



PEN injectors: Technology not without imPENDING risks

The availability of medications packaged in pen injectors has been steadily increasing. Interest in self-administration of medications in the home, particularly among patients with chronic diseases like diabetes, has propelled the use of this unique delivery method. Intended primarily to facilitate easy and accurate self-administration of subcutaneous drugs, pen injectors can now be found in hospitals for nurses to administer medications to patients.

ISMP has received numerous reports of medication errors that have occurred in patients' homes and healthcare facilities when using pen injectors. Since use of these devices will likely continue, ISMP will be establishing safe practice guidelines that can be employed in all settings to reduce the risk of serious errors. To accomplish this, we need to learn as much as possible about the types of risks occurring with pen injectors. Here we offer a glimpse of what we have gathered so far from reports submitted to the USP-ISMP Medication Errors Reporting Program.

Error-prone device design

- Patients and nurses have injected epinephrine into their thumbs when attempting to remove the black cap

on an **EPIPEN** (epinephrine). See Figure 1. Although the cap looks like it should be removed, it actually houses the needle and activates the injection when appropriately pressed against the patient's thigh or inappropriately in a thumb, in these cases. Failure to activate the device has also occurred when patients have not properly pressed the device against



Figure 1. EpiPen injector: The black end (left) shields the needle. The grey safety cap (right) must be removed before use.

the thigh to cause injection of the drug. (Recent changes in packaging and labeling might help reduce the risk of misusing this pen injector.)

- The display of a digital dose in the window of the **LANTUS OPTICLIK** (insulin glargine [rDNA]) and **APIDRA** (insulin glulisine [rDNA]) pen injectors could be misread if the pen is held upside down, as a left-handed person might do. For example, if the pen is held incorrectly, a dose that looks like '25' units is actually '52' units, or what appears to be a dose of '21' units is actually '12' units. See Figure 2 in next column. Digital displays on other pens might cause similar problems.

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Figure 2. Opticlik injector: Dose of 52 units appears as 25 units if held upside down.

Unsafe practices with prefilled saline flush syringes: Is it really saline in that syringe?

ISMP has long been a supporter of prefilled, labeled syringes for several safety reasons:

- The syringes are available in typical patient-specific doses, requiring no further manipulation
- The syringes do not carry the risk of cross contamination that the use of multidose vials do
- The syringes are clearly labeled with the drug name and dose/strength, thus avoiding the risk of using an unlabeled syringe.

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safetywires

Free videos. The **FDA Patient Safety News** videos posted for February 2007 involve the two main topics, contributed by ISMP and covered in this month's **Nurse Advise-ERR®** newsletter.

- **Possible Dosing Errors with the OptiClik Insulin Injection Device**
- **Dangerous Use of Saline Flush Syringes.**

FDA Patient Safety News is a free satellite broadcast series that features information on new drugs and medical devices, product recalls, and safety issues when using medications and medical devices. Each month, new 'shows' are posted online for free viewing. Visit www.ismp.org/Tools/fdavidios.asp to download these videos. Viewing them during a staff meeting is a great way to begin discussions on important safety issues and to gather ideas on the best ways to avoid patient harm.

Caution with Zydys technology.

Some new medications come in tablets that dissolve within seconds in the mouth and deliver more active drug at a lower dose. One of the technologies used to produce medications in this formulation is called 'Zydys.' Unfortunately, one of the drugs that uses this technology has

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Using pens like vials

● In response to the rising costs of medications, some healthcare providers have replaced insulin vials on nursing units with insulin pen injectors or pen cartridges from which nurses routinely withdraw a prescribed dose using an insulin syringe and needle. In some cases, the pens or cartridges are used as multiple-dose vials for a single patient and each dose is removed with a sterile needle and syringe; in other cases, the pens or cartridges are used as floor stock 'vials' from which nurses obtain insulin doses for multiple patients using a new sterile needle and insulin syringe for each puncture into the cartridge membrane. Manufacturers do not recommend the withdrawal of medication from the pen cartridge, except in an emergency with a malfunctioning pen. In these instances, the pen cartridge should then be discarded, even if insulin remains in the pen cartridge.

