A few years ago, the Institute for Safe Medication Practices (ISMP) conducted a survey of its nursing audience on Carpuject prefilled syringe cartridges for injectable medications. The survey revealed two troubling safety issues that could place patients at risk:

- Many nurses were unaware of an important product safety issue at the time with Carpuject cartridges that could lead to overdoses with high-alert medications.
- Many nurses reported using Carpuject prefilled cartridges as single-and multiple-dose vials, withdrawing all or part of the medication in the cartridge into a syringe, often unlabelled, before administration.

Background

On May 18, 2012, Hospira issued a safety alert to health care professionals about potential, clinically significant volume overfill in prefilled Carpuject and iSecure syringe systems—more than twice the expected amount in some cases. A manufacturing problem with the filling equipment led to the possibility of cartridges containing more than the labeled fill volumes. Hospira asked health care professionals to visually confirm that cartridges contained the labeled fill volume, and to return any cartridges with overfill.

ISMP conducted a short survey of front-line nurses who used Carpuject prefilled syringe cartridges for injectable medications, primarily to learn whether they were aware of this issue and to gather information about any other safety concerns with using the Carpuject prefilled syringe system.

Survey Findings

The survey was completed by 540 nurses, predominantly staff-level registered nurses (78%) and, to a much lesser extent, nurse managers (8%) and nurse educators (8%). Most participating nurses (87%) worked in organizations that had been using Carpuject prefilled syringe cartridges for more than two years.

When preparing a Carpuject syringe, 8% of nurses told us they did not check the actual volume in the cartridge; they assumed the volume was as stated on the label.

Approximately two of every three nurses (68%) in our survey were unaware of the potential for clinically significant overfill in some Carpuject prefilled cartridges, as mentioned in the 2012 Hospira safety alert. (It is possible that pharmacists in some hospitals inspected all Carpuject supplies in patient care units without alerting nurses to the potential problem; however, ISMP believes nurses also should have been made aware of the potential risk.) Nurses who reported awareness of the problem had heard about it most often through a safety alert email or a posting from the hospital, pharmacy, nurse educator, professional organization, school faculty, Hospira, or the Food and Drug Administration; signage at automated dispensing cabinets; or word of mouth from supervisors or peers. One nurse reported that a safety alert was issued after an event took place associated with overfill of the cartridges; however, no details about the event were provided.

Irrespective of the Hospira safety alert, if nurses noticed a discrepancy in the volume of a Carpuject cartridge, one in ten nurses (10%) told us they would not report the discrepancy at all, and about one in five nurses (19%) would not report it to the pharmacy (although their managers might). Comments from these nurses implied that they did not believe the risk of overfill was a significant concern given their current practice of withdrawing the prescribed amount of drug from the cartridge, using it more as a single- or multiple-dose vial than as a prefilled syringe delivery system. To withdraw the medication from the cartridge, nurses were removing the needleless adapter and puncturing the rubber diaphragm with a needle attached to a syringe. These nurses told us they expected overfill and would simply withdraw the correct prescribed amount from the cartridge and either dispose of the remaining drug or save it for another dose (which is an unsafe practice).

Twelve percent of all nurses reported awareness of “other current safety issues with Carpuject prefilled syringe cartridges,” which turned out to be, almost exclusively, concerns associated with using the cartridges as vials. These nurses expressed concern about potential safety issues with this practice, including:

- Risk of contamination after entry into a medication cartridge not intended for puncture as a vial.
- Risk of contamination when using single-use cartridges as multidose vials.
- Risk of contamination when preparing sterile medications under conditions that might not meet standards in the U.S. Pharmacopeial Convention (USP) Chapter 797.
- Risk of unlabeled syringes once medications have been withdrawn from the labeled, prefilled cartridges into a new unlabeled syringe.
- Risk of mislabeled syringes if a drug was withdrawn from a Carpuject cartridge into a prefilled, labeled syringe of diluent (e.g., drug added to a normal saline flush cartridge).
- Risk of dosing or measurement errors when transferring medication from one syringe to another.
- Risk of staff needlestick injuries.
- Risk of conditions that may facilitate drug diversion of products documented as “wasted.”

