



Nurse Advise-ERR®

Educating the healthcare community about safe medication practices

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Mix-up between lactated Ringer's and oxytocin

A woman in advanced labor (8 cm dilated) received an unspecified amount of IV oxytocin (PITOCIN) after a nurse mistakenly picked up an oxytocin infusion instead of a bag of lactated Ringer's intended for hydration. Believing the oxytocin was lactated Ringer's, the nurse set the infusion pump to deliver a maintenance flow rate (about 125 mL/hour). The oxytocin infusion quickly affected the patient's contractions, causing significant pain as well as deceleration of the baby's heart rate from 110 to 70.

Labor and delivery nurses depend on teamwork and hand-offs of supplies and medications from others.

The nurse who hung the oxytocin instead of lactated Ringer's noticed the error while she was squeezing the bag to speed up the rate of infusion and facilitate intrauterine resuscitation. The infant was delivered as soon as possible using vacuum extraction. The infant had a low Apgar score and required care in the neonatal intensive care unit to treat respiratory distress. The mother sustained a third degree laceration.

Both the oxytocin and lactated Ringer's were available in the patient's room near each other. The oxytocin bag was prepared and brought into the room for use after delivery of the placenta. The environment in the patient's room was hectic even though the patient's labor had progressed normally and no problems with the fetal heart rate had been detected prior to the error. Nursing care had been fragmented, with one nurse preparing and bringing IV medications into the room, another nurse hanging the infusions, and a third nurse interacting with the patient and other medical personnel in the room. Distracted by the activities, the nurse who hung the bag of oxytocin by mistake failed to notice she had picked up the wrong IV bag.

Because oxytocin is typically administered immediately after delivery of the placenta and may be needed urgently to control postpartum bleeding, the product is often brought into the labor-delivery-recovery (LDR) room. To avoid mix-ups like the one described, follow the recommendations in the **check/out!** column.

check/out! ✓✓✓✓

To prevent mix-ups between IV solutions in LDR rooms, consider the following:

- ✓ **Distinguish with bold labels.** IV bags of oxytocin should be prepared in the pharmacy and boldly labeled to differentiate it from other IV solutions. The label should be applied below the manufacturer's listing of the product so the pharmacy and manufacturer's label are visible together.
- ✓ **Separate and organize products.** In LDR rooms, identify designated areas for medications needed during different phases of the labor and birth process (e.g., boldly labeled containers, baskets, bins, or drawers where the products for each step of the process can be placed in an organized manner). Do not keep products needed during labor with products needed immediately after birth.
- ✓ **Restrict access.** Although care needs must be anticipated in birthing units, avoid bringing unneeded medications or solutions into the LDR rooms whenever possible. Restricting access to unneeded medications or making their appearance distinctive with easy-to-read labels are key error-reduction strategies.
- ✓ **Provide clear handoffs.** Labor and delivery nurses often depend on teamwork and handoffs of supplies and medications from others because they cannot leave the patient's bedside at critical times. A process should be established to clearly communicate what has been brought into the LDR room and where it was placed (in clearly marked bins, as noted above). Require repeat back and encourage clarifying questions to make sure there is common understanding.
- ✓ **Use bar-coding technology.** Use of point-of-care bar-coding technology can also help ensure that the right product has been selected for administration.

Double Trouble

Lyrica-Lopressor mix-up

A patient with a past medical history of atrial fibrillation was admitted to a hospital with an order for **LOPRESSOR** (metoprolol tartrate) 100 mg BID (see photo). However, the physician's handwriting was poor, and the order was misinterpreted and dispensed as **LYRICA** (pregabalin) 100 mg BID. The patient received three doses of Lyrica and experienced atrial fibrillation that was temporally related. A nurse recognized the error. Lyrica is used to treat pain due to nerve damage in patients with diabetes or shingles (herpes zoster), and to treat pain in people with fibromyalgia. Along with other drugs, it has also been used to treat certain types of partial onset seizures. The patient exhibited none of these conditions. Matching the drug's indication to the patient's health condition is the best way to avoid confusion between products with look-alike names.



