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ISMP
An ECRI Affiliate

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

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

Problem: 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.

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

Although NaturaLyte has a barcode, the barcode may not be

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Worth repeating...

Fluzone packaging leads to a double dose

In our September 7, 2023 newsletter, we published a ***SAFETY* brief** about the potential for double dosing of **FLUZONE** (influenza) high-dose vaccine. Sanofi Pasteur sells Fluzone in cartons of 10 single-dose syringes. However, the packaging is confusing because each carton holds five sealed trays, containing two 0.7 mL single-dose syringes (**Figure 1**). Given that two syringes are packaged together, it is predictable that someone might think both are needed for a dose, especially since the vaccine is referred to as "high dose" influenza vaccine (intended for people 65 years and older). Since that ***SAFETY* brief** was published, we did receive a report in which a patient was given a double dose due to the confusing packaging. We have notified Sanofi Pasteur once again about this concern. If your organization purchases this vaccine, notify staff about the potential for errors. Ensure barcode scanning is used where available. Either dispense as a unit dose syringe or, if the entire carton must be dispensed, add auxiliary labels noting that each dose requires only one syringe.

Figure 1. Fluzone (high-dose) comes with two single-dose syringes sealed in each tray.

SAFETY briefs

Hazard Alert! Medisca 20 mL oral syringes could lead to dosing errors. Due to a supply shortage involving the usual oral syringe supplier, a pharmacy purchased 20 mL oral syringes from an alternative manufacturer, Medisca.

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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 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 condition 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 hospital areas, leaving the nurse involved with this patient caring for two other high acuity patients as well, 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.

Safe Practice 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

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The pharmacy warned us that, rather than the typical 1 mL increments, the syringe scale measures in 0.5 mL increments, which is easy to miss (**Figure 1**). According to the reporter, this has resulted in close calls in which doses were prepared with the incorrect volume. The pharmacy also noted that the syringes contain teaspoon markings instead of metric units only, which is something that ISMP has warned against for many years, due to increased error potential when household measures are used for drug dosing (www.ismp.org/node/496).

Figure 1. Medisca's 20 mL oral syringe has 0.5 mL increments and non-metric units.

We have reached out to Medisca and reported the potential for incorrect dosage errors due to the markings on the syringe. For now, if your organization carries this product, you may want to select a different vendor to avoid the risk of dosing errors.

Some Cardinal Health Monoject syringes incompatible with syringe pumps. In a September 1, 2023 letter (www.ismp.org/ext/1246), Cardinal Health notified customers that they had received reports regarding compatibility issues with certain Monoject Luer-lock syringes when used with certain syringe pumps. The letter states that a "quality hold" has been placed on specific lot numbers of syringes to facilitate an investigation into the root cause of this problem. Our affiliate, ECRI, was aware that some facilities reported syringe pump flow/volume inaccuracies when using Cardinal Health Monoject syringes and released an alert (www.ismp.org/ext/1233) on September 8, 2023. In a follow-up letter dated September 11, 2023 (www.ismp.org/ext/1247), Cardinal Health stated the hold was placed in response to customer complaints related to certain sizes of the Monoject Luer-lock syringes not being recognized by syringe pumps. Cardinal also said that 1 mL tuberculin Luer-lock syringes were not delivering the

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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.

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. 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.

Message in our Mailbox

Follow up on amiodarone dosing error

In our recent article about an amiodarone dosing error (www.ismp.org/node/85405), a patient developed hepatic toxicity after receiving what was referred to as a loading dose (400 mg per day for 8 months instead of the intended 4 weeks). It was noted that even though 400 mg per day can be used as a maintenance dose for ventricular tachycardia, this was not the intended dose for this patient's maintenance regimen. It was also noted that once a patient is stable, the dose may be reduced to 100 to 200 mg per day to lessen the risk of adverse effects and toxicity.

We thank **William Alvarez**, Jr., PharmD, BCPS; **Nisha Parikh**, MD, MPH; and **Michael Moranville**, PharmD, FCCP, BCCP, BCPS from Wolters Kluwer, who pointed out that while every effort should be taken to reduce the dose for adults to a range of 100 to 200 mg per day, not all patients with ventricular arrhythmias (e.g., refractory ventricular tachycardia, recurrent ventricular fibrillation) will be able to achieve this dosing range. Some patients will require maintenance doses of 400 mg per day, and sometimes 600 mg per day, along with careful monitoring for adverse effects (Giardina EG, Passman R. Amiodarone: clinical uses. In: UpToDate, Lévy S, Zimetbaum PJ, Parikh N, eds. Wolters Kluwer. Updated July 24, 2023. Accessed August 4, 2023). In such a scenario, a dose of 400 mg per day is not considered a loading dose and should not be considered a dosing error or overdose. Communicating the contrary could result in inappropriate dose reductions without a thorough evaluation of the patient's history, increasing the risk of recurrent ventricular arrhythmias.

Due to the complexities of this drug, variations in dosing, and risks of significant adverse reactions, including fatal hepatotoxicity, it is critical that patients are closely monitored for symptoms of toxicity. It is also critical to ensure the patient's dose is effective in treating the arrhythmia. During transitions of care and at each patient encounter, assess the patient's condition, including any signs and symptoms of toxicity or treatment failure. Review the patient's current dosing regimen along with their medication history to ensure proper dose adjustments have been made as intended.

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expected volume when used with needleless intravenous (IV) connectors. Covidien also branded Monoject Luer-lock syringes, which are NOT included in this quality hold. Because Cardinal Health has placed a shipping hold on some of their products, we recommend that you sequester any supply of the impacted syringes until the problem is resolved. As stated in the communication, contact your sales representative or Cardinal Health Customer Service at 800-964-5227.

