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Another nurse criminally charged—LTC must improve systems, not blame nurses—Part I

We recently heard about a series of latent and active system failures, which contributed to a licensed practical nurse (LPN) administering another resident's opioid infusion to a patient in a long-term care (LTC) facility instead of the prescribed antibiotic infusion. The patient died, and first and foremost, our heartfelt condolences go out to the patient's family for their tragic loss. This event occurred in 2017, at which time the nurse voluntarily surrendered her license but was indicted on second-degree reckless manslaughter in 2022. Unlike the *2022 conviction of RaDonda Vaught* for criminally negligent homicide and gross neglect of an impaired adult following the 2017 death of Charlene Murphey, this event did not gain national attention.

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. However, in the subsequent layers, if the holes are aligned, the error reaches a patient/resident. 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/resident. As you read additional details about the LTC event described below, notice how a series of latent and active failures can be identified at multiple steps in the medication-use process.

Event Details

The nurse, who had been an LPN for 30 years, came on to her 3 to 11 pm shift where she was responsible for taking care of 27 residents (latent failure). Her shift started with an in-service from a hospice nurse in which the management of a resident receiving hospice care was discussed. The physician prescribed a subcutaneous **HYDRO**morphone infusion for that resident to be administered by a continuous ambulatory delivery device (CADD) pump. Opioids, administered by any route of administration, are on the ***ISMP List of High-Alert Medications in Long-Term Care (LTC) Settings***. High-alert medications are drugs that bear a heightened risk of causing significant patient/resident harm when they are used in error. The LTC facility had no prior experience using the CADD pump nor with storing/administering **HYDRO**morphone (latent failure) via the pump. The hospice nurse, who was responsible for changing out the **HYDRO**morphone infusion bag when needed, explained the process to the staff. The LTC staff were to monitor the resident and notify the hospice nurse if there were any changes in the patient's condition.

The LTC facility expectation was for the LPN to listen to the in-service, but she was not provided with designated time and several interruptions distracted her, including phone calls and resident care issues (latent failure). At some point, a backup **HYDRO**morphone 1,250 mg/250 mL infusion bag was handed to another nurse who was told to place it in the locked compartment used to secure controlled substances in the only medication refrigerator for this 60-bed, two-wing unit (latent failure). The nurse attempted to secure the **HYDRO**morphone bag in the small, locked compartment, but it would not fit due to the other controlled substance medications stored there (latent failure). The nurse notified the nursing supervisor of this space limitation, and the nursing supervisor instructed her to place the **HYDRO**morphone bag on a shelf in the unsecured part of the refrigerator (active failure). This information was not communicated to other nurses who had access to this refrigerator (active failure). Medication infusions, especially opioids, were not

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SAFETY wires

Proxy scan leads to child receiving the wrong drug. A prescriber ordered an intravenous (IV) leucovorin infusion for a patient on a pediatric oncology unit. This was part of the child's chemotherapy regimen, so the hospital policy required a second nurse verification before administration. The nurse scanned a "proxy" patient identification (ID) barcode that she printed and stored with a stack of other patient ID barcodes at the nurses' station (**Figure 1**). The nurse then scanned the barcode on a pharmacy-generated label attached to the leucovorin infusion. A second nurse verified the information on the leucovorin label and in the medication administration

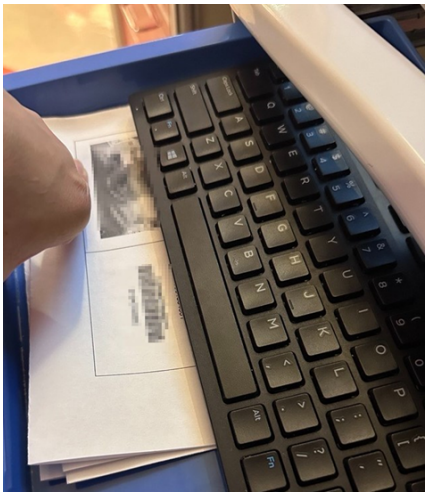

Figure 1. Printed copies of patient ID barcodes that nurses were using as a proxy scan.

