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ISMP
An ECRI Affiliate

Nurse AdviseERR®
Educating the Healthcare Community About Safe Medication Practices

Latent and active failures perfectly align to allow a preventable adverse event to reach a patient

A physician prescribed 2 g of intravenous (IV) magnesium sulfate for a patient in palliative care to treat hypomagnesemia. To administer the dose, a night nurse went to an automated dispensing cabinet (ADC) and removed what was thought to be two 100 mL bags of magnesium sulfate 1 g, then hung both bags on the patient's IV pole. The nurse attached the first 100 mL bag, scanned the barcode on the bag, and administered the infusion. After the 1 g magnesium dose had been administered, the nurse replaced the empty bag with the one remaining on the IV pole, but scanned the empty bag that had already infused to document the administration of the second bag. The nurse did not realize that due to a pharmacy error when refilling the ADC, the second bag contained midazolam 100 mg in 100 mL and administered that instead of magnesium. The patient experienced respiratory depression which the medical team initially attributed to progression of the patient's illness. The patient had a "do not resuscitate (DNR)" order and thus aggressive measures including intubation were not to be used. Later, the nurse removed both empty bags from the IV pole and discovered that one of the bags was midazolam. The prescriber ordered several doses of the benzodiazepine antagonist, flumazenil. Although the patient died later that morning, the erroneous administration of IV midazolam was not believed to be a proximal cause of death.

Figure 1. The label on the WG Critical Care midazolam 100 mg per 100 mL overwrap (left) displays the medication name in a bright orange rectangle and warns practitioners that this is a high-alert medication. WG Critical Care uses a different color design and color font to display the medication name on the magnesium sulfate 1 g per 100 mL overwrap (right).

Most preventable adverse events, including this one, happen when multiple latent failures in the organization align perfectly with the active failures of individuals. Latent failures refer to less apparent failures embedded in the organizational systems of care, the environment, or equipment, which often go unrecognized until they harm patients. Organizational latent failures (e.g., lack of, inaccurate, or incomplete policy or procedure) are less obvious than the active failures of individuals, such as human error (e.g., misprogramming a pump) or at-risk behaviors (e.g., choosing not to follow a procedure). Thus, latent failures are "accidents waiting to happen"—they often make it easier for an individual to make an error or engage in an at-risk behavior. It is the job of leaders at all levels within healthcare to identify and address latent failures that exist upstream before errors have a chance to reach our patients.

Many are familiar with James Reason's "Swiss cheese" model used to describe how latent and active failures lead to preventable adverse events. Reason suggests that a system is analogous to a stack of Swiss cheese slices. Each slice represents a part of the organizational system that defends against errors. A hole or gap in one slice of cheese, or system, represents a latent

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SAFETY wires

Broken tamper-evident oral syringe cap. Many hospitals use plastic, tamper-evident caps for oral and parenteral syringes containing controlled substances. These may also be used by some 503B outsourcing companies for both controlled and non-controlled drugs. The syringe caps can be useful in making it easier to identify if tampering has occurred. But an organization reported that the stopper pin of an International Medical Industries (IMI) tamper-evident cap (**Figure 1**) made for Baxter Oral Dispensers broke off and remained within the tip of the syringe (**Figure 2** and **Figure 3**, page 2). Consequently, the plunger would not move when the nurse pressed it to administer the medication. When the nurse retrieved a second syringe, the same thing happened. They had to use a third syringe to administer the medication.

Figure 1. Tamper-evident caps by International Medical Industries (IMI) for use with Baxter oral syringes.

The pharmacy uses these caps after preparing a variety of oral liquid controlled substances in oral syringes. This was not the first time practitioners at this organization had experienced instances of cap tips snapping off in a similar fashion. The broken pin may prevent delivery of the medication, causing a delay in care and/or

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failure that may allow an active failure to get through a single layer. But, if the holes are not aligned in the subsequent layers, the error may be prevented before it reaches a patient. For a preventable adverse event to occur, the latent failures (holes in the cheese) need to align perfectly with the active failures of individuals to get through the many defense layers of the system and reach the patient. As you read additional details about the event described below, notice how a series of latent and active failures can be identified at multiple steps in the medication-use process.