QuarterWatch™ (3rd quarter 2008)
Safety concerns with generics, Chantix aggressive behavior, and more

QuarterWatch™, an ISMP program used to identify new drug risks reported to the US Food and Drug Administration (FDA), evaluated 24,872 serious, disabling, and fatal adverse drug events submitted during the third quarter of 2008. The reports involved 854 different drugs which led to 2,778 deaths, 1,162 cases of disability, and 20,932 other serious injuries. Of the 854 different drugs associated with death and disability, 53 drugs accounted for 100 or more reported cases. The leading drugs in this category appear in Table 1.

Specific Drugs

Interferon Beta (AVONEX, REBIF, BETASERON). Used to treat multiple sclerosis, this drug, accounted for 1,380 reported serious adverse drug events—more than any other prescription drug in the third quarter. Most events involved complaints about relapse or exacerbation of multiple sclerosis. After contacting the manufacturer with the largest number of reports, we concluded the frequency of reports resulted primarily from consistent contact with patients by one manufacturer to uncover relapses and exacerbation of symptoms, an expected outcome since the drug slows rather than eliminates the disease.

Digoxin. More than 1,000 deaths have now been reported, potentially linked to the recall of 800 million digoxin (branded generic DIGITEK) tablets manufactured by the Actavis Group in NJ. The strength of the tablets may have been greater than labeled, exposing patients to a potentially lethal overdose. One year after this recall—no doubt one of the largest class 1 recalls recorded—testing of the returned tablets has not been performed to establish how many deaths resulted from a manufacturing defect, and how many occurred for other reasons. In March 2009, another recall from Caraco Pharmaceutical Laboratories, underscores weaknesses in the US system

for ensuring quality in the manufacture of generic drugs.

Baclofen (LIORESAL INTRA-THECAL). Lioresal ranked third among all prescription drugs for injuries and fatalities in the third quarter of 2008, despite use of the

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Table 1. Most frequent drugs involved in serious, disabling, and fatal events in 2008 Q3.

Drug	Cases
interferon beta	1,380
digoxin	1,023
baclofen	872
varenicline	659
estrogens	586
rosiglitazone	494
etanercept	412
insulin	399
exenatide	399
inFLIXimab	369
fentaNYL	369
QUetiapine	339
adalimumab	336
Dianeal	335
natalizumab	319

Table 2. Terms used in varenicline reports describing aggression-violence since 2006.

Term used in reports	Mentions
Anger	383
Aggression	331
Irritability	291
Abnormal behavior	268
Agitation	263
Paranoia	164
Homicidal ideation	148
Psychotic disorder	108
Mania	96
Personality change	94
Bipolar disorder	76
Violence-related symptom	49
Screaming	45
Hostility	37
Psychomotor hyperactivity	37
Physical assault	30
Injury	18
Affect lability	16
Gunshot wound	15

safetywire

Unusual reason for hyperglycemia. NovoFine Autocover is a needle-stick protection device for use with the **NOVOLOG** (insulin aspart) **FlexPen** (see Figure 1). The user holds the cover while the system is screwed onto the insulin pen. The cover is then removed, exposing a plastic needle shield that initially covers a 30-gauge needle. As the insulin is injected, the shield slides and allows the skin to be punctured, needle unseen (a demonstration can be viewed at: www.novonordisk.com/diabetes/public/needles/novofine_autocover/quickguide/view.asp?id=intro). When the needle is removed, the shield retracts and locks over the needle, which remains hidden, so it can't be used again.

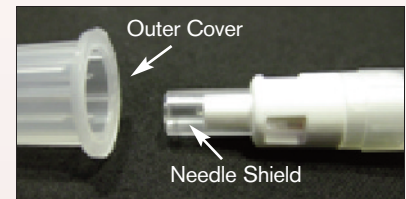


Figure 1. NovoFine Autocover has clear plastic needle shield that retracts. Needle remains unseen.

The Autocover system is different than the standard insulin pen needles patients purchase at their pharmacy. A pharmacist and nurse recently reported some patients who became familiar with the NovoFine Autocover while in the hospital were later confused as they began to use a standard pen needle (BD Ultra-Fine III) after discharge. This needle also has a cover that, when removed, exposes a needle shield. However, the shield is actually just a needle cap that must first be removed to expose the needle for injection of the insulin (see Figure 2 next page). Some patients were confused and thought the needle would be exposed when the cap was pushed against the skin, just like the Autocover shield. After realizing that some patients' blood glucose levels were high, clinic nurses investigated and learned that patients were misusing the standard pen needles and not getting any insulin. Patients who use Autocover devices and then switch to standard