Nurses also shed light on some of the factors that encouraged the practice of withdrawing medications from the
Medication Errors

Table 1 Reasons Nurses Withdraw Medications From Prefilled Cartridges

- Unavailable syringe holders (or no awareness of their existence)
- Unfamiliar with how to use the syringe holder
- Difficulty in viewing the volume in the cartridge once inside the syringe holder
- To prevent drug waste during shortages (using cartridges as multidose vials)
- To prevent infection transmission with reuse of unclean syringe holders for multiple patients
- Desire or need to dilute medication before injection
- Cartridge sometimes slips in syringe holder, making administration difficult
- The rubber plunger pulls out of the cartridge too easily
- Incompatibility of syringe holder with some needleless IV connectors
- Risk of breaking the glass cartridges

cartridges (Table 1), most often citing unavailability of syringe holders (or no awareness of their existence!), the desire or need to dilute medications before administration, and concerns about the transmission of infections from syringe holders that have not been properly cleaned.

Other Safety Concerns

ISMP can envision other problems not mentioned in response to the survey when using prefilled cartridges as vials. Nurses may want to dilute small volumes of intravenous (IV) push medications to aid slow administration, or they may want to dilute doses of IV analgesics to speed initial delivery to the patient (rather than having the drugs remain in the IV tubing longer than necessary). It is not necessarily the dilution of these medications that is concerning, although in many cases the dilution is unnecessary given the very few Carpuject medications that actually require dilution according to the manufacturer’s labeling (e.g., lorazepam). Rather, the concern lies with the means of diluting them by using a syringe cartridge as a single- or multiple-dose vial. Under these conditions, diluting medications unnecessarily poses a risk that exceeds the benefit, particularly given that the process occurs outside pharmacy-controlled admixture under USP 797.

Also, transfer of the Carpuject medication from its bar-coded, labeled syringe to an unlabeled syringe reduces the effectiveness of a bedside bar-code scanning system because the drug and diluent are not in their original, bar-coded containers. The bar-codes on the original containers might be scanned, but this does not verify that the products are in the syringe used for drug administration because the transfer process often does not occur at the bedside.

Safe Use of Carpuject Syringes

ISMP has long endorsed the use of unit-dose syringes of injectable drugs, including Carpujects, as a safe practice. If Carpuject cartridges are stocked in patient care units, to ensure proper use ISMP highly recommends convening a small team of pharmacists and front-line nurses to discuss how the cartridges are really being used to prepare and administer medications, and to determine the safest way to dispense, prepare, and administer each drug supplied in the Carpuject prefilled syringes. Based on our survey results, such a meeting, if conducted in a nontreating environment, will likely be quite an eye-opener regarding why and how nurses manipulate some medications in Carpuject cartridges.

Under the best of circumstances, transferring medications from one syringe to another increases the risk of errors and contamination, and is, therefore, not a practice ISMP can recommend. It is an at-risk behavior where the risk associated with the unsafe practice is most likely not recognized or mistakenly believed to be minimal or justified. Furthermore, the cartridges were never intended for use as a single- or multiple-dose vial by the manufacturer, Hospira, even though a few drug cartridges may contain preservatives. In addition, practically all of the Carpuject drugs can be administered without further dilution.

For drugs that require further dilution prior to administration, the pharmacy should prepare and dispense the diluted formulation in syringes or minibags whenever possible or dispense single-use vials of the drug and diluent together. Syringe labels should be readily available in areas where the drug and diluent might be mixed. If dilution using approximately a 1:1 ratio is acceptable, drawing a small volume of an appropriate diluent from a single-dose vial directly into a Carpuject cartridge (1 mL fill or less) may be considered in patient care units. An adequate supply of Carpuject syringe holders (one for each nurse is suggested) should be provided (free from Hospira), cleaned, and restocked on a routine basis. All nurses should be re-educated on how to use the Carpuject prefilled syringes as intended by the manufacturer, and to ensure they understand the risks associated with using the cartridges as vials. The iSecure syringes from Hospira, which are designed to prevent manipulation of the contents, or other secure prefilled syringes could be considered as an alternative to Carpuject syringes.