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ISMP
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Educating the Healthcare Community About Safe Medication Practices

Patient death tied to lack of proper escalation process for barcode scanning failures

A patient who was hospitalized in the intensive care unit (ICU) for rectal bleeding was scheduled to have a colonoscopy the following day. A prescriber ordered **SUPREP BOWEL PREP KIT** (sodium sulfate, potassium sulfate, and magnesium sulfate) (**Figure 1**) to be administered orally for cleansing of the colon as a preparation for the colonoscopy. Unfortunately, instead of Suprep, the patient was mistakenly given **NATURALYTE**, which is a liquid acid concentrate for bicarbonate hemodialysis, used as a dialysate with hemodialysis equipment after proper dilution. The patient later died and local media covered the incident. Via an open records request to the state board of nursing that investigated the situation given a nurse's involvement in the error, ISMP obtained a report that helped to detail system failures that contributed to this tragic medication error.

Figure 1. Suprep Bowel Prep Kit was ordered in preparation for a colonoscopy.

NaturaLyte, which is available in a large plastic container, had been left in the ICU by the dialysis team for a different patient who was undergoing hemodialysis about 3 days before this incident. The large container was placed in the same medication area as are other bulk items when delivered from pharmacy. When it was time to administer the bowel prep, the nurse went to the medication area and saw two large plastic containers labeled NaturaLyte, containing a clear liquid. The nurse assumed these were similar to **GOLYTELY** (polyethylene glycol 3350 and electrolytes for oral solution), which is widely used as a bowel prep and apparently more familiar than Suprep. The board report voiced a concern that the NaturaLyte label was not visually double-checked before giving it to the patient in error. However, this may not have raised a red flag if the nurse thought NaturaLyte was a generic replacement for GoLYTELY, given that many generic products have different brand names than the original product name. In addition, NaturaLyte and GoLYTELY show similarities, namely the NaturaLyte label lists ingredients including magnesium, potassium, and sodium, in the same manner as the container of GoLYTELY lists electrolytes. Also, both are in large plastic containers (**Figure 2**). The board report did not mention whether the actual Suprep product had been dispensed by the pharmacy and was present on the unit but not located by the nurse.

Although NaturaLyte has a barcode, the barcode may not be recognized by many barcode scanning systems since NaturaLyte is not a drug and the barcode does not contain a national drug code (NDC). In this case, the nurse did try to scan the item several times, but when the misidentified product could not be successfully scanned, the nurse called pharmacy before proceeding. Rather than sending a new labeled medication (Suprep), or physically reviewing the product that would not scan, a

Figure 2. NaturaLyte, a liquid acid concentrate for bicarbonate hemodialysis (left), and GoLYTELY, used for bowel cleansing (right), are packaged in large plastic containers.

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SAFETY wires

Accidental overdoses and adverse effects from compounded GLP-1 agonists. Glucagon-like peptide-1 (GLP-1) receptor agonists (e.g., **OZEMPIC** [semaglutide], **VICTOZA** [liraglutide]) were originally approved to treat patients with type 2 diabetes by improving glycemic control, along with diet and exercise. They are available primarily in prefilled pen devices. After clinicians and researchers observed that these medications also helped patients lose weight, manufacturers developed products (e.g., **WEGOVY** [semaglutide], **SAXENDA** [liraglutide]) indicated specifically for chronic weight management. An increase in demand for these products combined with the discontinuation of certain Ozempic presentations, has resulted in drug shortages for some of the injectable GLP-1 agonists. Because of these shortages, compounding pharmacies have been preparing versions of the drugs. However, medication errors and adverse events have occurred after patients received compounded GLP-1 agonists.

In less than a week, a hospital had three patients admitted to the intensive care unit due to hypoglycemia from compounded semaglutide. In a hotel room gathering, akin to a "Botox party," patients were given multiple pens, without a prescription, from people they thought were nurses.

In another report, a provider prescribed semaglutide for weight loss. However, due to a shortage of prefilled syringes, the patient received compounded medication in a vial with instructions to inject 0.05 mL (5 units) using an insulin syringe. The patient did not understand the instructions and injected 0.5 mL (50 units). They presented to an emergency department (ED) with severe abdominal pain, nausea, vomiting, and diarrhea. The hospital noted that there had been an increase in ED visits by patients experiencing accidental overdoses after using insulin syringes to prepare their doses of semaglutide from compounded vials.

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pharmacist sent a patient label that contained a barcode through the tube system for the correct medication, Suprep.

When used properly as dialysate, NaturaLyte must first be diluted in a 1:44 ratio with purified water and base concentrate (bicarbonate) before it can be instilled. However, thinking that the NaturaLyte product was the same as GoLYTELY (and assuming that was substituted for Suprep), the nurse scanned the patient's armband, scanned the label provided by pharmacy, and administered about 240 mL of the NaturaLyte in its concentrated form. The patient began to drink the liquid but could not tolerate it all due to the bad taste and became nauseous.