Similar bag labels inside the overwrap (latent failure)

Both midazolam and magnesium sulfate premixed products, manufactured by WG Critical Care, are in 100 mL bags within aluminum overwraps. The label on the overwraps has features to differentiate the products, including the addition of a high-alert medication symbol and a bright orange rectangle containing the drug name on the midazolam overwrap (**Figure 1**, page 1). However, once practitioners remove the IV bags from the overwrap, the inner labels printed on the bags are not as easy to distinguish and may contribute to look-alike errors (**Figure 2**).

Unaccounted for midazolam discrepancy (active failure)

A few days before this event, a pharmacist reported a single bag of midazolam was missing in the controlled substance safe. After a pharmacy supervisor could not account for the missing bag, the pharmacy decided the discrepancy was an error in the count of the midazolam bags stored in the safe and adjusted the count. However, the root cause of the discrepancy was never determined.

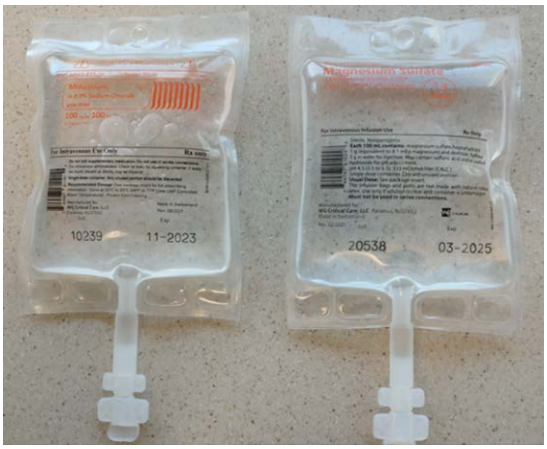

Figure 2. Once removed from the overwrap, midazolam 100 mg per 100 mL (left) and magnesium sulfate 1 g per 100 mL (right) bags by WG Critical Care have similar labels with the drug name and dose printed using a light orange font on a clear background.

Scanning process flaw (latent failure)

Although the pharmacy required technicians to scan medication barcodes when refilling the ADC, the process (as designed) only prompts scanning of the first barcode when refilling multiple units of the same medication (e.g., scanning the barcode on one bag to open the bin, and then refilling all the required bags without scanning each one).

Stocking error (active failure)

The organization's investigation revealed that a pharmacy technician had misplaced the midazolam bag in the magnesium bin in the ADC during the filling process.

Selection of the wrong infusion (active failure)

Although the nurse looked at the labels of the two infusions that had been removed from the ADC, the difference between the two medications was not noticed.

Difficulty scanning the barcode (latent failure)

Infusion bag barcodes have been chronically challenging for practitioners to scan.

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medication waste. There is also a possibility that the broken pin may be dislodged from the oral syringe tip when the plunger is pushed, resulting in accidental ingestion of the broken pin when administered to the patient together with the oral solution, causing choking or asphyxiation.

Figure 2. A tamper-evident cap tip broke off and remained in the syringe tip, preventing a nurse from administering the medication from the oral syringe.

Figure 3. An intact tamper-evident syringe tip cap (top) and a broken one (bottom).

We reached out to IMI regarding concerns about delays in medication administration, or accidental ingestion or asphyxiation. IMI stated they have no reported instances of a broken pin becoming dislodged and no reports of patient harm due to this failure. Refer to the IMI product data sheet (www.ismp.org/ext/1176) to confirm the cap is compatible with the syringes used in your organization. Educate staff to pull the cap straight off the syringe, and to inspect the cap and the syringe tip opening after they remove a tamper-evident cap and before administering the medication. Do not attempt to administer doses from an oral syringe if the cap appears damaged. Report any other issues to ISMP.

It should be noted that this is a different issue than what was reported in a 2019

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Proxy scan (active failure)

Because some barcodes on infusion bags were difficult to scan, nurses had developed a workaround (at-risk behavior), where they scanned the barcode on the empty infusion bag already hanging instead of the subsequent infusion bag, believing it to be the same infusion. This allowed the nurse to document the subsequent infusion quickly but, in this case, inaccurately.