record (MAR). The nurses co-signed the documentation of administration in the MAR, using the computer at the nurses' station. The nurse then entered a different child's room, with a similar name and age as the child who had been prescribed the leucovorin, and administered the infusion. Shortly after, the nurse identified that leucovorin had not been prescribed for that child. She discontinued the infusion and notified the prescriber. Fortunately, there was no patient harm. During the event investigation, it was discovered that the unsafe process of using a proxy scan for

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something that nurses in this facility would expect to find in the open part of the refrigerator (latent failure).

The only other patient who was prescribed a medication infusion was a post-operative (post-op) knee surgery patient who was staying at the LTC facility temporarily to receive an intravenous (IV) infusion of cef**TAZ**idime. The **HYDRO**morphone and cef**TAZ**idime infusions (both at a dose of 1,250 mg in bags and requiring refrigeration) (latent failure) were stored next to each other on the lower refrigerator shelf when the opioid infusion could not fit into the secured compartment (latent failure). The LPN caring for the post-op patient reviewed the medication administration record (MAR) and saw that cef**TAZ**idime was due at 10 pm. She went to the medication room, obtained the cef**TAZ**idime 1,250 mg/500 mL infusion bag from the refrigerator, and went into the patient's room. However, the cap was missing from the end of the patient's peripherally inserted central catheter (PICC) line, so the LPN returned the antibiotic bag to the refrigerator to search for the cap. There were no caps in the box where they were typically stored, so the nursing supervisor had to go look for a cap. Not having appropriate supplies available added to time constraints and unnecessary distractions for the LPN (latent failure). When the LPN had the required equipment to administer the antibiotic, she returned to the medication room, removed what she thought was the cef**TAZ**idime infusion (active failure), and brought the medication to the patient's room.

From the technology perspective, the LTC facility implemented barcode medication administration (BCMA) scanning for non-injectable medications, but not for medication infusions (latent failure). At the time of this event, the barcode scanner was broken, and the device had a note around it stating that it was not functioning (latent failure). In addition, in this facility, patient/resident wristbands did not include a barcode (latent failure), so the technology would not have helped to confirm whether the medication was administered to the correct patient/resident. There were computers at the nurses' station, but there was not a method (e.g., computer on wheels) to bring the computer to the patient's room (latent failure). Although the organization used infusion pumps to administer IV medications, they did not have any smart infusion pumps with drug libraries (latent failure).

The LPN read the label on the **HYDRO**morphone 1,250 mg/250 mL infusion bag but her attention was focused on the "1,250 mg" dose. Although the cef**TAZ**idime order was for a 500 mL bag, the pharmacy had previously dispensed a 250 mL bag of cef**TAZ**idime for this patient, so this was the size that the nurse expected (latent failure). The LPN did not realize it was actually the **HYDRO**morphone infusion for the resident in hospice care, so she attached what she thought was the cef**TAZ**idime infusion to the post-op patient (active failure) and programmed the pump to infuse over one hour. This occurred around 11 pm when there was deliberate low-level lighting in the patient's room (latent failure).

The night shift nurse was late to arrive, so the LPN was unable to leave until a little after midnight and fatigue may have been a factor (latent failure). Before ending her shift, the LPN documented in the electronic health record (EHR) that the patient was tolerating the antibiotic. The LTC facility did not have a policy or practice for nurses to complete a bedside handoff for patients receiving infusions (latent failure). What is uncertain is if the LPN began the infusion, and if so, how much had infused, because around 1 am, the night shift nurse checked on the patient and noted that the pump was beeping and occluded. This nurse turned the pump back on but did not read the infusing medication's label (active failure) to note that it was the incorrect medication (e.g., wrong drug, wrong patient). She documented that the patient was awake, alert, and oriented, which would not be expected if **HYDRO**morphone had been infusing since 11 pm at the antibiotic rate. Around 3 am during rounds, the patient was found unresponsive, and the error was identified. Unfortunately, the patient was not able to be resuscitated.

