ISMP Medication Safety Alert!®

Nurse Advise-ERR®

Educating the healthcare community about safe medication practices

May 2008 ■ Volume 6 Issue 5

Seven lapses add up to tragedy

In 2006, a 43-year-old Canadian woman with advanced nasopharyngeal carcinoma was getting treatment in an ambulatory clinic when her therapy took a tragic turn.[1-2] Facility protocol called for the patient to receive high-dose fluorouracil and cisplatin. The order for fluorouracil was written as follows:

5-Fluorouracil 5,250 mg (at 4,000 mg/m²) intravenous once continuous over 4 days... Continuous infusion via ambulatory infusion pump (Baseline regimen dose = 1,000 mg/m²/day = 4,000 mg/m²/4 days).

On day 1, the patient received the entire fluorouracil dose over 4 hours instead of 4 days. She'd gone to the clinic to have the infusion started and a nurse reviewed her orders, lab results,

Figure 1. Pharmacy label on fluorouracil bag.

height, and weight. A pharmacy technician prepared the fluorouracil and cisplatin, and a pharmacist checked the drugs before dispensing them to the clinic. As specified in the protocol, the patient received prehydration, premedications, and 100 mg of IV cisplatin.

The fluorouracil bag contained about 130 mL of solution (45.57 mg/mL). The nurse used a calculator to determine the infusion rate and programmed the pump (Abbott AIM Plus, no longer marketed in the US). However, instead of programming it to deliver the infusion at the ordered rate of 1.2 mL/hour, she set the rate at 28.8 mL/hour, which was the total volume to be infused in 24 hours.

The nurse asked a second nurse on her way to another task to confirm the calculation. Not finding a calculator, the second nurse computed the dose mentally and on a scrap of paper. Failing to detect the first nurse's miscalculation, she confirmed the programming and locked the pump. After making sure the pump was infusing the medication, the first nurse discharged the patient with instructions to return in 4 days to have the pump disconnected.

Four hours after the patient's discharge, the IV bag was empty. She returned to the clinic. The evening nursing supervisor recognized the error and notified an on-call physician. The physician suggested that there was no treatment and that the patient should call again the next morning. The supervisor advised the patient that she'd received a large amount of drug and needed to drink plenty of fluids.

The next morning (day 2), the unit manager called the patient to advise her of possible serious side effects and asked her to come to the clinic for monitoring. The patient was feeling well and chose not to come in. When her attending physician became aware of the error, he conducted a literature search for potential treatments without reaching any conclusions. Meanwhile, the unit manager advised the patient to call if she developed any sign of mouth sores. On day 3, the physician called the patient and arranged for her to come in the next day for assessment.

When the patient came to the clinic on day 4, she complained of nausea, vomiting, and throat discomfort. She

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check it out! ✓✓✓✓

The following recommendations can help safeguard chemotherapy.

✓ **Standardize labeling.** Pharmacy chemotherapy labels should display the information needed to program an infusion pump (hourly infusion rate, concentration, total volume) prominently, preferably in the order it is needed. Data should be easy to read and in a standard format. Infusion rates should be communicated only as hourly. Information that is not useful to the nurse (e.g., mL/24 hours) should be eliminated.

✓ **Update certification.** Review the processes by which nurses are certified to administer chemotherapy. Make necessary changes to make sure they exhibit appropriate skills, knowledge, and abilities before working independently.

✓ **Safeguard pump use.** Conduct a failure mode and effects analysis to evaluate current pumps and those under consideration, to uncover risks and reduce the chance of programming errors. When smart pump technology is available for ambulatory pumps, its use should be encouraged to provide dose alerts and other feedback to help nurses detect programming errors.

✓ **Enhance double-checks.** Develop a structured process for conducting and documenting independent double-checks; educate the staff about this and monitor compliance. Minimize the need for calculations by using dosing charts when possible.

✓ **Use checklists.** Promote critical thinking during chemotherapy preparation and administration, and use checklists to standardize sequencing and workflow, ensuring that the steps necessary to safely dispense and administer chemotherapy are carried out.

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was treated and discharged but was admitted to the hospital on day 5 when a bed became available on the inpatient medical oncology unit. Over the course of 22 days following the error, the patient developed profound mucositis and pancytopenia, hemodynamic collapse, and multi-organ failure, and she ultimately died. The cause of death was sequelae of fluorouracil toxicity, cumulative with cisplatin toxicity.

When ISMP Canada performed a root cause analysis (RCA) of this event, they identified seven factors that contributed to this patient's fluorouracil overdose and death.