The *myth* about the safety of the *"Five Rights"*

The idea of the "five rights" for medication safety has been taught in nursing schools since at least World War II, and continues to be used as a memory tool that nurses are expected to rely on to administer medications safely. Even though no one can identify where the concept of the five rights came from, the idea is embedded in medication safety programs and appears frequently in error reports submitted to the ***ECRI and the ISMP Patient Safety Organization***.

In our March 23, 2023 article (www.ismp.org/node/68931), we presented three of the top medication safety issues discussed in our publications that were also included in ***ECRI's Top 10 Patient Safety Concerns for 2023*** (www.ismp.org/ext/1128). One of the concerns, *Overreliance on Holding Practitioners Accountable for the Five Rights*, has been a long-standing issue. In fact, this topic is so compelling, a podcast was just released that highlights our concerns.

Susan Paparella, Vice President, Services, ISMP, points out how the five rights are inadequate as a safety tool. They do not address the system-level issues that contribute to medication errors, even when the five rights have been followed. During the podcast, Susan discusses more about the shortcomings of the five rights, and provides recommendations for better starting points for medication safety programs. To access the podcast, please visit: www.ismp.org/ext/1244.

Fatal N-acetylcysteine overdose due to pump programming errors

Our sister organization, ISMP Canada, has received two error reports of fatal N-acetylcysteine (acetylcysteine) overdoses. Both involved patients under the age of 18 who were being treated for acetaminophen poisoning. A protocol for intravenous (IV) administration of the antidote, acetylcysteine, was used. In one case, the error was noticed when the patient experienced nausea, vomiting, and seizures as a result of the acetylcysteine overdose. In both cases, the pump was programmed erroneously and continued to deliver acetylcysteine at the rate intended for the loading dose instead of the maintenance dose. Both events resulted in fatal outcomes (www.ismp.org/ext/1222).

According to the prescribing information (www.ismp.org/ext/1231), the IV acetylcysteine three-bag method (21-hour regimen) for acetaminophen overdose consists of 3 doses with a 300 mg/kg total dose administered. First, a loading dose of 150 mg/kg is infused over 1 hour, followed by a second dose of 50 mg/kg infused over 4 hours. A third dose of 100 mg/kg is then infused over 16 hours. The prescribing information also includes a recommended maximum dose and recommended diluent (e.g., 5% dextrose in water [D5W], 0.45% sodium chloride, and sterile water for injection) volume which vary based on the patient's weight. A two-bag regimen with the same total dose of 300 mg/kg has been used but is not FDA-approved.

As ISMP Canada notes, overdose of IV acetylcysteine has been linked to serious life-threatening adverse effects, including hemolysis and hemolytic uremic syndrome, cerebral edema, and seizures. Given that acetylcysteine for IV administration may be prepared in D5W, an overdose results in a substantial amount of "free water" (fluid and other osmotically active components), administered into the circulation that can lead to severe clinical harm. Nurses may have to manually reprogram a pump to administer the maintenance dose after completion of the loading dose, especially if the doses are prepared in one infusion bag, as was the issue with the case examples published by ISMP Canada.

To prevent these types of errors, consider the following recommendations:

- **Create a standard order set.** Create a standardized IV acetylcysteine order set (or review/update your order set) in your electronic health record (EHR). Include orders for the three phases of therapy, with the appropriate sequential administration times (e.g., now, to start in 1 hour, to start in 5 hours), and dispense three individual doses.
- **Match display options.** Align the smart pump drug library options with how the entries are displayed on the medication administration record (MAR).
- **Encourage feedback.** Encourage all practitioners to provide initial and ongoing feedback to ensure that the dose and corresponding administration instructions are clear for each phase.
- **Review pump data.** Evaluate your smart pump data periodically to see if acetylcysteine is being administered correctly in your organization, or if additional adjustments are needed.
- **Implement interoperability.** Plan for bi-directional (i.e., auto-programming and auto-documentation) smart infusion pump interoperability with the EHR.

Special Announcements

Workshop on human factors

Our affiliate, ECRI, will be offering an in-person, 2-day workshop, ***Advancing Patient Care Excellence through Human Factors Engineering***, on **October 11-12, 2023**. Participants will learn how to identify critical risks where the system may facilitate error. For details, visit: www.ismp.org/ext/1230.

Survey on high-alert medications

It has been 5 years since we last surveyed readers and updated ***ISMP's List of High-Alert Medications in Acute Care Settings***. Please take 20 minutes to complete our survey and submit your responses by **October 20, 2023**, at: www.ismp.org/ext/1228.

Virtual MSI workshops

Don't miss the opportunity to register for one of our unique 2-day, virtual ***ISMP Medication Safety Intensive (MSI)*** workshops. The next program is **October 4-5, 2023** (later start time for West Coast participants). For more details about the program, please visit: www.ismp.org/node/127.

Last call…apply now!

The Just Culture Company, in cooperation with ISMP, will award three ***Judy Smetzer Just Culture Champion Scholarships*** to honor Judy Smetzer, BSN, RN, FISMP, a retired ISMP vice president. Applications are due by **September 28, 2023**. For details and to apply, visit: www.ismp.org/node/30840.

To subscribe: www.ismp.org/node/10

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

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HITTING THE SAFETY HIGH NOTES

ISMP 26TH ANNUAL CHEERS AWARDS

When: Tuesday, December 5, 2023

Where: House of Blues – Anaheim

The Cheers Awards honor those who have hit the high notes in medication safety.

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https://www.ismp.org/node/83407

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