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ISMP 25 YEARS ADVANCING MEDICATION SAFETY

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Partnering with families and patient advocates:

Another line of defense in adverse event surveillance

In the July 16, 2019, issue of *Pharmacy Practice News*, ISMP president, Michael R. Cohen, published a noteworthy commentary about what healthcare consumers can do to help prevent medication errors.[1] The inspiration for the commentary arose from significant dialog and questions received in response to articles ISMP published in this newsletter in early 2019.[2-5] These articles were about a fatal error in which a woman received the paralyzing agent vecuronium, retrieved from an automated dispensing cabinet (ADC), instead of the sedative **VERSED** (discontinued brand of midazolam) (see **Sidebar** below).

In sharing the story of this terrible tragedy, we attempted to extract all the lessons learned about the risks associated with using neuromuscular blocking agents and ADCs, and contemplate the importance of a Just Culture of safety in healthcare. One thought-provoking question stood out and was recently asked not by a healthcare provider but by a long-time consumer advocate focused on improving patient outcomes, Ilene Corina, president and founder of the Pulse Center for Patient Safety Education and Advocacy: "Is there anything that healthcare consumers themselves could have done to prevent or detect this event that might have improved the patient outcome?"

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SIDEBAR

Six steps to tragedy: The error revisited

1. A woman was admitted to the hospital with a hematoma of the brain, possibly related to a mass. Several days later, she was transported from a step-down unit to radiology for a full body positron emission tomography (PET) scan.
2. After a radiology technician had explained the PET scan, the patient requested medication to help ease anxiety due to claustrophobia. This led to an order for Versed (midazolam), and a nurse from the step-down unit was called to come to radiology to administer the drug to the patient.
3. To obtain "Versed" from the automated dispensing cabinet (ADC), the nurse typed just the first 2 letter characters of the drug name, "VE," into the search field but did not find the drug under that name, notably because the cabinet was set to retrieve drugs by the generic name—midazolam in this case.
4. The nurse set the ADC to override and again typed "VE" into the search field, this time retrieving vecuronium instead of what she thought was Versed.
5. The nurse traveled to the radiology department and prepared the drug as per instructions on the vial label. Not realizing she was administering a paralyzing agent to the patient instead of Versed, the nurse injected the vecuronium intravenously.
6. The unventilated patient was then left in a holding room under camera surveillance while awaiting perfusion of a radioactive tracer that had been injected in preparation for the scan. The patient stopped breathing and was unable to call for help.

SAFETY briefs

HIGH-ALERT

Fiasp confused with NovoLOG. Medication errors have occurred due to confusion between **NOVOLOG** and **FIASP**, which are both marketed formulations of insulin aspart manufactured by Novo Nordisk. However, Fiasp and Novo**LOG** have different onsets of action after subcutaneous injection and are not substitutable. Fiasp contains niacinamide, which increases the speed of absorption and allows for administration at the start of a meal or within 20 minutes of starting a meal. Novo**LOG** should be administered within 5 to 10 minutes before a meal.

Both product container labels have the same non-proprietary name, insulin aspart. The Fiasp package insert lists niacinamide as an inactive ingredient, so the carton does not list this ingredient on the principal display panel (Figure 1).

Figure 1. Niacinamide is not mentioned on the Fiasp carton principal display panel.

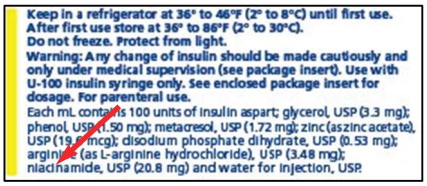

Figure 2. Niacinamide is listed as an ingredient on carton's back panel.

Rather, it appears only on the back of the package along with the list of other inactive ingredients (Figure 2). Also, because drug monographs may not list inactive ingredients, drug information systems that pull data from monographs may not list the niacinamide in Fiasp.

Prescribers and pharmacists may not be aware that Fiasp and Novo**LOG** are differ-

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The answer to that question formed the basis of the *Pharmacy Practice News* commentary, which is summarized in the description that follows.