Confusing pharmacy label. The label on the medication bag was difficult to read and it unnecessarily listed the 24-hour infusion rate (28.8 mL/24h) followed by the hourly infusion rate (1.2 mL/h) in parentheses (see Figure 1 on page 1).

Miscalculation. The nurses who programmed the pump did complex calculations at the bedside to verify the infusion rate (mL/hour), but both forgot to divide the daily dose by 24 hours. As Figure 1 shows, the mL/hour infusion rate appeared on the label, but not in a prominent spot. Not noticing that pharmacy had listed the 24-hour infusion rate *before* the hourly infusion rate, the nurses exhibited confirmation bias, thinking their calculations were correct when they saw "28.8" as the first "rate" on the label.

Failed double-check system. The checking process was informal and unstructured. The nurse who was asked to double-check the initial infusion rate calculation was on her way to another task at the time. Unable to find a calculator, she did the calculation mentally and on paper.

Complex workload. Work processes on the unit weren't sequenced in a stepwise fashion, and nurses often multitasked in order to check lab results; weigh patients; perform physical assessments; review orders, labels, and calculations; program pumps; and educate patients. As a result, performing complex calculations and verifying pump programming were not viewed as high-risk activities that required particular attention and safeguarding.

Pump design flaws. The pump wasn't a smart pump, so it lacked dosage error-reduction software that could detect excessive doses or programming errors. In fact, certain design factors added cognitive burdens to programming:

- Infusion choices were listed as "mg/mL," "µ/mL"(µ is an error-prone abbreviation that should be avoided), or simply "mL" (meaning mL/hour)
- The prompt for "Container size" actually required entry of the volume to be infused
- The review screen didn't indicate how long the infusion would take.

Lack of familiarity with protocol. The nurse who programmed the pump wasn't suspicious about the high infusion rate. She was new to the unit and had never administered a 4-day fluorouracil infusion. Compared to other infusions delivered in the clinic, the rate of 28.8 mL/hour wasn't unusual.

No protocol for managing overdoses. Staff were uncertain how to best treat and support the patient after the overdose. Patients who receive prompt treatment for chemotherapy overdoses or serious adverse effects from prescribed doses may be less likely to experience irreversible harm.

You can read ISMP Canada's full RCA on the website listed in Reference 1. For techniques to resolve the seven factors that contributed to this tragic error, see **checkitout!**

References: 1) ISMP Canada. Fluorouracil incident root cause analysis. April 30, 2007 (formatted for posting on the Alberta Cancer Board website on May 23, 2007). Available at: www.cancerboard.ab.ca/NR/rdonlyres/2FB61BC4-70CA-4E58-BDE1-1E54797BA47D/0/FluorouracilIncidentMay2007.pdf. Accessed on May 12, 2008. **2)** ISMP Canada. Fluorouracil incident RCA: follow-up. *ISMP Canada Safety Bulletin* 2007;7(4):1-4.

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✓ **Include the patient.** Review pump data-input screens when educating patients about therapy. This gives nurses a final chance to detect programming errors.

✓ **Develop overdose protocols.** Define treatment protocols for chemotherapy overdoses that includes aggressive supportive care (e.g., hospitalization, IV hydration and forced diuresis, timely administration of hematopoietic growth factors, prophylactic antibiotics) as soon as an overdose is discovered. Require all staff who prescribe, dispense, and administer chemotherapy to demonstrate proficiency in identifying and managing toxicities.

safetywires

Say again? A physician called a poison control center for advice about treating an adult with ethylene glycol poisoning. Among the suggestions he received was the use of fomepizole (**ANTIZOL**). Later, he again called the poison center to check the spelling of the drug and learned that he'd misheard the earlier recommendation; he thought the poison control staff had said "omeprazole" (**PRILOSEC**), not "fomepizole." Because fomepizole is used primarily for methanol and ethylene glycol poisoning, many healthcare practitioners aren't familiar with it. The patient was treated appropriately and had no adverse effects. Medications with sound-alike names pose problems during telephone communication. If taking a phone order, The Joint Commission requires that you write down and read back drug names; spelling drug names provides an added safeguard. Similarly, read-back should occur when receiving phone recommendations for drug therapy to ensure that the medication and dose has been heard correctly.

SSRI or SSKI? In our July 2004 newsletter, we described an error in which an order to discontinue "SSRI," intended to mean "**s**liding

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Anonymous patches

Pharmacists and nurses have often reported that CATAPRES-TTS (clonidine transdermal therapeutic system) patches do not include the name of the drug or the strength on the patch itself. The patches are available in a variety of strengths and worn for a week at a time. Problems arise if the dose of a patch is changed, or if the patient requires multiple patches. In a hospital setting, there can be numerous caregivers interacting with a patient during the week; upon visualization, these caregivers can only determine that something is on the skin. They cannot determine the drug or dose, or even whether it's a transdermal medication patch or some sort of band-aid. This can lead to errors.