When the evening shift LPN returned at 7 am to work an extra shift due to short staffing, she learned of this tragic event and was completely devastated. While visibly distraught, she was asked to provide statements verbally and in writing, and the nursing supervisor fired her on the spot. The LPN immediately surrendered her nursing license without the State Board requiring it. The patient's family later filed a civil case against her.

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patient ID bands was a common practice by nurses who were trying to avoid disturbing patients in the pediatric oncology unit by entering their room to scan the patient ID on their wristband.

Barcode medication administration (BCMA) and positive patient identification (PPID) prior to administering any medication is a crucial step to prevent errors. However, workarounds such as using a proxy scan (e.g., scanning a patient ID barcode that is not attached to the patient) limit the effectiveness of this technology. Regularly observe BCMA practices within your organization to help identify potential workflow issues leading to workarounds. Educate staff on when and how to report BCMA-related workflow issues, and why it is dangerous to use a proxy scan. This is an example of at-risk behavior that may stem from the culture of individual nursing units. Discuss similar concerns with nursing leadership to foster a culture of safety. Work with the informatics team to determine if it is possible to only allow for scanning of the patient ID band, and not the barcode on patient stickers/paperwork. Use internal and external published events related to incorrect BCMA utilization to educate staff to further highlight the importance of BCMA.

Nymalize oral solution now available in prefilled ENFit syringe. NYMALIZE (ni**MOD**ipine) 6 mg/mL oral solution is indicated for the improvement of neurological outcomes by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage. ISMP has been a proponent of the commercially available oral solution since it was first marketed. Prior to Nymalize, only liquid-filled gel capsules of ni**MOD**ipine were available. In order to facilitate administration of the liquid orally or through a feeding tube, the drug was extracted from the liquid-filled gel capsules with a parenteral syringe and needle. Unfortunately, errors sometimes occurred when the extracted drug was accidentally administered intravenously (IV). An IV injection of the drug can cause profound hypotension, sometimes leading to fatalities.

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Outcome

Five years after the patient's death, the nurse, who noted she was still struggling to cope with what had happened, was charged with second-degree reckless manslaughter and faced a 5-year minimum prison sentence. During the deposition process, the prosecutors and expert witnesses claimed that the nurse did not complete the "five rights" of medication administration and even brought up that she had made a medication error in 2011 and "must not have learned from it." Although not everyone on the jury thought this case should be brought forward, the grand jury indicted her. Feeling incapable of going through a trial, the nurse took a plea deal where she admitted she was guilty of a misdemeanor, but not criminal negligence, for which she was given community service.

The Absence of a Culture of Safety

In a Just Culture, the outcome or severity of an event should never determine or influence the response to the individuals involved. The problem with allowing the outcome to determine the course of action is that one can potentially overreact to a singular harmful event and mete out unwarranted disciplinary sanctions, or one can underreact to a potentially fatal system flaw simply because, by luck, it did not harm a patient. Outcome bias is inherent in the American civil and criminal justice system, meaning that whenever patient harm occurs, the prosecutors consider the degree of harm. If the very same event had happened but had not resulted in a patient's death, it might **not** have resulted in criminal charges. A more immediate actionable injustice occurred when the organization fired the nurse "on the spot," an act that indicates their system of workplace justice is outcome biased. The degree to which the medication-use system that these practitioners operated in was so inadequately under-guarded adds to the injustice.

Similar to RaDonda Vaught's conviction, the prosecution chose to ignore the fact that the tragic outcome was a culmination of multiple system failures throughout a very poorly designed medication-use system. In this case, the nurses' choices appear to be driven by a desire to provide care under conditions that gave rise to human errors. Based on the information we have, there was no discussion by any party about the latent failures that allowed this error to happen—only the active failures of one nurse. The LTC facility did not take responsibility for the system errors, including gaps in workflow, lack of technological safeguards that contributed to this event, and the nursing supervisor who instructed a nurse to place the **HYDRO**morphone bag on the shelf of the refrigerator, nor were any lessons learned shared with others to prevent a similar event from occurring.