● Large pockets of air have been observed in cartridges of insulin pen injectors after aspirating some of the drug with a needle. If the pen injector or cartridge is not discarded, and the air is not eliminated before delivering a subsequent dose, the patient could receive less than the desired dose of insulin as well as a subcutaneous injection of air.

Treating available volume as dose

● Patients and healthcare practitioners have administered the entire volume available in a multiple-dose pen injector, believing it was a single-use device. For example, a nurse administered the full contents of a pen containing 750 mcg of **FORTEO** (teriparatide [rDNA]) to a hospitalized patient with osteoporosis. The pen actually contained enough medication for 28 daily doses (typically 20 mcg/daily). The manufacturer lists the contents of the pen (750 mcg /3 mL) on the carton label and pen injector, but the notation

that the pen contains a 28-day supply is much smaller and may be overlooked. Based on the label, the patient thought she gave herself 750 mcg daily, but she was actually receiving 20 mcg. She told her physician that she took 750 mcg daily, which was subsequently prescribed. Since the pen had been dispensed accidentally without a needle, the nurse drew its entire contents into a syringe and administered it.

Variable designs

● The variety of pen injector designs makes it difficult for nurses to learn how to use them properly and maintain device-related competence.

Dispensing errors

● Insulin products with look- and sound-alike names have contributed to errors in which the wrong pen injectors have been dispensed, resulting in poor glycemic control.

● Adult and junior strengths of EpiPen have been confused, leading to dispensing errors and unfavorable responses to this emergency drug.

Inadequate patient education


● The patient's insurance may not cover the cost of pen injectors, and the use of coupons and samples to help patients obtain these devices is often short-lived. Thus, patients who are educated about using a pen device, but then cannot afford to purchase the medication in this fashion, will not be prepared to draw doses from a vial. Conversely, patient education before discharge might not be with the actual pen injector that will be used at home.

● Many patients do not tip and roll their insulin suspension pen injectors adequately to assure proper mixing. This may result in large clumps of aggregated insulin flowing from the pen injector during the first injection, leading to hypoglycemic symptoms with new cartridges followed by subtherapeutic doses.

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also included the term in its brand name: **ZYPREXA ZYDIS** (olanzapine), an antipsychotic agent used to treat agitation. Another newer product that uses Zydis technology is **ZELAPAR** (selegiline), a quickly dissolving medication used as an adjunct therapy for patients with Parkinson's disease. Unfortunately, we have numerous reports of mix-ups between these medications, caused by either misreading a handwritten order as the wrong drug, due to name similarities, or misunderstanding when either drug has been prescribed using just 'Zydis.' Both medications have sometimes been identified by the 'Zydis' description, potentially encouraging prescribers to call the drug by this name. If 'Zydis' alone is prescribed, call the prescriber to clarify which drug is intended.

 **Color consistency.** The use of colorful labels to bring attention to selected drugs that may be confused could actually introduce the risk of error if the labels are not applied consistently. In one example, a nurse mistakenly hung Lactated Ringers (LR) containing **PITOCIN** (oxytocin) instead of plain LR, caused in part by the absence of a customary orange sticker on the bag with Pitocin. The nurse had taken a plain bag of LR and a pharmacy-prepared bag of LR with Pitocin into the patient's room. While Pitocin had not yet been prescribed, she anticipated its use later during the patient's labor. The night pharmacist had not applied the usual orange label to the Pitocin to help differentiate the solutions. The nurse mistakenly administered the Pitocin infusion, as it looked very much like the bag of plain LR. The patient and baby were not harmed. While nurses should never rely on color to identify products, if an expected colored label on a particular product is missing, its absence may contribute to mix-ups with look-alike products. Talk to your pharmacist if your hospital has similar label inconsistencies. It is also safest to bring only ordered solutions into patient's rooms.

