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

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

Problem: 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 flumazenil. Although the patient died later that morning, the erroneous administration of IV midazolam was not considered to be a proximal cause of death.

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 failure that may allow an active failure to get through a single layer. But in the subsequent layers, if the holes are not aligned, 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 2). However, once

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Worth repeating...

Missing information on OTC liquid acetaminophen risks overdose

It has been over 4 years since we warned about misleading labels on acetaminophen liquid products sold in locations such as Walgreens, CVS, and Walmart (www.ismp.org/node/1067). The problem was that the product labels displayed "500 mg" without a corresponding volume on the principal display panel, which confused patients when trying to determine the right amount of medication to take. It turns out this is still a problem! Two different pharmacists recently reported that CVS over-the-counter (OTC) acetaminophen liquid displays the strength as "1000 mg" without the corresponding volume (**Figure 1**, page 2). Information about the proper strength (1,000 mg per 30 mL) and dose is found by peeling back the label on the back of the container which reveals the *Drug Facts* label. Not everyone knows how to find this information or even reads the *Drug Facts* label. For patients with poor vision,

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Become an ISMP Fellow

ISMP will soon be accepting applications for our unique Fellowship program that will begin in the summer of 2023. The **ISMP Safe Medication Management Fellowship** and **FDA/ISMP Safe Medication Management Fellowship** will help you grow in your career and enable you to make major contributions to medication safety worldwide. For a brief description of our Fellowship program, candidate qualifications, program brochure and outline, please visit: www.ismp.org/node/871. More information, including application deadline, will be coming soon!

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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**).

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).

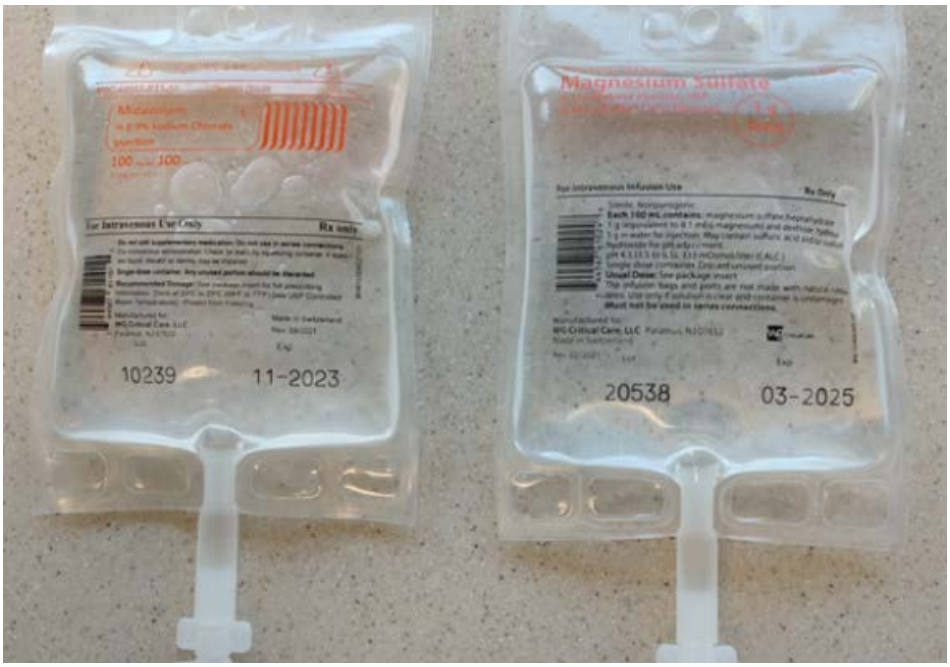

Figure 2. Once removed from the overwrap, midazolam 100 mg per 100 mL (left) and magnesium sulfate 1 g per 100 mL (right) bags by WG Critical Care have similar labels with the drug name and dose printed using a light orange font on a clear background.

Unaccounted for midazolam discrepancy (active failure)

A few days before this event, a pharmacist reported a single midazolam bag discrepancy in the controlled substance safe. After a pharmacy supervisor could not account for the missing bag, the pharmacy cleared the discrepancy in the safe. However, the root cause of the discrepancy was never determined.

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compromised manual dexterity, or low health literacy, this important information may be missed. Without easy and accessible dosing information, a patient or even a healthcare professional may mistakenly assume the full bottle contains 1,000 mg. In addition, the accompanying dosing cup only has a marking at 30 mL, which measures 1,000 mg of acetaminophen (**Figure 2**). If the patient required a different dose, such as 500 mg or 15 mL, they would not be able to accurately measure this using the cup provided.