ISMP, along with others, fear that criminal charges against healthcare practitioners set a dangerous precedent with worrisome implications for safety. We are concerned that this may prevent practitioners from reporting errors, undermine the creation of a culture of safety, accelerate the exodus of practitioners from clinical practice, exacerbate the shortage of healthcare providers, perpetuate the myth that perfect performance is achievable, and impede system improvements.

Recommendations

ISMP urges all organizations to learn from this tragic event and take action to improve systems rather than placing blame on the individual(s) involved. Follow these recommendations to evaluate processes and implement technologies and workflows to minimize errors.

Safeguard high-alert medications. Use the ***ISMP Lists of High-Alert Medications*** (Acute Care Settings, LTC Settings, Community/Ambulatory Care Settings) to determine which medications require special safeguards to reduce the risk of errors in your organization. Strategies include the following: standardizing the ordering; safe storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to high-alert medications; using automated alerts and auxiliary labels; and employing redundancies such as automated (e.g., barcode scanning) or independent double-checks when necessary.

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In our June 2020 newsletter, we shared that the manufacturer of Nymalize was discontinuing their unit dose cups and 473 mL bottles and transitioning to a prefilled legacy oral syringe with a new concentration of 6 mg/mL (formerly 3 mg/mL). This led to concerns from hospitals that had converted to ENFit connectors, which are not compatible with legacy oral syringes. The company was considering ISMP's concern, with an aim to establish a resolution to the ENFit incompatibility issue. Since then, in addition to offering the new concentration in prefilled oral syringes and bottles containing 237 mL of the oral solution, on September 3, 2024, the manufacturer, Azurity Pharmaceuticals, announced the US Food and Drug Administration (FDA) approved their new formulation of Nymalize 30 mg/5 mL prefilled ENFit syringe. Providing the medication in ENFit syringes, which are only compatible with ENFit connectors, can prevent misconnections and further reduce the risk of oral liquids being administered intravenously (IV).

Of note, Camber Pharmaceuticals has announced that a generic ni**MOD**ipine 473 mL (3 mg/mL) oral solution bottle will be available. This product's concentration differs from the 6 mg/mL product, which has been the only concentration available for the last 5 years. Organizations should assess which formulation(s) (e.g., oral syringe, ENFit syringe, bottle) should be available on their formulary based on their patient population (e.g., adult versus pediatric). We recommend standardizing to a single concentration, when possible.

Do not administer vancomycin via IV push. In our November 2024 newsletter, we discussed concerns about the fluid shortages as a result of Hurricane Helene and a lack of understanding of how to administer medications via intravenous (IV) push that were previously administered by infusion. We heard that an organization was considering administering vancomycin via "IV push." If infused too quickly, vancomycin is known to cause an infusion reaction called vancomycin flushing syndrome (formerly "red man syndrome"). According to the prescribing information (i.e., generic

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Ensure adequate space for medication storage. Provide sufficient space for secure medication storage (e.g., additional or larger refrigerator and/or lock box). If there is a special patient need, such as a concentrated opioid infusion that is "out of the norm" for practitioners at the facility, provide clear and multimodal communications on how this medication will be handled.

Separate storage. Take steps to separate the storage of look-alike high-alert medications. Consider affixing warnings to alert practitioners.

Employ BCMA. Organizations should implement and use bedside barcode scanning technology for all medications (e.g., do not exclude infusions or other routes of administration). For patient identification, scan the barcode on the patient/resident's wristband as well as the barcode on the medication. Review the workflow that describes when and how staff should attach a wristband to the patient (e.g., ensure they are secure and do not easily slip off), especially since they may need to be replaced with a regular cadence for LTC residents. Regularly review BCMA compliance data and conduct direct observations to help identify potential workflow issues. Educate end-users to scan medication barcodes prior to administration and the risk if this process is bypassed. Coach staff to escalate issues such as device problems (e.g., broken scanner) and ensure that leaders promptly take action to resolve them.

