February 2015 ■ Volume 13 Issue 2

ISMP

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

Unverified patient-reported error: A false alarm can have real consequences

When faced with a possible medication error, obviously, one should never assume that it is just a *false alarm*. Timely investigation is required, and a high index of suspicion is paramount. On the other hand, assuming that patient-reported events are always accurate can also be dangerous and costly if they are not verified via a timely investigation. In an unusual turn of events, we recently learned about a *false alarm* that set into motion unnecessary anxiety and wasted resources when a potentially fatal error was suspected, but not confirmed. The *false alarm* involved a patient who reported too-rapid home infusion of chemotherapy, but later analysis revealed that no error had actually occurred.

The patient-reported error

A cancer patient was receiving her second cycle of IV fluorouracil as a continuous infusion over 4 days via a Leventon **Dosi-Fuser** (**Figure 1**), a portable elastomeric delivery system (www.ismp.org/sc?id=446). A hospital pharmacy had prepared the chemotherapy, but the patient was receiving the infusion at home, with delivery and follow-up by a home-infusion service. After 1 day, the patient called the home-infusion triage nurse to report that the entire contents of the infusion had been delivered over 30 hours instead of the planned 96 hours (4 days). The nurse called the covering oncology fellow, who recommended sending the patient to the emergency department (ED) for evaluation.

After advising the patient to go to the ED, the home-infusion triage nurse called the ED charge nurse and physician to alert them to the impending visit for what appeared to be a fluorouracil overdose due to a delivery device failure. The home-infusion triage nurse also contacted the on-call home-infusion pharmacist, who then called her supervisor. The home-infusion service asked the nurse to save the device so it could be inspected the following day.

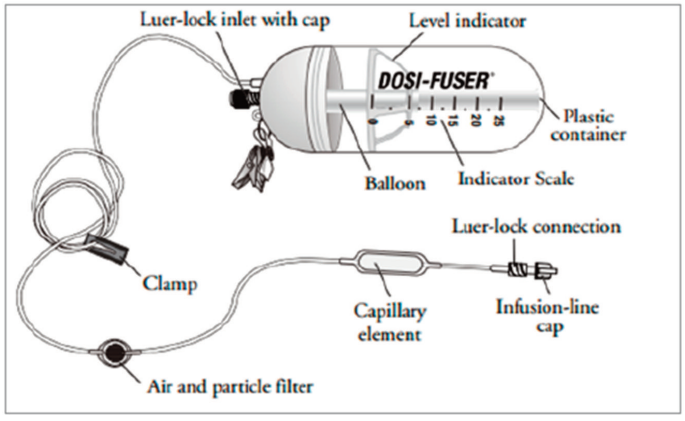

Figure 1. Dosi-Fuser continuous infuser. *(Diagram courtesy of Memorial Sloan Kettering Cancer Center, which had no involvement in this case.)*

The patient presented to the ED and was evaluated by a nurse and physician (different than the nurse and physician initially contacted by the triage nurse). The nurse had received report from the charge nurse and believed the too-rapid infusion had been confirmed. She never saw a Leventon Dosi-Fuser before and, although she looked at it, she failed to notice that the solution had NOT entirely infused. Using personal

continued on page 2—**False alarm** >

We need your *input!*

A draft set of best practices to facilitate safe administration of **IV push medications** has been posted on our website for public comment. The best practices were developed after ISMP held a national summit in 2014 during which participants identified the risks with IV push medications and recommended best practices for preparation and administration. To view and comment on the draft best practices, visit: www.ismp.org/sc?id=475. Public comments will be accepted until **February 27**. The final document will be available on ISMP's website. Funding support was generously provided by BD.

SAFETY wires

Confusion between Naropin for epidural infusion and Ofirmev IV. Glass 100 mL and 200 mL infusion bottles of 0.2% or 0.5% **NAROPIN** (ropivacaine) injection can be mistaken as intravenous (IV) piggyback containers. Naropin is intended for epidural infusion when a prolonged block is needed. Unintended IV injection of ropivacaine may result in cardiac arrhythmia or arrest.