Since the entire amount of product was supposed to be administered for the prep, and since the patient could not tolerate it and refused to drink the liquid, the nurse notified the physician. The physician noted that a feeding tube would be needed to administer the remainder of the medication. Another nurse (on the next shift) administered the rest of the concentrated NaturaLyte liquid through the feeding tube. The second nurse also thought that Suprep was similar to GoLYTELY, and was substituted with NaturaLyte. A physician who later assessed the situation as the patient deteriorated, also thought the container looked like GoLYTELY. Later, an electrocardiogram (EKG) revealed significant changes and the patient died the following morning. The cause of death was not mentioned in the report.

It should be noted that on the day the error happened, some ICU nurses were pulled to other areas of the hospital, leaving the nurse involved with this patient caring for two other high acuity patients, rather than the typical assignment of just two patients total. Also, we do not know if staffing levels in the pharmacy may have impacted the pharmacist's ability to visually confirm the product. In addition, since the product was a large plastic container, this may have prevented it from being tubed back to the pharmacy for visual confirmation.

ISMP has previously received reports from other hospitals in which dialysis products were left in patient care areas where staff may be unfamiliar with or do not know about their proper use. For example, we have previously published a report (www.ismp.org/node/93635) involving 23.4% sodium chloride injection vials left on nursing units by hospital-contracted dialysis staff while providing treatment to inpatients using portable hemodialysis machines. Hypertonic sodium chloride injection is sometimes used to reduce cramping during hemodialysis. However, the vials have been confused with sodium chloride 0.9% by staff unfamiliar with the highly concentrated product.

We also know that it is not only dialysis staff that might leave items that are unfamiliar to others on nursing units. We wrote about similar events, first in 2005, then in 2010 (www.ismp.org/node/92440), in which a transplant team left behind a bag of **VIASPAN** cold storage solution used in organ transplantation, which ended up in a pharmacy return bin because it looked so much like an intravenous (IV) solution bag. Inadvertent IV administration of the solution would almost certainly cause cardiac arrest due to the high potassium content (about 125 mEq/L). We have also received reports where providers have brought in nonformulary medications for their patients.

Recommendations

Serious medication errors often involve unfamiliar products, as happened in the current case. Therefore, it is important to have processes in place to prevent these types of errors. For non-unit dose products, rather than include a pharmacy-generated barcode on the medication label, practitioners should scan the manufacturer barcode directly on the product. This type of forcing function ensures the right container is in hand to prevent the risk of a false positive barcode scan from just a pharmacy or patient label. Also, develop an escalation process for what to do when a medication barcode will not scan. When a barcode will not scan, pharmacists need to visually verify that the medication matches what is ordered for the patient. It is not safe to send a label by itself. Labels must be considered part of the dispensing process and should only be placed on products by pharmacy personnel. Nurses should send unscannable products back to pharmacy.

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The US Food and Drug Administration (FDA) has informed the public that some compounders are not using the same bulk drug substance that Novo Nordisk uses for its commercially available semaglutide products. Both Ozempic and Wegovy are produced using the base form of semaglutide. However, some compounders appear to be using a salt form of semaglutide, including semaglutide sodium and semaglutide acetate.

The FDA is not aware of any basis for compounding using the salt forms that would meet the Federal Food, Drug, and Cosmetic (FD&C) Act requirements for types of active ingredients that can be compounded (www.ismp.org/ext/1324). The use of the salt formulations of semaglutide may have contributed to a different strength or concentration of the compounded products. In addition, compounded preparations using the semaglutide salts have not been proven to be safe and/or effective. There have also been reports of counterfeit semaglutide products that were thought to contain insulin.

Educate staff about these cases and risks involved with compounded semaglutide. Monitor patients for accidental overdose (e.g., hypoglycemia) and adverse effects (e.g., gastrointestinal) from compounded GLP-1 receptor agonists. When obtaining a medication history from patients who take GLP-1 agonists, ask about the medication's name, indication, dose, frequency, formulation (e.g., base, salt), and where they obtained the medication. Encourage patients to obtain prescription drugs only from state-licensed pharmacies that are located in the United States. When problems are found with compounded products, after identifying the compounder, report the problems to the State Board of Pharmacy and the FDA. Share FDA's BeSafeRx campaign (www.ismp.org/ext/618) with patients. This website provides valuable information about how to safely buy prescription medicines online. Report errors to the FDA (www.ismp.org/ext/544) and ISMP (www.ismp.org/report-medication-error).

