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

Another case of nursing criminalization—LTC must improve systems, not blame nurses—Part I

Problem: 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 a hospice nurse in-service 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

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Medication syringes may be mistaken for sodium chloride flush. A nurse removed what she thought was a 10 mL 0.9% sodium chloride flush from a tray in the patient's room to administer during a bedside procedure. Before administration, the nurse read the label and identified that it was a phenylephrine 1,000 mcg/10 mL syringe. The prescriber ordered phenylephrine to be stored at the bedside "just in case" the patient experienced hypotension during the procedure. The hospital purchased the phenylephrine syringe (NDC 73177-0108-03) from STAQ Pharma, a 503B outsourcing facility. The hospital reported that this product previously had a red cap, but now has a white cap, similar to the sodium chloride flushes they purchase (by BD) (**Figure 1**). STAQ Pharma told the hospital that they changed the phenylephrine cap color from red to white due to reported look-alike packaging concerns with their succinylcholine syringe.

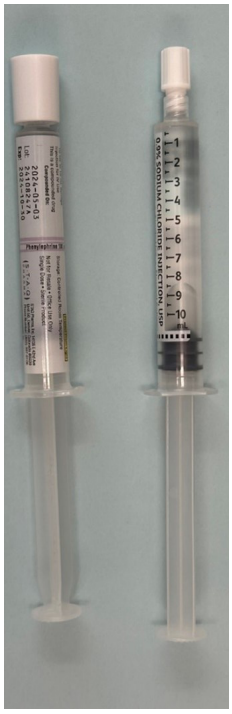

Figure 1. A nurse intending to administer a 0.9% sodium chloride flush (right, BD) almost administered phenylephrine (1,000 mcg/10 mL) that was in a similar looking 10 mL syringe with a white cap (left, STAQ Pharma), which was stored at the bedside prior to a procedure.

In a second case, a hospital recently procured atropine sulfate injection 1 mg/10 mL syringes manufactured by Amneal. A nurse contacted the pharmacy to report that the atropine syringes were nearly indistinguishable from

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information was not communicated to other nurses who had access to this refrigerator (active failure). Medication infusions, especially opioids, were not 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

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the 0.9% sodium chloride flush syringes made by BD (**Figure 2**). The nurse noted that the atropine syringes do not come with an overwrap like the previously purchased atropine product, and the labels on the syringe are incredibly small and easily missed. The nurse was concerned that the atropine syringes could be easily mixed up with the sodium chloride flushes, which are not always scanned prior to administration. In this case, the hospital is planning to purchase atropine from an alternative manufacturer.

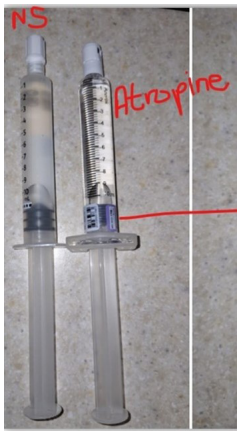

Figure 2. The 0.9% sodium chloride flush syringes by BD (left) look similar to atropine syringes by Amneal (right).

Manufacturers' and outsourcers' product labels and packaging might change so that alone should not be used to identify any medication. This speaks to the importance of reading the product label three times (when obtaining the item, just prior to use, and when discarding it or returning it to stock). Use barcode scanning when receiving, dispensing, filling the automated dispensing cabinet (ADC), and prior to administering any medication, including sodium chloride flush syringes. Communicate with staff when there is a change in product packaging, or when a new product is available, and review the packaging, storage location, and other pertinent information. Consider purchasing a product from a different vendor when problems are recognized. Store look-alike products separately and in a way that keeps their labels visible, and consider the use of auxiliary label warnings.

HIGH-ALERT

Lack of EHR integration between health systems leads to incomplete medication lists. A pharmacist was reviewing the medication list in the electronic health record (EHR) for a patient who was being treated in a transitions of care clinic with new onset numbness and lethargy. Based on the patient's medication list, the pharmacist did not find

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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.

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.

