks. For example, in the Nevada case, clinicians at a busy endoscopy clinic employed syringes that had been previously used on a patient, using the syringe, capped with a new needle, to withdraw from a vial medication that was subsequently injected in a different patient. Because a used syringe can contain fluid drawn from the patient receiving an injection, this can contaminate medication vials later reused on patients. The clinic was also routinely using vials of medication intended for single-dose use for multiple patients, a practice that can expose patients to bacteria in contaminated vials or to blood-borne pathogens in cases of needle or syringe reuse.

Unfortunately, data indicate that risky injection practices are not uncommon. A survey of 550 health care professionals found 1% of clinicians reported sometimes reusing syringes and 6% reported reusing single-dose vials (Pugliese G et al. Am J Infect Control. 2010;38[10]:789-798). Similar behaviors, such as reusing insulin pens (which may also retain patient fluids) on multiple patients and reusing syringes after injections through tubing, have been linked to outbreaks of infection, Perz noted.

**ONE & ONLY CAMPAIGN**

Public health officials and agencies have tried to curb such misuse by launching initiatives to educate clinicians at outpatient facilities and elsewhere about safe injection practices.

In 2009, the CDC and the Safe Injection Practices Coalition launched a campaign to educate clinicians about the need to follow the CDC’s standard precautions to ensure safe injections (http://www.cdc.gov/injectionsafety/1anonly.html#Background). The One & Only campaign emphasizes using each needle and each syringe only once. The CDC is providing funding for 3 states—North Carolina, New Jersey, and New York—to disseminate campaign materials.

In addition to participating in the campaign, New York has made changes to its laws to facilitate investigations of outbreaks, increased regulation of ambulatory surgical centers, and mandated clinician training in safe injection practices, Birkhead said. The state has also created a substantial disease transmission working group that includes epidemiologists, public affairs staff, physician discipline board representatives, and other stakeholders who meet regularly to review ongoing investigations.

But Birkhead noted a major challenge to these efforts has been refusal by clinicians to acknowledge that unsafe injection practices are a problem. “Providers need to be educated and de-nial addressed,” he said.

Perz also highlighted the problem of physician denial, explaining that the agency has received push-back from pain management specialists about the safety of using single-dose vials for multiple patients. Perz said defense of the practice is based on a lot of “ifs”—for example, if only a new syringe is used.

Since the Nevada outbreak, which occurred in a CMS-certified facility, CMS has partnered with the CDC to give teeth to the public health agency’s evidence-based guidance on injection practices. As the largest purchaser of health care in the world, CMS has considerable enforcement authority, noted Hamilton. It conducts unannounced surveys of a range of organizations providing outpatient care, including ambulatory surgical centers, clinical laboratories, dialysis centers, hospitals, nursing homes, rural health centers, and home health agencies. To be certified and receive payment for care of beneficiaries of Medicare and Medicaid, facilities must promptly remedy problems identified by surveyors.

But CMS has also faced growing challenges in its oversight of outpatient facilities. The number of such facilities has grown substantially, with the number of ambulatory surgical centers participating in Medicare increasing from 3094 in 2000 to about 5368 in 2011, Hamilton said. Similarly, the number of dialysis centers has increased from 3957 in 2000 to almost 5706 in 2011. He also noted that most of these facilities operate on a for-profit model, which may lead to efforts to cut costs by using single-dose vials for multiple patients or by reusing syringes.

Alignment of CMS and CDC’s capabilities to tackle the problem is a good strategy, said Hamilton, and CMS has also been requiring credentialing organizations to address these issues.

Perz noted the need to engineer foolproof injection products or systems, to build “a safer system from the ground up.” For example, he noted that auto-safe syringes have been promoted for use overseas. Such products may automatically retract the needle after use and become disabled to prevent reuse.

The CDC has encouraged outpatient facilities to move toward prepared single-dose injections, said Bell, but he acknowledged that many of these facilities lack the resources hospitals may have, such as dedicated space and personnel for such preparation. In such circumstances, the agency has recommended that facilities consider compounding pharmacies as a source for single-dose products. Now, however, he noted that the recent fungal meningitis outbreak traced to contaminated medication from a large compounding pharmacy calls such a strategy into question. It has led the agency to recommend pharmaceutical manufacturers, who are held to tighter standards, as a source for single-dose products, he said.

Hamilton noted there are several more steps CMS is taking as well, starting with declining to pay for medical errors, as well as championing those individuals within facilities who are working to promote patient safety and calling on top management to support those efforts.

Addressing the need for improved injection safety will not be easy, given the number of outpatient facilities springing up and the competing demands for clinicians’ and facilities’ attention, Bell acknowledged. “This is a huge mountain of work that needs to be done,” he said.