We have received three reports in which a Naropin glass vial was confused with **OFIRMEV** (acetaminophen injection), which is also in a glass bottle but intended for IV administration (**Figure 1**). Doses of either drug can be administered without further dilution. In one case, the Naropin bottle was attached to IV piggyback tubing and administer-

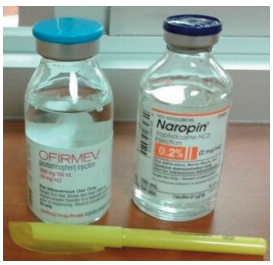

Figure 1. Glass containers of Ofirmev (L) for IV infusion and Naropin (R) for epidural infusion.

continued on page 2—***SAFETY* wires** >

Baxter

Supported by educational grants from Baxter and BD

BD

> False alarm—continued from page 1

protective equipment, she disconnected the Dosi-Fuser from the patient and placed it into a hazardous waste bag. The oncologist came to the ED and looked at the device through the bag. He also was not familiar with the device and assumed it was empty. He did not remove it from the bag for closer inspection because it contained chemotherapy and was labeled as hazardous waste.

Both the oncologist and the ED physician had called poison control and were told that the rapid infusion of fluorouracil could cause a potentially fatal overdose that should be treated accordingly. The oncologist made arrangements for the patient to receive an investigational antidote, uridine triacetate (formerly vistonuridine), which would require air freight delivery from a distant state. This was ordered with the assistance of the inpatient pharmacist, who also took possession of the Dosi-Fuser device. The inpatient pharmacist called his assistant director, who alerted their director, but no one from the inpatient pharmacy actually looked at the Dosi-Fuser device.

The next morning, word of the error reached the ambulatory oncology center pharmacist. He retrieved the device that was removed from the patient and immediately noticed that it did not "feel" empty—this was obvious to him and his staff because they handled the devices often. After closer inspection and weighing the device, they learned it was NOT empty, and no overdose had occurred. Fortunately, because the uridine triacetate had not yet arrived, the patient did not receive the antidote. The patient was reassured that she did not receive an overdose and was discharged home.

There are a number of lessons to be learned from this event, many of which can help avoid a *false alarm* or a failure to see and appreciate important risks.

Confirm patient-reported errors

Issue: The triage nurse trusted the patient's self-report of a too-rapid infusion without further investigation. The patient sounded knowledgeable and had received a previous course of therapy, so the nurse thought the patient's account was fully credible. The patient was a nurse (unknown at the time of the event) and spoke in a manner in which others would rely on what she was saying. Knowing nothing about the specific device, the triage nurse did not ask the patient to confirm that the level indicator was at zero. After contacting the on-call home-infusion pharmacist, the triage nurse made an (appropriate at the time) assessment that time was of the essence, so he sent the patient to the ED believing this represented a higher level of care that could better assess the potential error more effectively. However, the ED staff were not familiar with the device either.

Lesson learned: While reports of errors or other concerns from patients about medications should never be dismissed without a thorough investigation, neither should they be accepted without an assessment by staff with experience in the processes of care involved in the event, or the equipment or technology under evaluation. In this case, the ambulatory oncology center pharmacist or hospital pharmacy that filled the device should have been consulted. However, if timely treatment of a potential error is of the essence, err on the side of caution and begin the process of treatment while conducting a full investigation.

Keep a high index of suspicion

Issue: None of the healthcare professionals who encountered the patient considered scenarios outside of a device failure as a cause for the "error." Other possibilities that should have been considered include: the device could have been filled with the wrong volume; the pharmacy could have used the wrong infuser type; the pump could have been set at the wrong infusion rate; or the patient was mistaken.

continued on page 3—False alarm >

> SAFETY wires continued from page 1

ed instead of Ofirmev. The patient began to experience shortness of breath, dizziness, visual changes, and anxiety after receiving 20 mL of the drug. The symptoms lasted for 5 minutes after the medication was stopped. Both Ofirmev and Naropin were stocked in the same automated dispensing cabinet (ADC). Two "near misses" between Ofirmev and Naropin have also been reported in a critical care unit of a community hospital. In addition, we have learned of another case in which Naropin was given IV, although it was not mentioned what it may have been confused with or the patient's outcome.

On examination, the labels for each product clearly indicate the bottle content, which means an error can be avoided if the labels are properly read. Still, in some areas of the hospital, these may be the only two products in glass infusion containers with a similar shape. The risk of confusion is highest in areas where they are stored near one another, such as in the same ADC drawer, especially if the drugs can easily be accessed via an override. If possible, limit storage in ADCs to only one of the drugs, and store the products in locked, lidded compartments. Some ADCs may allow "issue confirmation," where you scan the product's barcode to assure it is placed in the correct location in the ADC, and "removal confirmation," where you again scan the barcode to assure the correct product has been removed from the ADC. New label technologies that use barcode scanning may also be helpful in confirming that the correct product has been selected.