Our initial response to the question was "No," as we could not think of anything that a consumer could have done to prevent this tragedy. But the consumer advocate clearly had been thinking about this event and delved a little deeper, asking: "What if the patient had been encouraged to have a relative or patient advocate go along with her to radiology to sit with her while waiting for the radioactive tracer to perfuse?" The idea gave us pause as we thought about the numerous events that had been reported to ISMP in which a family member or patient advocate had noticed something unusual about their loved one and brought it to the attention of healthcare providers, thus avoiding a potentially catastrophic outcome.

What harm would it cause to allow, even encourage, a family member or consumer advocate to accompany a patient to a diagnostic area to wait with them prior to a test? In this case, the patient was observed via a camera that was not sensitive enough to identify that the patient's chest was not rising and falling after receiving the neuromuscular blocking agent in error. But a family member or advocate, sitting with the patient, could have recognized that the patient had stopped breathing and alerted radiology staff to the emergency. We had to agree that the presence of a family member or patient advocate might have saved this patient's life.

Engaging the Family and Patient Advocates in Safety

Studies have shown that family members can help detect harmful or potentially harmful critical events before injuries occur, or mitigate the duration and severity of harm, particularly when family members spend time with patients observing their care.[6-11] While hospitalized patients may be too young, ill, or confused to meaningfully participate in their own care, family members are often keen observers who are highly motivated to ensure that the right treatments are correctly provided to their loved ones.[8-11]

The types of critical events detected by family members or patient advocates are diverse, though respiratory distress, medication errors, and tubes or drains that become disconnected are the most commonly reported safety problems.[6-11] In many cases, the events were intercepted before an injury occurred. Examples of events detected and reported by family members include:[6-11]

- Missed medication doses
- Wrong drug, wrong time, wrong route, and wrong patient medication errors
- Known allergies to prescribed medications or diagnostic contrast dyes
- Inadequate monitoring post procedure or following drug administration
- Wrong weights listed on medical records used for prescribing medications
- Intravenous (IV) lines disconnected at the patient access port
- Swollen, painful arms when IV infusions became infiltrated
- Abscess at IV catheter site complicated by deep vein thrombosis
- Respiratory distress, respiratory failure, or unusual respiratory sounds
- Symptoms of significant hypoglycemia and hypotension
- Diarrhea and hemorrhoidal bleeding that required transfusion
- Cords or swaddling blanket wrapped around an infant's neck, causing strangulation

Patient advocacy begins by including the family or advocate in the patient's care and keeping them well informed so they know what to expect and can recognize if something is not right. Family members and patient advocates should be encouraged to speak up about any concerns or worries. They know the patient better than anyone on the medical team, so communication of their observations is extremely important.

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ent. If insulin aspart is prescribed, it may result in dispensing either NovoLOG or Fiasp if the brand name is not included on the prescription. For example, a prescriber recently ordered Fiasp for a patient and submitted the prescription to the pharmacy electronically. Although he selected Fiasp, the electronic system communicated the selection as "insulin aspart injection 100 units/mL." The brand name was not included in the prescription, and NovoLOG was dispensed from the pharmacy.

The company is aware of the potential for mix-ups and mentions this in company literature as something to watch for, saying that practitioners (particularly pharmacists) should confirm the brand name if it isn't specified on the written prescription or in the electronic prescribing system. Indeed, if Fiasp is intended, prescribers should include the brand name on prescriptions, and electronic order systems should communicate the brand name if selected by the prescriber instead of only including the generic name. Also, patients should be made aware of the differences between the two insulins and the product intended for them, so they are prepared to check the drug they receive from the pharmacy.

Given that inclusion of niacinamide makes for a product that is more rapidly absorbed than NovoLOG, the US Food and Drug Administration (FDA) and the manufacturer should consider modifying the nonproprietary name and the packaging in some way so people are more aware of the difference compared to NovoLOG.

Concern with Saphris packaging. SAPHRIS (asenapine), an atypical antipsychotic, is a sublingual tablet that is supplied in blister packs of 2.5, 5, and 10 mg strengths. The instructions state to not remove the tablets until one is ready to administer them. Note that all Saphris strengths are available in both child-resistant packaging (intended for outpatients) and hospital unit doses. The child-resistant blister packs do not have a barcode over each unit-dose package and will require additional steps for inpatient use to repackage each blister and affix a barcode. The hospital unit-dose product has a barcode on each individual blister. Be sure that your purchasing staff know which type of packaging to order.