Low lighting (latent failure)

The adverse event occurred during the night shift, where there was deliberate low-level lighting in the patient's room. Thus, the nurse had difficulty reading the labels of the bags hung on the IV pole.

Safe Practice Recommendations

This event demonstrates that, typically, many things must go wrong for a medication error to reach the patient. To minimize errors, identify active and latent failures and evaluate your processes by considering the following recommendations:

New product review. When the pharmacy receives a new product (e.g., new product added to formulary, drug shortage), conduct a review to identify potential risks with the product's design and/or packaging including any issues with scanning the product's barcode. Also, identify any look-alike labeling and packaging concerns with other products on the formulary. Communicate similarities with manufacturers, ISMP, the US Food and Drug Administration (FDA), purchasers, and group purchasing organizations as appropriate.

Purchase from a different manufacturer. When problems are recognized, consider purchasing the product (or one product of a problematic pair) from a different manufacturer. We reached out to the manufacturer, WG Critical Care, to notify them of this event and to recommend differentiating the infusion bag labels.

Prompt resolution of discrepancies. A controlled substance discrepancy could be an indication that the pharmacy dispensed the wrong product or there could be a diversion issue. Practitioners may be able to identify a dispensing or stocking error prior to it reaching a patient. Investigate and identify the root cause of discrepancies and educate practitioners to escalate concerns to leadership for prompt resolution, which may involve designating resources (e.g., pharmacy staff) to physically check the stock in the pharmacy and in all ADCs.

Manage pharmacy ADC stock. Designate an area in the pharmacy for ADC stock management with space to avoid the intermingling of medications and minimal interruptions and distractions.

Employ dispensing barcoding technology. Use barcode scanning technology in the pharmacy to confirm that medications chosen for distribution to the ADC match the medications listed on the ADC fill report. Segregate and secure all medications designated for an individual ADC during transport. Use barcode scanning at the cabinet to promote the accurate placement of medications in the correct drawer or pocket location. Determine if your ADC has the functionality for practitioners to scan each individual product when refilling the ADC, and consider requiring barcode scanning of each medication before placing it in the ADC. Review the ISMP ***Guidelines for the Safe Use of Automated Dispensing Cabinets*** (www.ismp.org/node/1372; Core Safety Process #6).

Require an independent double check during selection. Provide a final independent double check of all medications selected in pharmacy for ADC distribution to ensure the right drug, strength, dosage, and correct quantity are verified. Even if barcode technology is used in the selection process, a physical independent double check should be done in the pharmacy prior to distribution.

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article (www.ismp.org/node/12337), in which the plastic ring connected to the tamper-evident cap fell off and was not properly disposed of prior to administration. According to IMI, that oral tamper-evident cap was redesigned in 2021 such that there are no loose parts that separate from the tip cap.

Ryanodex demo carton and vial look too much like the real thing. A hospital that stocks **RYANODEX** (dantrolene sodium) for injectable suspension in areas where patients are at risk of malignant hyperthermia, reported confusion between the actual medication cartons and demonstration (demo) cartons that look remarkably similar (**Figure 1**). When the demo product was received after a request to the manufacturer, Eagle Pharmaceuticals (Eagle), hospital supply staff shelved it with the actual product, possibly because of their similar appearance. Fortunately, the storage error was identified before the product was used for patient care. Ryanodex is available as a 250 mg vial of lyophilized powder which is administered as a single dose after reconstitution with 5 mL of sterile water for injection without a bacteriostatic agent (reconstitution yields 50 mg/mL). The manufacturer informed us that the demo vials contain actual (expired) medication.

Figure 1. The Ryanodex medication carton (left) looks nearly identical to the demo carton (right).

The manufacturer provides demo vials for staff to gain experience with preparing doses during training sessions. Hospital educators may take these vials to patient care areas (e.g., operating room) where malignant hyperthermia must be treated emergently, which may contribute to the risk of a mix-up.