Implement smart pumps. If your organization administers IV medications or hydration fluids, procure smart infusion pumps and implement dose error-reduction systems (DERS) to safeguard the appropriate rate of administration. Leaders must have a system to monitor compliance and gather feedback from end-users to ensure use of the smart infusion pump drug library is maximized. Develop and share compliance goals and regularly evaluate if system changes are needed. Review our ***Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps*** for additional information.

Read the label and confirm the programming. Educate staff to carefully review medication labels after removing the medication from the storage location (e.g., medication room, automated dispensing cabinet [ADC]), when spiking an infusion bag, and prior to administration or restarting an infusion. Confirm that the infusion dose and rate are programmed accurately.

Handoffs at shift changes. During handoffs, nurses should round on the patient/resident together to check medications that are infusing on the pump.

Safeguard unique patient needs. Prepare for circumstances when patients require medications (e.g., opioid infusion) or devices (e.g., CADD pump) that deviate from those typically used in your facility. Consider completing a failure mode and effects analysis (FMEA) to determine potential failure points and mitigation strategies. Gather feedback from practitioners and determine how to communicate (e.g., huddles, handoff) a patient's special needs to all applicable staff.

Educate staff. Develop organization-specific competency assessments for those who prepare and administer medications. These competencies should be completed during orientation and annually. Include simulations for verification of the medication label compared to the order in the MAR, BCMA scanning, and pump programming prior to administration. LTC facilities should consider providing additional education to a few designated nurses (all shifts) as infusion experts, with one serving as the primary contact to work closely with prescribers and the pharmacy.

Provide staffing support. Consider creating an "on-call" staffing infrastructure based on defined conditions (e.g., nurse-to-patient ratio, patient acuity metrics). This would allow nurse leaders to review the situation, gather feedback from frontline staff, and have an action plan to divert or bring in additional resources as needed. Encourage staff to speak up in situations where they feel that their workload and/or patient acuity is overwhelming or creating an unsafe environment in which an error may be more likely to occur.

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vancomycin prescribing information from Baxter), vancomycin should be infused over 60 minutes or greater to reduce the risk of an infusion reaction. Hypotension, shock, and cardiac arrest have been reported with too rapid of a vancomycin infusion.

When organizations are considering switching any medication from an infusion to IV push, ensure any change in drug concentration and/or rate of administration is appropriate based on the patient's clinical status and drug properties (e.g., pH, osmolarity). Refer to prescribing information, literature, and resources such as *Adult and pediatric IV push medication reference*: Vizient, Inc. 2023. For all IV medications, include a rate of administration in the medication administration record (MAR). For additional information, refer to the recommendations listed in the ISMP ***Safe Practice Guidelines for Adult IV Push Medications***.

Topical agent packaged similar to an injectable vial. Practitioners have reported concerns with the packaging of **MURI-LUBE** (light mineral oil), a sterile mineral oil lubricant for surgical instruments. The manufacturer, Fresenius Kabi, supplies it in a 2 mL flip, tear-top vial and a 10 mL aluminum tear-top vial (**Figure 1**) that resembles a parenteral injection vial. The vial label contains the statement "NOT FOR PARENTERAL USE;" however, practitioners may overlook this, given it resembles a parenteral injection vial. Topical product packaging that encourages practitioners to use parenteral syringes to prepare the dose risks the potential of inadvertent intravenous (IV) administration and presents a significant risk to patient safety and can result in harm.

Figure 1. Muri-Lube topical agent used for surgical instrument lubrication is provided in a vial that resembles those used for parenteral injections.

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Support a safe environment. Ensure the physical environment offers adequate space and lighting and allows practitioners to remain focused on the medication-use process without distractions. Ensure optimal placement of equipment (e.g., computer, scanner) to support practitioners' workflow. When possible, ensure equipment is available in patient rooms to prevent practitioners from needing to leave the room to check the MAR or scan a barcode after administering a medication.

