ASCs seek dialog on drug shortages, single-use vials

A new villain has emerged in the struggle against drug shortages that continue to plague health care: the single-use vial.

When a vial of injectable medication contains more than a particular patient needs, if the vial is designated “single-use,” the remainder must be discarded, according to recommendations from the Centers for Disease Control and Prevention (CDC). The recommendations have been adopted by the Centers for Medicare and Medicaid Services (CMS) under its infection control regulations.

Clinicians have begun to challenge the rule, which they say leads to waste and expense. Until recently, most challenges have been aimed at regulatory agencies such as the CDC and the Food and Drug Administration (FDA).

Now there is talk of bringing the pharmaceutical industry into the discussion. Regulators say they generally accept drug manufacturers’ protocols for use.

The risk of reuse

CDC records show that between 2001 and 2011, there were 18 known outbreaks of viral hepatitis associated with unsafe injection practices in outpatient settings, affecting 358 patients and potentially exposing 100,000.

Among these, 2 outbreaks were in ASCs, and 4 were in endoscopy clinics.

In a 2008 random survey of ASCs in 3 states, the CDC found 28% of ASCs were cited for deficiencies related to injection practices or medication handling, including reuse of single-use vials. The following year, CMS instituted its infection control survey-reporting requirement.

A pair of outbreaks early in 2012 renewed concerns. The CDC, in its Morbidity and Mortality Weekly Report of July 13, 2012, reported that patients at an Arizona pain management clinic and a Delaware orthopedic clinic were infected with methicillin-resistant Staphylococcus aureus (MRSA) after sharing medication from single-use vials, even though needles and syringes were not reused. The outbreaks, in which 1 person died and 10 were hospitalized, bring to 20 the number the CDC has recorded since 2001—after tracking a half billion procedures in ambulatory settings of many kinds.

At the Arizona clinic, reports indicate that it was standard procedure to mix contrast media with saline solution each morning and store the diluted media in 10 mL vials for use during the day. Three patients required inpatient treatment for MRSA infection, and a fourth subsequently died after receiving injections from 1 of the refilled vials.

In the Delaware case, a hospital-affiliated orthopedic clinic had been reusing vials of the anesthetic bupivacaine. Of 7 patients who developed MRSA infections, 5 had been treated on the same day.

The CDC notes that difficulties obtaining vials in the appropriate sizes, either because of a drug shortage or because the vial size needed was not manufactured, might have led to the deviation from recommended practices.
**Request to revisit requirements**

Members of the ASC industry are asking regulators to revisit single-use-vial requirements in the hope of conserving medications without compromising patient safety. Of the 20 outbreaks the CDC reported during the 10-year period it collected data, 2 were associated with Medicare-certified ASCs—the only providers studied that were subject to CMS’s health and safety standards.

“Those outbreaks occurred under the current rules,” explains Bill Prentice, chief executive officer of the Ambulatory Surgery Center Association (ASCA). “But to say we couldn’t construct a process to protect patients is false logic.”

**Few good substitutes**

One alternative to running out of medications is to find other drugs that will do the same job.

According to pediatric anesthesiologist Keith Metz, MD, medical director of Great Lakes Surgical Center in Southfield, Michigan, that is not always easy. For example, he prefers fentanyl for postoperative pain relief because it is both effective and short acting.

When Dr Metz runs out of fentanyl, he turns to morphine, which is longer acting and can depress breathing. “We have to monitor patients for a longer time,” he says, “and that’s silly, because we have better drugs.”

“It’s one of the drugs that is most frustrating to us,” he says of fentanyl, “because when we can get it, we don’t have a choice of container.” Most ASCs order the 2 mL size, which is the average dose for both adults and most children. Lately, they have had to settle for larger vials, he says. “So we get 5 mL, use 1 or 2 ccs, and have to dispose of the rest.”

To have the drug repackaged at a local compounding pharmacy costs 3 to 5 times the original manufacturer’s price.

The preferred preoperative drug midazolam (Versed) is also in short supply. A common alternative is diazepam (Valium) to reduce anxiety. Diazepam, however, is longer acting and the injection is painful, Dr Metz says.

Worst is the case of ondansatron (Zofran), used to prevent nausea after surgery. “It’s simply unavailable,” Dr Metz says. “Unfortunately, there aren’t even any good alternatives, so we have had to do without it and have more postsurgery nausea.”

**Meeting with CDC, FDA**

Prentice and other ASCA officials met in July and August with CDC and FDA officials to express their concerns. According to Prentice, the CDC officials were not aware that, unlike hospitals, ASCs do not have pharmacists on staff.

The ASCA officials also raised the concern that the CDC’s suggested alternative to discarding single-use injection vials—repackaging the drugs into smaller-dose containers—is not always practical for ASCs because of the controlled environment required.

Outsourcing the procedure to compounding pharmacies is also impractical in many cases, they said, because of the cost and, in certain locations, lack of access to such facilities.

Plus, with the fall 2012 meningitis outbreak from spinal injections linked to medication from the New England Compounding Center, more focus on the oversight of compounding pharmacies is sure to arise.

In a statement following the CDC meeting, ASCA said that it had voiced concerns...
from its members about the single-use rules and asked for clarity from the agency about whether “a more-nuanced process” could be developed that would protect patients while eliminating waste that occurs currently.