Incomplete verbal order leads to wrong dose. An intensive care unit patient required conscious sedation. An intensivist asked a nurse to administer "one and twenty-five" of midazolam and fenta**NYL**, intending to

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In addition, Suprep is not available in a large plastic container. Instead, bottles of Suprep must be further diluted and patients must drink with additional water. Given that staff were apparently unfamiliar with the product versus GoLYTELY, it points out the need for widespread inservice education, memos, internal newsletter articles, and/or huddles when new products are being introduced to the formulary and when they are being dispensed to areas of the hospital where they are not normally used. Non-medication oral and IV solutions should never be stored in close proximity to medication solutions. When performing monthly unit inspections, pharmacists and pharmacy technicians should notify pharmacy and unit leaders of products that are found in patient care areas that do not belong there and remove them immediately. When outside groups contract to provide services, hospital leadership must notify the pharmacy director to ensure that the medications and dosage forms that might be used are reviewed and agreed upon by the Pharmacy and Therapeutics Committee. At that time, alternative products may be discussed and/or arrangements made to securely store products normally unavailable at the hospital.

Your *Reports* at *Work*

FDA requires updates to promethazine labeling

Due to the risk of severe chemical irritation and tissue injuries related to intravenous (IV) administration of promethazine injection, the US Food and Drug Administration (FDA) is requiring manufacturers to add administration recommendations to prescribing information as well as carton and container labels (www.ismp.org/ext/1288). The FDA recommends injection via deep intramuscular (IM) administration instead of IV administration. If it must be administered IV, it should first be diluted and infused through an IV catheter inserted into a large vein, preferably through a central venous catheter. FDA specifically mentions that the drug should not be given via veins in the hand or wrist.

ISMP first brought attention to this serious issue in a 2006 article, *Action needed to prevent serious tissue injury with IV promethazine* (www.ismp.org/node/934). This topic received a lot of attention and included more stories about this serious issue (**Figure 1**).

Then, in 2007, the drug was added to ***ISMP List of High-Alert Medications in Acute Care Settings*** (www.ismp.org/node/103). Promethazine injection is a vesicant that is highly caustic to the intima of blood vessels and surrounding tissue. Parenteral administration can result in severe tissue damage, regardless of the route of administration. However, inadvertent intra-arterial injection associated with IV use has resulted in significant complications, including burning pain, erythema, swelling, severe spasm of vessels, thrombophlebitis, venous thrombosis, phlebitis, nerve damage, paralysis, abscess, tissue necrosis, and gangrene.

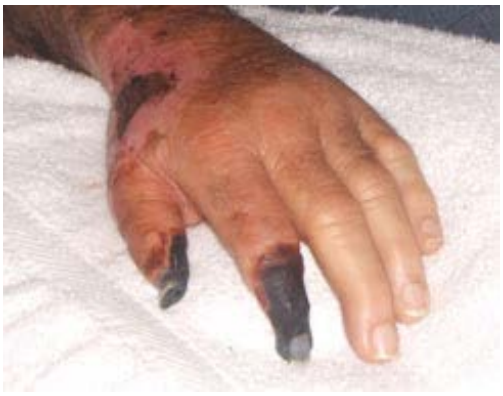

Figure 1. A patient accidentally received promethazine via an arterial line in his wrist, leading to pain that he described as "squeezing my thumb and index finger with pliers." The arterial line was quickly removed. Redness, pain, and swelling extended from his fingers to his forearm. Believing the patient had developed a thrombus, his physician performed an embolectomy, but no clot was found. About a month after the event, the patient's gangrenous thumb and finger were amputated.

Although the labeling changes are a step in the right direction, we believe stronger action is needed. For this reason, the ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice #13* (www.ismp.org/node/160) recommends organizations eliminate injectable promethazine from the formulary.

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order 1 mg of midazolam and 25 mcg of fenta**NYL**. The nurse reported that she had administered 100 mcg of fenta**NYL**, perhaps thinking "one" signified one hundred mcg of fenta**NYL**. The patient was monitored and did not require additional intervention. In the error report, the physician stated that "one and twenty-five" is a common nomenclature used in the organization when referring to "1 of midaz and 25 of fenta**NYL**." This cultural assumption, acceptance of an incomplete verbal order, and lack of read back contributed to the misinterpretation of the order and administration of an incorrect dose.

To begin with, verbal orders should be limited to emergent situations. In addition, educate practitioners to never accept cryptic verbal orders and explain the danger of this at-risk behavior. At-risk behaviors are behavioral choices that are made when individuals have lost the perception of risk associated with the choice or mistakenly believe the risk to be insignificant or justified. Teach practitioners who give and receive verbal orders about the need for a complete order (i.e., full drug name, dose, unit of measure, route), and to perform (or expect) a read back of the verbal order to the prescriber for verification to ensure that what was heard and transcribed is correct. Do not use or accept drug name abbreviations or unnecessary jargon that can easily be misunderstood. Identify any barriers (e.g., cultural norms, intimidation, staff competency) prohibiting staff from speaking up when receiving unclear orders.

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