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Promote optimal conditions. Ensure the physical environment offers adequate space and lighting and allows practitioners to remain focused on the medication-use process (e.g., drug selection, barcode scanning) without distractions.

Read overwrap and inner labels. Carefully review and read individual product labels after removing the medication from the ADC, when removing infusions from overwraps, when spiking an IV bag, and prior to administration.

Employ bedside barcode technology. Use bedside barcode scanning technology to confirm that medications selected for administration match the patient's medication administration record. Coach staff to never use a proxy scan, such as scanning the barcode on an already hanging empty bag or a medication label not affixed to what is actually being administered and explain why this is so important. Share this event to emphasize the risk of proxy scanning and workarounds.

Troubleshoot difficult barcodes. Test new product barcodes in the pharmacy prior to distribution. If a practitioner has trouble scanning a barcode, manufacturers have suggested holding the scanner 4 to 6 inches from the bag, scanning at an angle, and/or putting a contrasting color behind the bag. Develop a process within the organization for end users to report barcode issues so that pharmacy leadership can consider an alternative product, when possible. Report barcode scanning issues to ISMP so we can work with manufacturers and FDA to improve the safety of product labeling and packaging. Instruct staff on the accepted best practice to use when a barcode scan does not work.

Conclusion

We encourage practitioners who investigate events to always consider multiple latent system failures and multiple active failures by practitioners that might have contributed to the error or hazard. Our natural tendency is to look for simple, singular answers during event investigations, and these often focus on errors at the sharp end—the active failures. But there are often many hidden twists and turns along the path to a medication error. By themselves, latent failures are often subtle and may not cause problems. Their consequences are hidden, becoming apparent only when they occur in proper sequence and are combined with the active failures of multiple individuals to penetrate or bypass system safety nets. This event provides clear evidence that medication errors are almost never caused by the failure of a single system or the fault of a single practitioner. Rather, a preventable adverse event like this is the result of the combined effects of latent failures in the system and active failures by practitioners. Therefore, the goal of the investigation should be to proactively make system changes to correct latent failures, making it harder for an active failure by a practitioner to result in an error reaching a patient.