Figure 1. CVS acetaminophen oral liquid product displays only "1000 mg" on the front label (left). To know how much liquid to measure, the patient must peel back the label on the back of the container and review the ***Drug Facts*** label (right).

Figure 2. The acetaminophen liquid labeled as "1000 mg" without a corresponding volume or concentration, comes with a dosage cup that only has a 30 mL mark.

In the *Statement of Identity and Strength — Content and Format of Labeling for Human Nonprescription Drug Products Guidance for Industry* (www.ismp.org/ext/1007), the US Food and Drug Administration (FDA) recommends that the strength of the drug product's active ingredient(s) immediately follows the statement of identity (the drug name) on the principal display panel. The lack of clearly labeling the medication's strength (i.e., concentration) is problematic and can result in harm. We reached out to FDA and CVS to recommend that the label on the front of the container clearly display the strength of the liquid without requiring the patient to take additional steps.

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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.

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

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SAFETY brief

HIGH-ALERT

Wrong route HYDROmorphone administration. A prescriber ordered **HYDRO**morphone 4 mg **injection** but was able to select the **oral route** of administration in a Cerner electronic health record (EHR). The pharmacist did not identify the oral-parenteral product type mismatch, so they did not contact the prescriber to recommend oral tablets or liquid. The computer system also allowed the pharmacist to verify the order since there were no alerts. Later, the nurse did not notice the oral route of administration, removed a 4 mg/2 mL injectable vial from an automated dispensing cabinet (ADC), and administered the 4 mg dose of medication intravenously (IV). The patient lost consciousness and required naloxone to reverse the opioid's effect.

We reached out to Cerner about this event, and a representative mentioned that the Cerner recommended settings would help prevent this wrong route error. However, the organization where this error occurred was not using Cerner's recommended settings. In the organization's search configuration, the first five order sentences (how the drug is listed on the medication selection screen) for **HYDRO**morphone have the IV route linked to the injectable product. But after prescribers select one of these order sentences, they can modify the route field to any route from the drop-down list. For this order, the prescriber changed the route from IV to oral, intending to prescribe an oral formulation. However, the system had automatically assigned the 4 mg/2 mL injectable vial based on the order sentence. If the hospital had configured the Cerner preferred setting, once a prescriber selects an order sentence linked to an injectable product, only appropriate parenteral routes will be available in the drop-down list. If prescribers select "more," they can choose an oral route, but the system no longer automatically assigns an IV product since it is not compatible. Instead, a filter option displays the route/dosage form compatible products for the pharmacist to dispense. Cerner plans to notify all clients about the importance of the recommended configurations for route-form compatibility. Cerner will also let clients know about

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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.

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 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.

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.

Summary. 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.

>SAFETY brief

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audits they may apply to ensure they are using the recommended configuration. Consider reviewing your EHR functionality to determine if a wrong-route mismatch can occur and update your system as needed.

There are situations, usually off-label, in which a different route of administration is needed. And while injectable products are sometimes administered orally, organizations should restrict routes that are not intended for products (e.g., only IV route should be allowed for vinca alkaloids). Review order sentences and ensure they reflect common doses, routes, and frequencies. In addition, a **HYDRO**morphone 4 mg IV starting dose should not be the default option! Report EHR safety concerns to the vendor, the US Food and Drug Administration (FDA), and ISMP.

Special Announcement

We recently received reports from several healthcare organizations regarding the incorrect packaging of isoflurane labeled "for animal use only" in cartons intended to contain isoflurane for human use. If you use this product, inspect your supply to ensure it is correct. For more information, read our **ALERT** (www.ismp.org/node/56978) published on January 9, 2023.

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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Special thanks to our 2022 MSOS Member Briefings Presenters

The Medication Safety Officers Society (MSOS) holds Member Briefings every other month on various medication safety topics. The MSOS Member Briefings are webinars that feature three 10-minute presentations from volunteer MSOS members who highlight a project, initiative, or relevant medication safety topic. The goal is for participants to take the information presented and use it to implement similar medication safety initiatives within their own organization. At each Member Briefing, ISMP President Emeritus Michael Cohen also provides an update on ISMP activities. Please let us know (ismpinfo@ismp.org) if there is a medication safety topic you would like to present (or see presented) during a 2023 MSOS Member Briefing. We hope others can join us as presenters in 2023! To join the MSOS and attend the Member Briefings, visit: www.medsafetyofficer.org/user/register. MSOS membership and the 2023 Member Briefings are **FREE**.

Production of the MSOS Member Briefings would not be possible without the assistance of voluntary MSOS member presenters. ISMP sincerely thanks all of the 2022 presenters who helped make the Member Briefings a valuable medication safety resource for MSOS members.

Thank You!

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