Saline flush syringes cont'd from page 1

We recently learned about an unsafe practice with using prefilled saline flushes that negates some of these safety features, particularly the last point. Some nurses have been reconstituting drugs using prefilled saline flush syringes, particularly the 5 and 10 mL sizes. After discarding any unneeded volume of saline, the nurse adds the remaining saline to a vial of medication, mixes it, and then draws it back into the saline syringe. Herein lies the problem: now the syringe that is labeled '0.9% saline flush' contains an actual drug and not only saline. If the syringe leaves the nurse's hands before administering the drug, it might be used in error by another nurse, believing it is a saline flush.

We also learned that some parenteral medications, including morphine, are being diluted using prefilled saline flushes. Thus, the syringe labeled as a saline flush also contains a clear, high-alert medication that could be lethal if used as a saline flush.

One company that makes saline flushes has widened the gradations on the syringes to discourage this practice; more precise gradations are typically needed to measure drugs accurately, while an adult flush solution does not require the same degree of accuracy beyond mL gradations. Unfortunately, this measure has not stopped the unsafe practice described above.

There may be an additional problem with sterility. Some saline flush syringes are sterile from inside the cap on one end, to the 'seal' on the end of the plunger; the barrel is not sterile

between the 'seal' and the finger-grip. When injecting the saline into a vial to reconstitute a drug, the non-sterile portion of the barrel enters the syringe as the saline is injected. Then, when drawing the reconstituted drug back into the syringe, the medication is exposed to a non-sterile surface on the inside of the syringe.

Please take time to discuss this issue at staff meetings so that all nurses understand the risks associated with this unsafe practice. Medications should always be dispensed from the pharmacy in the most ready-to-use form possible, especially high-alert drugs such as morphine. There are relatively few medications with limited stability that require reconstitution or dilution immediately before administration.

If reconstitution or dilution of a medication must occur on the nursing unit, single-use vials of saline should be used. If feasible, pharmacy should dispense the medication and the saline vial together in a kit. If the medication is being dispensed for a specific patient, pharmacy may also be able to provide a preprinted label to apply to the syringe used to withdraw the final product. Otherwise, nurses should be supplied with blank syringe labels (not tape) that can be applied.

While using prefilled saline syringes to reconstitute medications is error-prone and often cost prohibitive, if this practice is used, a new sterile syringe, not the empty saline flush syringe, should always be used to withdraw the reconstituted or diluted medication.

with these devices, hear from patients about problems, or want to share safety guidelines you have employed, please let ISMP know via ismpinfo@ismmp.org. We look forward to learning more and building safe practices around pen injectors that we can share in a future newsletter.

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- When asked about current medications, patients have mistakenly misrepresented insulin pen devices as 'insulin pumps,' which are a vastly different mode of delivery.

We encourage nurses to contribute to our pool of knowledge about pen injectors. If you experience problems

► Special Announcements

Free Webinar for Nurse Leaders. On **March 15, 2007**, ISMP, the American Organization of Nurse Executives, Joint Commission Resources, and the National Patient Safety Foundation will be presenting a free 1-hour Webinar, sponsored by McKesson and Intel, on **Measuring Culture Change**. ISMP's Vice President, Judy Smetzer, and Covenant Health's Senior Vice President, Sandra Mashall, will describe the link between culture and safety, why culture should be measured, how it can be accomplished, the domains that should be evaluated to properly diagnose the culture, and the facilitators and barriers to using the findings to improve patient safety. Please visit www.nursingleadershipcongress.com/webinars.asp for details and to register.

PPAG Meeting. The Pediatric Pharmacy Advocacy Group (PPAG) will be holding a conference, **Pediatric Medication Safety and Technology**, from **March 30 to April 1, 2007**, at the Renaissance Austin Hotel in Austin, Texas. Topics include barcode point-of-care documentation, automated dispensing cabinets, computerized prescriber order entry and decision support, electronic medication administration records, smart pump technology, and more! Arrive early on Friday for a bonus pre-conference symposium on Medication Safety and Technology, co-sponsored by ISMP and PPAG! Nurses welcome! Visit www.PPAG.org for details.

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