For example, a nurse could receive a new order for a clonidine patch or an oral dose, and not realize that the patient is already wearing a clonidine patch. Or, if the patient is wearing a clonidine patch along with another patch without a visible drug name and dose (e.g., LIDODERM [lidocaine], various contraceptive patches), the wrong patch might be removed and replaced with the same patch that remains on the patient. Thus, the patient would receive double the dose of one medication and none of the other. The cover (slit release liner) on the Catapres patch has also been mistaken as the actual drug patch and applied directly to the skin.

We contacted the manufacturer, Boehringer Ingelheim, about this long-standing problem, but the company has no immediate plans to print the drug name and dose on the patch. We were also told not to write on the patch directly, because it is not known if the volatiles contained in ink might affect delivery of the drug. However, the manufacturer did suggest that the patch cover could be labeled and placed over the drug patch to protect it.

Figure 1. The BI 33 code on this Catapres TTS 3 patch indicates it contains 0.3 mg.

There's also a code on each patch (see photo) that can be used to identify the strength: BI 33 designates a 0.3 mg patch, BI 32 is 0.2 mg, and BI 31 is a 0.1 mg patch. You might want to ask pharmacy to add this code to the drug profile in the pharmacy computer so it appears on computer-generated medication administration records for reference.

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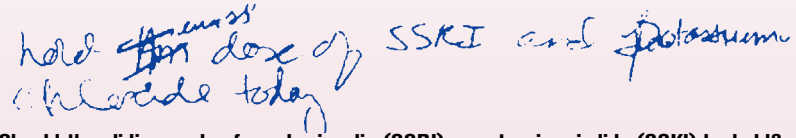
Scale **r**egular **i**nsulin," was misinterpreted as an order to discontinue the "**s**elective **s**erotonin **r**euptake **i**nhibitor" the patient was receiving—**ZOLOFT** (sertraline). The abbreviation "SSRI" can also be confused with SSKI" (**s**aturated **s**olution of potassium [**K**+] **i**odide). A patient who was receiving potassium iodide, potassium chloride, and regular insulin per a sliding scale had an order written to "hold dose of SSKI and potassium chloride" (see below). Initially, the nurse and pharmacist thought the physician wanted to discontinue the potassium chloride and the sliding scale of regular insulin, as they misread "SSKI" as "SSRI." But the physician intended to discontinue the potassium iodide (abbreviated as SSKI) and potassium chloride. The abbreviations SSKI and SSRI should not be used. If they are encountered, they should be clarified to prevent misinterpretation.



Should the sliding scale of regular insulin (SSRI) or potassium iodide (SSKI) be held?

Special Announcements...

Teleconference. On **June 18**, ISMP will offer a teleconference, **Using BPOC Data to Drive Quality Improvement**. ISMP's informatics specialist, **Stuart Levine**, and Lehigh Valley (PA) Hospital's director of pharmacy, **Christina Michalek**, will describe how to collect and use barcode point-of-care (BPOC) metrics, identify common failure points for these systems, and adopt an interdisciplinary approach to support safe use of BPOC technology. To register, visit: www.ismp.org/educational/teleconferences.asp.

Workshops. ISMP and USP will again be offering a 1-day interactive program, **Using Data Effectively to Manage the Risks to Medication Safety**, at various locations during 2008. The workshops will help participants learn how to select effective risk reduction strategies based on proven medication safety principles and report findings in an actionable format that will show results. Breakout sessions will be provided for hands-on practice working with data. For details, visit: www.ismp.org/educational/ismpuspworkshops.asp.

Webinar. On **June 12**, the American Organization of Nurse Executives, National Patient Safety Foundation, and ISMP will be presenting a **free webinar** sponsored by McKesson and Intel on **Measurement for Patient Safety**. Based on the 2007 ***Nursing Leadership Congress*** roundtable discussions, guest speakers will highlight positive measurement indicators and suggest the best metrics for monitoring patient safety. To register, visit: http://nursingleadershipcongress.com/webinars.asp.

ISMP Medication Safety Alert! Nurse Advise-ERR (ISSN 1550-6304) **Editors:** Judy Smetzer, RN, BSN, FISMP; Michael R. Cohen, RPh, MS, ScD; Russell Jenkins, MD. **ISMP, 200 Lakeside Drive, Horsham, PA 19044.** Tel. 215-947-7797; Fax 215-914-1492; E-MAIL: nursing@ismp.org. **Report medication errors to ISMP at 1-800-FAIL-SAF(E).**