Safe Practice 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

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any medications that could be causing these symptoms. During an interview, the patient told the pharmacist that she had a cancer diagnosis and had received a **TECENTRIQ** (atezolizumab) infusion at an outpatient infusion center, although the medication was not on her medication list. The infusion center was part of a different health system, so the EHR was not integrated with the clinic EHR. Although the pharmacist and medical team determined that atezolizumab was not the cause of the patient's symptoms, they were concerned that the drug was not listed on the medication list. The pharmacist reported that this was not the first time that outpatient infusions (mainly for oncology indications) were omitted from patient medication lists.

A complete and accurate medication list is critical to prevent medication errors during transitions in care. For this reason, the ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice 21*, calls for organizations to obtain the most accurate medication list possible upon patient admission. If you are using external medication history sources (e.g., clinic, outpatient infusion center, outpatient pharmacy), verify the information on the list with the patient or caregiver. Be aware that patients may forget to mention one-time injections or infusions that they receive in an outpatient setting. Add scripting to your medication reconciliation procedures to specifically ask patients about prescription, over-the-counter (including herbals and dietary supplements), and non-enteral medications, including one-time and regularly scheduled infusions and injections.

Epoprostenol reconstituted incorrectly. A prescriber ordered an epoprostenol infusion for a hospitalized patient. The drug is a prostaglandin vasodilator indicated for pulmonary arterial hypertension. The pharmacy had an intravenous workflow management system (IVWMS) with barcode scanning verification, but had not implemented gravimetrics to weigh the product. Therefore, confirmation of the medication volume relied on a manual pharmacist check. The IVWMS had instructions to reconstitute the epoprostenol 1.5 mg vial of lyophilized powder with 5 mL

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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.

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.

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of 0.9% sodium chloride injection, which was to be further diluted with 45 mL of 0.9% sodium chloride injection for a final compounded infusion of epoprostenol 1.5 mg/50 mL. However, the pharmacy technician overlooked the instructions in the IVWMS after reading the vial label which states, "10 mL Single-dose Vial" (**Figure 1**), and reconstituted the vial with 10 mL of 0.9% sodium chloride. The technician followed the next step of the IVWMS instructions to further dilute with 45 mL of 0.9% sodium chloride and prepared a 1.5 mg/55 mL epoprostenol infusion. The incorrect diluent volume and final volume errors were not caught by the verifying pharmacist, and the infusion was administered. The next day, the pharmacist identified the error with the previous day's infusion noting it was 5 mL more than the 50 mL infusion prepared for the current daily dose. The pharmacist notified the prescriber; there was no harm to the patient.

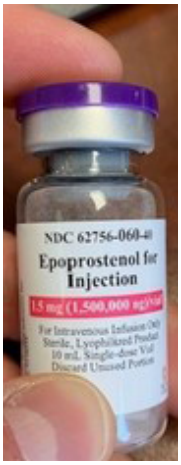

Figure 1. Sun Pharma epoprostenol for injection 1.5 mg vial label states, "10 mL Single-dose Vial," but the vial requires 5 mL of diluent for reconstitution.

We contacted the US Food and Drug Administration (FDA) and the manufacturer and notified them of the potential for reconstituting the vial incorrectly and recommended removing the "10 mL Single-dose Vial" statement from the label, which they are considering. IVWMS are valuable tools that reduce compounding errors, but only when used correctly, including the use of video or images and gravimetrics. Instructions must be built accurately and tested prior to use, and staff must be able to trust and rely on this information to use the system properly. If a discrepancy is identified (i.e., label instructions differ), there should be an escalation process to address the concern. Conduct initial and annual competency assessments for all personnel who use the IVWMS. For more information, refer to the ISMP ***Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology***.

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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.

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 May 16, 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

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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.

Additional ISMP/ECRI Resources*

- *Cultivate Discussions in a Psychologically Safe Workplace – Part I*
- *Psychologically Safe Workplace Enhances Root Cause Analysis Interviews – Part II*
- Aging Services Risk Management
- A Persistent Hazard: Workarounds Continue to Defeat the Purpose of Bar-Coded Medication Administration Systems
- Workarounds with Barcode Medication Administration Systems
- Disclosure of Unanticipated Outcomes in Health Systems
- *Just Culture and Its Critical Link to Patient Safety (Part I)*

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