Meanwhile, ASCA urges members to comply with the current injection recommendations.

**CMS reinforces requirement**

Prior to the ASCA-CDC meeting, on July 13, 2012, the Government Accountability Office (GAO) issued a report revealing some contradictions in the way the single-use rules are being enforced.

On June 15, 2012, CMS sent a memo to state surveyors saying that despite complaints from ASCs about hardship related to scarce drugs, it did not plan to relax the single-use rule.

The memo states in part:

“CMS shares the concerns of providers and suppliers about patient access to critical medications that are in short supply and appreciates the efforts of health care facilities to meet the needs of their patients. However, CMS is equally concerned about health-care associated infections caused by unsafe medication preparation and injection practices, including using [single-use vials] for multiple patients in the same manner as vials labeled as multi-dose. Such reuse is not compliant with infection control requirements and must be cited as a deficiency. We are not changing our policy on this matter.”

The memo goes on to say that ASCs using medications that have been properly repackaged should not be cited.

**GAO: Continue tracking**

Since 2009, CMS also has had a policy of requiring surveyors to report deficiencies using its Infection Control Surveyor Worksheet. The worksheet includes a section on injection practices including disposition of single-use vials.

CMS stopped collecting the worksheets in late 2011 in response to surveyor complaints about the administrative burden they presented, despite the concern for patient safety.

The GAO recommends that CMS find a more efficient way to collect data, such as random sampling or less-frequent reporting, rather than stopping altogether.

“Without some form of continued data collection, CMS will lose its capacity to monitor ASC compliance with its health and safety standards related to safe injection practices and to monitor how well the state surveyors collect and assess information about unsafe injection practices,” the GAO report concludes.

**Lack of awareness**

In 2010, the Premier Healthcare Alliance surveyed 5,446 registered nurses in hospitals about their injection practices, and 6% reported “sometimes or always” using single-use vials for multiple patients.

The Institute for Safe Medication Practices (ISMP) attributed the results to a “lack of awareness regarding safe injection control practices.” Some respondents thought a larger vial meant the contents were intended for more than one patient.

Often the reason medications are labeled as “single dose” or “single use” is the absence of preservatives.

According to CDC associate director for infection control Michael Bell, MD, the MRSA outbreaks occurred in part because of a lack of awareness of the danger of contamination in preservative-free medications.
“Because injections were prepared with new needles and syringes and, in one of the clinics, in a separate ‘clean’ medication preparation room, providers thought they were being safe,” he explains in his blog.

ASCA would like to see more use of preservatives, according to Prentice. “The question is, Why couldn’t there be preservatives? We’re not presuming there is [a way]; we’re just asking the question.”

ISMP executive vice president Allen Vaida, PharmD, has an answer: “Because of where they’re being used. For example, ASCs do a lot of pain treatment, with spinal and epidural injections. Those can’t have a preservative because they will be toxic to the body.”

Other medications, such as lidocaine, are available with or without preservatives, giving physicians a choice.

“Many of those products are preservative free because that’s how the physician wants them,” Vaida says.

**Going to the companies**

In its analysis of the MRSA outbreaks, CDC noted that proper repackaging using a laminar-flow hood based on US Pharmacopeia standards might have prevented the infections, while smaller vials would have made repackaging unnecessary.

In his experience as a pharmacist, Vaida says it is possible to convince pharmaceutical companies to redesign vials to avoid waste. Similar efforts in the past yielded an increase in premixed medications, he says.

As for the difficulty in finding affordable compounding pharmacies, Vaida says there are FDA-approved outsourcing manufacturers with nationwide distribution. “We often go out and visit compounding pharmacies around the country. They ship.”

He acknowledges that cost is a factor. “Availability is not the issue, but it’s going to be more expensive” to repackage, he notes.

**Is there a better way?**

Now, packaging is based on the “average” dose, but patients differ. “I think the problem is they have major concerns with certain drugs,” Vaida says of ASCs. “They should approach the manufacturers. With these products, it’s basically what the market wants.”

At their meeting in mid-August, the ASCA and FDA came to a similar conclusion. FDA officials advised ASCs to email drugshortages@fda.hhs.gov to report drug shortages and to contact drug suppliers directly to discuss their vial size preferences.

The FDA also has begun questioning vial sizes in its approval process, they said.

According to Dr Metz, who chairs ASCA’s government affairs committee, the point of the meeting was to begin involving the pharmaceutical industry. It may be possible to change a drug’s formulation to make it less susceptible to contamination or to provide a better range of vial sizes to avoid waste.

Meanwhile, he stresses, ASCs should never reuse single-use vials or repackage drugs except according to CDC protocols.

ISMP doesn’t dispute the need for discussion, according to Vaida, but safety must remain the highest priority.

“We are striving for the best, safest practice,” he says, “but we understand the need to be affordable. Yet, all you need is one outbreak, and there goes the money you saved. You really have to err on the side of safety. One infection costs tens of thousands of dollars to treat.”

—Paula DeJohn
References


Government Accountability Office. HHS has taken steps to address unsafe injection practices, but more action is needed. GAO-12-712. www.gao.gov/products/GAO-12-712

Perilous infection control practices with needles, syringes, and vials suggest stepped-up monitoring is needed. ISMP Medication Safety Alert! December 2, 2010. www.ismp.org