PACU ADC selection error. An anesthesiologist ordered prochlorperazine 10 mg slow IV push for a post-op patient in the post-anesthesia care unit (PACU). A nurse went to the PACU automated dispensing cabinet (ADC) to obtain the drug but removed a vial of phenylephrine 10 mg/mL by mistake and administered it to the patient (outcome unknown). The ADC was not profiled and did not allow pharmacy to verify new orders for patients prior to obtaining a medication from the cabinet. Both medications were located in two adjacent matrix pockets in the ADC.

To reduce the risk of error, the hospital moved phenylephrine vials to a different ADC cabi-

continued on page 3—SAFETY wires >

> False alarm—continued from page 2

Lesson learned: Contact healthcare providers recently involved in the care of a patient and consider all reasonable scenarios when determining cause and effect.

Examine evidence during handoffs

Issue: There were multiple handoffs during the patient's initial assessment and care: home-infusion triage nurse to ED charge nurse to ED staff nurse; ED physician to another ED physician; oncology fellow to oncologist; multiple pharmacists. During these handoffs, everybody assumed someone else had confirmed the overdose.

Lesson learned: When possible, practitioners should examine any evidence that is available during handoffs and ask questions to be sure they understand and verify any patient care issues associated with a hazardous condition or potential/actual error.

Promote inspection and monitoring

Figure 2. The labels on the front and back of the container covered most of the level indicator and the indicator scale, making it difficult to see the chemotherapy in the container.

Issue: Even if the home-infusion triage nurse had asked the patient to confirm placement of the level indicator (**Figure 1**, page 1), it was difficult to see because of the placement of 2 large labels on the container (**Figure 2**). This likely contributed to the patient's misunderstanding that the bottle was empty. The labels also inhibited the ability of the ED nurse, pharmacists, oncology fellow, and oncologist to visualize the indicator. While they could have visualized it by peeling back the label, this is not something they would be expected to do.

Lesson learned: Make sure that labels or other items do not obscure important information—in this case, the level indicator—needed to monitor effectiveness and accuracy of treatment modalities. Also, make sure the patient knows how to read the pump level indicator.

Consult staff with required skills and knowledge

Issue: This event clearly demonstrates the issues facing healthcare staff who are not knowledgeable about the types of home-infusion devices used in their community. In this case, it was the Leventon Dosi-Fuser. Once the patient arrived in the ED, nobody thought to call ambulatory oncology pharmacists, who frequently handle these devices.

Lesson learned: Develop the expectation that expert(s) (those most familiar with the device) will be consulted when issues are suspected. When feasible, educate staff about the most common devices used in the community setting. For example, if the Leventon Dosi-Fuser is commonly used in the community to deliver home-based chemotherapy, then both ED staff and oncology staff should have basic familiarity with the device.

Conclusion

Since the error reported by the patient in this case turned out to be a false alarm, actions taken by the healthcare practitioners in response to the reported error resulted in an adverse outcome for the patient—the premature disconnection of the Dosi-Fuser and interruption of the full course of therapy. The patient never received the full dose of fluorouracil for that cycle, and the impact this may have on the overall treatment outcome remains unknown. Had a more thorough investigation been conducted when the patient first presented to the ED, a lot of anxiety, medical care, and resources could have been spared, and the patient could have received the full dose of chemotherapy.

> SAFETY wires continued from page 2

net that holds only critical care agents, given that the drug is used primarily as a vasopressor most often after being diluted in either 5% dextrose injection or 0.9% sodium chloride injection, and then administered as a continuous infusion. Open matrix drawers and open cabinet type configurations are not used in the ADC that stocks critical care drugs, and the phenylephrine is also now stored in its own locked and lidded compartment. The hospital will be moving to profiled ADC cabinets in the PACU so pharmacy can verify medications in the ADC prior to removal. Barcode scanning technology will also be available with the profiled cabinets to ensure accuracy when stocking ADCs and removing products.

Lot number, not expiration date. The way expiration dates and lot numbers are currently printed on unit dose liquid products manufactured by Pharmaceutical Associates is unacceptable. The lactulose product in **Figure 1** expired in April 2014. However, a nurse recently used this medicine past its expiration date because the lot number "2D15" looks more like 2015 when placed

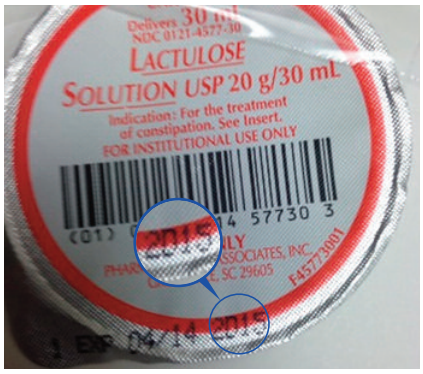

Figure 1. "2D15" is the Lot number, not the expiration year.

immediately after the expiration date of "04/14." Together, this makes it look like the product expires "04/14 2015." Similar events involving the company's acetaminophen liquid and aluminum-magnesium hydroxide with simethicone liquid appeared in our October 2012 issue. The company is changing lot numbers so that each will start with a letter so it won't be confused with a date. They are also including the word "Lot" when there is room. Meanwhile, be sure to do a floor stock/automated dispensing cabinet check to make sure no outdated cups are in stock.