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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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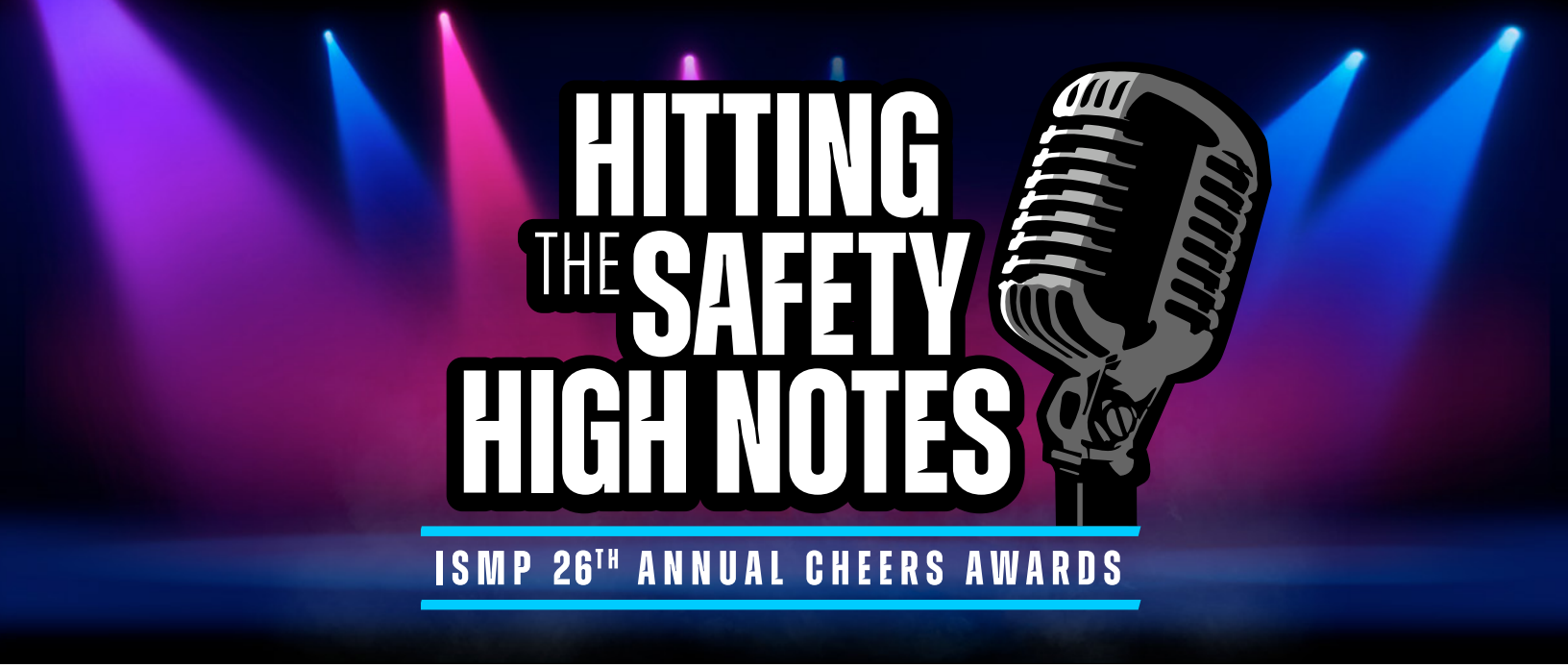
Ryanodex demo vials come in the same size carton and have the same shape and coloring as the actual Ryanodex product. Each demo carton and vial is labeled, "DEMO For Training Only Not For Human Use." The demo vial does not include a barcode, National Drug Code (NDC) number, or expiration date, and the lot number includes the word DEMO. Additionally, each demo vial features auxiliary over-seal tape that must be broken in order to access the product that says, "DEMO VIAL - FOR TRAINING ONLY." Practitioners may fail to read all the information on the label, especially in an emergency such as malignant hypothermia. Or, as many do, they often read container label information in vertical order, sometimes stopping once they identify the drug and its strength. They may fail to read the rest of the label once they identify the information they think they need, sometimes missing warnings. Even if the practitioner noticed the warnings, if demo vials are inadvertently stocked instead of Ryanodex, it can lead to the delay of a time-sensitive treatment.

Mix-ups involving other demo products have happened and have been reported to ISMP. For example, in 2015, ISMP (www.ismp.org/node/552) and the US Food and Drug Administration (FDA) alerted healthcare professionals not to use Wallcur simulated (demo) intravenous (IV) products in human or animal patients. More than 40 patients received these products intended for educational use only and developed chills and/or sepsis; one patient died.

We have notified the manufacturer and the FDA regarding this issue. Demo products not intended for human use should be packaged to appear distinctly different than the actual product. When ordering demo products, provide an alternative shipping location in a non-production/storage area of the pharmacy (e.g., pharmacy administrative offices). Ensure educational products are stored separately from medications in a classroom/training area and not in patient care areas. Consider adding auxiliary labeling to the package and storage areas to warn that they are for demo use only.



Tuesday, December 5, 2023

House of Blues – Anaheim

ISMP is showcasing medication safety stars at the 2023 Cheers Awards dinner, and we would love to see you there.

You can help honor this year's Cheers Award winners by attending the awards dinner and/or supporting the event. Your participation helps bring attention to safety advances and enables ISMP to continue the core of its lifesaving work – preventing medication errors.

Guest Speaker:

RaDonda Vaught

RaDonda Vaught is a former nurse criminally prosecuted for a fatal medication error who has a compelling story to tell. RaDonda self-reported her error and provided detailed information to help prevent similar mistakes in the future but was convicted of two felony charges and lost her nursing license. ISMP and many other healthcare organizations have spoken out in support of RaDonda and against the criminalization of medication errors. Today she is a passionate advocate for system-based medication safety and second victims of errors.

To show your support, visit:
www.ismp.org/node/83407

Register to attend:
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