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When family members and patient advocates do speak up, healthcare professionals should take the time to actually hear and understand their concerns and then take action in a manner that fosters true collaboration and empowerment. In fact, some hospitals have recognized the important role family members and patient advocates can play in detecting untoward events in their loved ones by allowing the family and advocates to call a rapid response team if they suspect something is not right.[12] Some even invite them to participate in medical rounds.

Conclusion

Certainly, the presence of family members and patient advocates during a loved one's hospitalization is not possible in all circumstances, but perhaps more could be done to encourage family members and/or patient advocates to remain with patients and to accompany them to diagnostic areas or other clinical areas of the hospital where patients might await interaction with a healthcare professional. This is an idea worth exploring, not only for patients visiting radiology but throughout a hospital encounter. Engaging family members and patient advocates as partners in identifying otherwise unrecognized errors and adverse events is a potentially promising approach for enhancing safety surveillance.

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Pet's medications on owner's medication list:

Barking up the wrong profile!

Problem: When a patient recently visited a hospital clinic, a practitioner was reconciling external medication information available in the patient's electronic health record (EHR) (Epic) via medication history data from Surescripts. Based on Surescripts information, the patient was taking oral enalapril 5 mg daily. When the patient was asked if she was still taking this medication, she reported that the enalapril was for her dog. The clinic staff called the patient's community pharmacy, which confirmed that the enalapril was for the patient's dog.

It is uncertain how Surescripts captured the prescription for enalapril as the owner's medication and presented it in Epic for reconciliation. Upon further investigation, the community pharmacist noted that it is company policy to use both the pet owner's last name and date of birth when creating a pharmacy profile for a pet. Also, the pet's owner was using a discount card (e.g., GoodRx for Pets [www.goodrx.com/pets]) for enalapril,

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Worth repeating...

Dangerous Alvogen product look-alikes

We continue to receive complaints about dangerous look-alike labeling of injectable products from Alvogen. As reported in our April 25, 2019 issue, vials of rocuronium 50 mg/5 mL were found stored in an automated dispensing cabinet (ADC) drawer that normally holds vials of metoprolol tartrate 5 mg/5 mL. Rocuronium and metoprolol vials each have yellow caps and yellow labels (**Figure 1**). Warnings about rocuronium being a paralyzing agent are included on

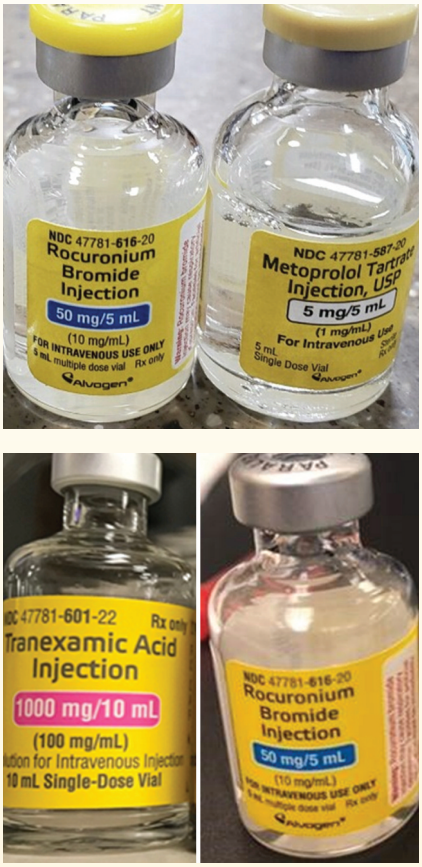

Figure 1. Look-alike Alvogen products: Rocuronium and metoprolol vials (top) have similar yellow labels and caps. Tranexamic acid vials have been reported to look similar to rocuronium vials when the caps are removed (bottom).

the side panel, but this critical information could be missed if the drug is stocked in error and thought to be another drug.