HAZARD ALERT

Demonstration (training) IV solutions administered to patients

The US Food and Drug Administration (FDA) alerted healthcare professionals not to use Wallcur, LLC, simulated intravenous (IV) products in human or animal patients (www.ismp.org/sc?id=472).These products are for training purposes only and should never be administered to humans or animals. Educators often utilize training products for simulations when training students and want these items to look like the real IV solutions. However, there have been serious adverse events associated with misuse.

We learned via FDA's MedWatch that more than 40 patients actually received these solutions and developed chills and/or sepsis; 1 patient died. One of the products, Practi-0.9% Sodium Chloride (**Figure 1**) 100 mL, contains distilled water, not sterile saline, so hemolysis also might be an issue.

Figure 1. Products for training purposes only.

These events may be related in part to IV saline product shortages from B. Braun, Hospira, and Baxter. Purchasers looking for replacement supplies may have confused these training products with the real thing, and then ordered them through their distributors. Although distributor listings state that these are training products, purchasers may not recognize this.The solutions may have then been misidentified upon arrival at the healthcare facility. Subsequently, internal distribution took place, and the fact that these were training products must have been overlooked. Since staff may be having trouble getting their usual IV products, they may not be suspicious of the unusual labeling. The product is labeled "for clinical simulation," but it appears in very small print below the company name and may not be seen. (Also, "for clinical *simulation*" looks very close to "for clinical *situations*.")

In a media release (www.ismp.org/sc?id=470), Wallcur said it has recalled current products, including Practi-0.9% sodium chloride IV bags supplied in 50 mL, 250 mL, 500 mL, and 1,000 mL sizes, and the Practi-0.9% sodium chloride 100 mL IV solution bag with sterile distilled water. The extent of distribution of these products is not fully known, but inpatient and outpatient locations have received supplies. About 90% of the distribution of training products is via independent distributors, including some drug wholesalers. Supplies can also be ordered on the company's website, in which case the company interacts with the customer to help ensure use is for training.

Wallcur is also working with FDA to identify ways to label these products to state more clearly that they are not to be used in humans or animals. The company has also notified its distributors and asked for their follow up. Please work with hospital educators, medical and nursing school affiliates, ambulatory surgical centers, and other inpatient and outpatient facilities in your health system to assure all are aware of this situation and taking action where appropriate.

If you suspect that any training products (IV or other) may have been administered to a patient, whether or not harm has resulted, please report it to ISMP (www.ismp.org/MERP) or FDA's **MedWatch** here: **MedWatch Online Voluntary Reporting Form**. FDA will continue to investigate and monitor this issue.

Special Announcements

ISMP webinar

March 19: **Evolution of Anticoagulants and the Effects on Patient Safety**
For details, visit: www.ismp.org/sc?id=476.

1-week "rotation" at ISMP

We have room for a few more participants in our weeklong **ISMP Practitioner in Residence Program** on **March 2-6** at ISMP's office near Philadelphia, PA. The program provides health professionals with a unique opportunity to learn while working closely with ISMP staff. For details, visit: www.ismp.org/sc?id=477.

Unique 2-day program

Attend one of the **ISMP Medication Safety INTENSIVE** workshops being held in 2015: **Indianapolis** on April 16-17; Bellevue (near **Seattle**) on September 17-18; and **New Orleans** on December 4-5. This workshop provides hands-on experiences with risk assessment, event investigation, error analysis, error-reduction strategies, measuring effectiveness, and more! Special pricing is available before **February 15**! For details, visit: www.ismp.org/educational/MSI.

ISMP Fellowships

Apply for the **ISMP Safe Medication Management Fellowship Programs.** For details, visit: www.ismp.org/sc?id=484.

To subscribe: www.ismp.org/sc?id=384

ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

ISMP Nurse AdviseERR (ISSN 1550-6304)

Report medication and vaccine errors to ISMP: Call 1-800-FAIL-SAF(E), or visit www.ismp.org/MERP or www.ismp.org/VERP. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.