Monitor patients. Establish appropriate protocols for monitoring infusion therapy with defined actions to be taken if the therapy is not achieving its desired outcome or an adverse event occurs. Develop specific parameters based on the medication being infused and/or patient/resident vulnerabilities, including vital signs and laboratory testing. Practitioners should be guided via procedures for recording the assessment of the patient/resident's IV access site.

Implement a Just Culture. Implement a Just Culture with fierce attention to workarounds and decisions workers must make "on the fly" to manage an immediate care need. When evaluating the conduct of individuals, consider the quality of choice rather than the relative "luck"—good or tragic—of the outcome. Incorporate policies about error reporting that align with a Just Culture.

Identify problems. Routinely meet with practitioners to discuss concerns and foster increased communication and feedback. Ask staff about safety issues and exhibit appreciative listening. Maintain confidentiality of those involved in errors while sharing event details and lessons learned. During safety huddles, share impactful stories and recognize staff for good catches.

Report errors. Encourage staff to report close calls and errors internally and externally through the ***ISMP National Medication Errors Reporting Program*** (ISMP MERP). Review internally reported errors as well as published external events.

Provide support systems. Although the patient/resident and their families are at the center of such tragic events, involved healthcare providers may become "second victims," who may require or benefit from organizational support. Implement peer support programs and the use of employee assistance programs (EAPs). To learn more, refer to *Strategies to Improve Aging Services Worker Well-Being*.

Conclusion

ISMP pleads with those involved in prosecuting and sentencing practitioners, including nurses, to reconsider their course and take actions that will be just and improve, not diminish, medication and patient safety. In our June 2024 article, *Kentucky law prevents practitioners from being criminally charged for medical errors*, we shared that Kentucky Governor Andy Beshear signed a bill (House Bill 159) into law that protects healthcare practitioners from being criminally charged for medical errors, making Kentucky the first state to do so. Under this bill, practitioners, including nurses, pharmacists, and physicians, "shall be immune from criminal liability for any harm or damages alleged to arise from an act or omission relating to the provision of health services" with exceptions for gross negligence and intentional misconduct. We are thankful for the path Kentucky has taken with this new law. We hope similar actions will be taken by other states.

Likewise, ISMP implores organizations, including long-term care facilities, to implement and practice principles of Just Culture, implement medication safety technologies, and address all the system issues in this case, so the error is not repeated. Furthermore, ISMP encourages practitioners to continue to report medication errors, factually and completely, to their internal organization, to ISMP, to state agencies where required, and/or to a patient safety organization (PSO) to facilitate learning about the causes and prevention of medication errors.

In the next issue of this newsletter, we plan to publish a follow-up article (**Part II**) describing how organizations can learn from active failures and evaluate the quality of the choices of individuals using Just Culture principles.

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In addition, we have previously written about the use of negative statements on products. The concern with negative warning statements is that the practitioner may only see the active action and miss the "NOT" in the beginning part of the statement or warning, especially if the vial is turned, the label is obstructed, or the statement is separated on to two lines. Instead, using affirmative statements, such as "FOR TOPICAL USE ONLY" is better than using the negative statement, "NOT FOR PARENTERAL USE."

We have reached out to the US Food and Drug Administration (FDA) and Fresenius Kabi and recommended modifying the packaging of Muri-Lube to a container practitioners would expect for a topical agent, such as a tube or a jar, rather than a vial that resembles an injectable medication. If the package cannot be changed, we recommend that the manufacturer improve the warning statement on the label.

If your organization purchases this product, ensure staff are aware of its appropriate preparation and use. Apply auxiliary labels to these vials and storage areas that clearly indicate the product is for topical use for surgical instrument lubrication. Do not store Muri-Lube next to mineral oil products intended for oral or rectal use. Report close calls that do not reach the patient and actual errors to your organization's error reporting program and to ISMP.

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