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drug in a relatively small patient population to lessen involuntary muscle contractions from brain or nerve injuries, cerebral palsy, and multiple sclerosis. Problems with an implantable pump used to administer the drug into cerebrospinal fluid were associated with approximately 140 cases of serious injury including one death. Medtronic Neuromodulation, which provides both the implantable pump and the drug, issued an urgent alert (www.medtronic.com/neuro/spasticity/itbtherapy/downloads/SafetyAlert.pdf) to doctors that the catheter tubes delivering the drug to the spine were not being properly attached to the pump. This led to interruption of the drug supply and severe withdrawal symptoms. This cluster of cases was among 872 reports of serious injury associated with baclofen.

Varenicline (CHANTIX). This anti-smoking drug continued to account for more reports of serious psychiatric side effects than any other prescription drug. Although the FDA and manufacturer have already warned consumers about the possible risk of suicidal behavior, the case reports also suggest a possible link to violence towards others. Table 2 (page 2) provides the terms used in reports when describing this aggression and violence. Since the 2006 approval of varenicline, **QuarterWatch™** has identified 30 cases that describe physical assaults, 148 cases that mention homicidal thoughts, and 331 cases of aggression. (One case could include multiple symptoms.)

Strengths and limitations

One of the primary strengths of FDA's adverse drug event reporting system is its capability to detect adverse drug effects that may have been overlooked or underestimated in clinical testing prior to approval. Nevertheless, **QuarterWatch™** results should be interpreted with caution because reporting is voluntary and likely represents just a small fraction of adverse drug events that occur.

Conclusions

Quality of generic products. Concerns continue regarding serious problems our nation seems to be facing to ensure generic drugs are manufactured with adequate quality controls. In the first quarter of 2008, there were urgent recalls of most of the nation's supply of one form of generic heparin and millions of fentaNYL patches from several generic drug manufacturers. In the second quarter, about 50% of the nation's supply of generic digoxin was recalled because over-strength tablets may have been manufactured and distributed. Another generic digoxin recall was announced in March 2009. In the third and fourth quarters of 2008, urgent recalls were announced for generic versions of morphine sulfate, propafenone, and isosorbide—all involved over- or under-strength tablets that could lead to significant health consequences. Several pharmaceutical plants were recently closed and all generic products manufactured at these plants were recalled due to manufacturing concerns. It would appear FDA's current system for inspecting plants, dealing with violations, and managing drug recall notices requires systematic, independent review.

Warnings with varenicline. We continue to be concerned about the safety profile of varenicline. No action has been taken to provide a prominent warning about the drug's potential to cause motor vehicle accidents through its effects on mood, memory, vision, and motor control. Little follow-up has occurred in response to reports of aggression, physical assaults, and homicidal thoughts. We might assume these serious side effects have been disclosed to patients who consent to take varenicline, but such violence affects patients' families and the public at large, from whom consent to the possibility of violence has clearly not been obtained.

The full **QuarterWatch™** report can be viewed at: www.ismp.org/QuarterWatch/2008Q3.pdf.

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pen needles must be educated about the need to remove both caps. Removing the gray cap is an extra step that is not required with the NovoFine Auto-

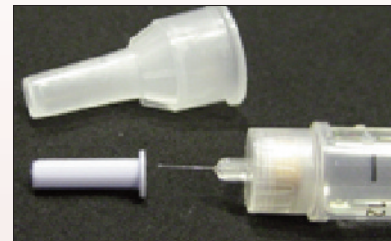


Figure 2. BD Ultra-Fine pen needle has gray cover that must be removed prior to injection. Some remove the larger, clear outer cover only.

cover needles. If blood glucose levels are elevated after injection, remind the patient to consult with their diabetes educator or physician, who should review injection techniques with them. Community pharmacists dispensing pen device supplies should also educate patients regarding their proper use.

Teleconference Announcement

ISMP teleconference. Join us on **June 11** for our teleconference, **Patient Falls and Medication Use: Making the Safety Connection**. Our speakers will be discussing: 1) the link between certain classes of medications and the risk of patient falls, 2) pharmacist and nurse interventions that can proactively reduce these risks, and 3) outcomes in their organizations related to implementing these interventions. To register, visit: www.ismp.org/educational/teleconferences.asp.

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