Since April, we have also received reports about tranexamic acid vials that look similar to rocuronium. Tranexamic acid has a green cap but looks similar to the other Alvogen

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which would have voided any insurance coverage. For Surescripts to capture a prescription, it has to be adjudicated via the owner's insurance, implying the pet's profile may have been linked to the owner's profile, or the owner's profile could have been erroneously selected at some point when entering the enalapril prescription given similarities with the profiles (i.e., last name, birthdate, address, telephone number), which was never corrected.

Fortunately, the patient was able to confirm that she did not take enalapril and that the medication was for her dog. However, if the patient had been admitted to a facility and was not able to help during the reconciliation process (e.g., confused, too ill, unaware of medication names), the risk of an error would be high. The pet's medication could have been added to the patient's list of "home medications" and prescribed during hospitalization, and even upon discharge. This is particularly a concern with medications such as insulin, anticonvulsants, antidepressants, anxiolytics, and analgesics, which are commonly prescribed for pets and often filled in community pharmacies.

Follow-up with several other community pharmacies indicated that no formal policy exists on this subject, and that practices often vary. Creating a profile for a pet under the pet owner's last name, address, and telephone number is common, making the profiles very similar. Some pharmacies have a separate field for the pet owner's name in the pet profile. One pharmacy reported a checkbox in the profile to indicate that the patient was a pet. Another pharmacy said staff often add "canine" or "feline" to the name field. However, all the community pharmacies we contacted noted that they do not use the owner's date of birth for the pet. Instead, they use the pet's actual birthdate or a fictitious birthdate (e.g., 01/01/01, or January 1 with an educated guess for the year) if the pet's actual birthdate is unknown. When pet owners pick up medications for their pets, verification of identity is usually by name and address, although some pharmacies require entry of the (fictitious) birthdate (mm/dd) as a standard check.

Safe Practice Recommendations: Community pharmacies should create a standardized policy and procedure that describes exactly how to create a unique pet profile in the pharmacy computer system. When designing the pet profile, make it look as different as possible from the owner's profile (e.g., different color background, different fields, paws, pet pictogram). Do not use the owner's birthdate for the pet's profile—use a standard process to determine a fictitious birthdate if the pet's birthdate is unknown. All pharmacy staff should be educated about the policy and procedure (and never enter a pet's prescription into the owner's profile for convenience). The pet and owner profiles should not be linked together in any way. When new prescriptions or refills are entered into pharmacy profiles, verification that the correct profile has been selected should include both the first and last name, along with the birthdate.

In hospitals, clinics, and other healthcare facilities, be sure to confirm all the active medications presented in the EHR from both internal and external (e.g., Surescripts) sources with the patient, family member, and/or with the patient's local pharmacy, at the start of every patient encounter.

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Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit our website at: 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.

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vials once the caps are removed. Also, the color band that lists the product strength may distract one's eyes away from the drug name. These drugs may be stored near one another in critical care areas, emergency room settings, and perioperative areas.

Other complaints we have received involve look-alike vials of deferoxamine mesylate, dexrazoxane, midazolam, labetalol, vancomycin, and ketorolac. These products have carton and vial labels with the same distinct yellow background. Mix-ups between these vials could lead to patient harm.

We highly recommend purchasing these vials from different manufacturers when possible. Application of auxiliary labels may also help prevent mix-ups. ISMP has repeatedly alerted the company to these complaints, but no information has been provided to us about addressing the look-alike issues or the inadequate paralyzing agent warning on rocuronium vials. ISMP has also contacted the US Food and Drug Administration (FDA) about the situation.

Special Announcements

Accepting Cheers Awards nominations

Nominations for this year's **Cheers Awards** will be accepted through **September 6, 2019**. Outside and self-nominations are accepted. The prestigious awards spotlight efforts to improve medication safety from all healthcare disciplines. To submit a nomination, please visit: www.ismp.org/node/1036.

Get intensive about medication safety

The **Medication Safety Intensive (MSI)** workshops sold out quickly last year! Act now to avoid being put on the waiting list in 2019. You won't want to miss this unique opportunity to maximize your error prevention efforts and learn to look at your organization through the eyes of leading safety experts. For information and to register, visit: www.ismp.org/node/127.

2019 MSI dates

- **September 12-13**—Orlando, FL
- **December 6-7**—Las Vegas, NV