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

A deeper dive into active failures and accountability using Just Culture principles—Part II

Problem: In our last newsletter, in the main article, *Another case of nursing criminalization – Long-term care facilities must improve systems, not blame nurses - Part I*, we discussed how a series of organizational latent system failures and practitioners' active failures contributed to a patient in a long-term care (LTC) facility receiving an opioid infusion instead of the prescribed antibiotic infusion. A nurse attempted to place a **HYDRO**morphone infusion bag for a hospice patient in the locked compartment of a medication refrigerator. When it would not fit, the nursing supervisor instructed her to place it on a refrigerator shelf. The only other patient on the unit receiving a medication infusion was a post-operative (post-op) patient who was prescribed cef**TAZ**idime. The opioid and antibiotic were subsequently stored next to each other in the refrigerator. A second nurse obtained the antibiotic from the refrigerator to administer to her patient, but the intravenous (IV) cap was missing, so she returned the infusion to the refrigerator. After locating the supplies needed, she removed what she thought was the antibiotic and brought it to the patient's room. The nurse did not realize the medication she selected was the opioid for the resident in hospice care. She attached what she thought was the antibiotic to the post-op patient's IV line. The night shift nurse checked on the patient and noted the pump was beeping and occluded. She turned the pump back on but did not read the infusing medication's label. A few hours later, the patient was found unresponsive, the error was identified, and tragically the patient was not able to be resuscitated.

We called for organizations to learn from this event and take action to improve systems and implement technologies and workflows to minimize patient harm. In **Part II**, we will take a deeper dive into workplace accountability using the principles of Just Culture. We recognize that we do not have 100% of the information necessary to fully evaluate the quality of the choices made by the individuals in this case. However, nothing in the facts presented suggests any of these individuals—the nursing supervisor, the evening shift nurse, nor the night shift nurse—acted with the purpose to cause harm or with the knowledge that the actions taken would lead to harm. The array of compelling, latent system performance-shaping factors discussed in **Part I**—inadequate drug storage, workload, lighting, practice norms—likely set the stage for human errors and at-risk choices, decisions made in good faith without appreciation that these choices represent a substantial and unjustifiable risk.

Beyond implementing necessary system-based risk-reduction strategies as discussed in **Part I**, we suggest managers and leaders look more closely at the active failures—the errors and choices of individuals—to be certain the organizational response is fair, consistent, and just. ISMP interviewed *Barbara Olson*, MS, RN, CPPS, FISMP, Chief Clinical Officer from the Just Culture Company about how this case would be handled through the lens of Just Culture.

ISMP: *While organizational leaders, practitioners, and peers may know they are not supposed to judge based on the outcome (e.g., outcome bias), they often cannot articulate what should be judged. Can you start by explaining why focusing on the outcome is problematic?*

Barbara: Removing outcome bias—the notion that we would punish practitioners for acts that lead to a bad outcome when we would not otherwise punish them—is a very tough thing to do, particularly in the aftermath of a horrific event. Before addressing the question about the problems that arise with outcome bias, let me first say that suspending outcome in a Just Culture does not mean that an organization does not care about the outcome experienced by the patient or the

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SAFETY brief

Magnesium almost administered instead of heparin. A nurse obtained a bag of what she thought was heparin sodium injection (25,000 units/250 mL) from an automated dispensing cabinet (ADC). Right before the nurse hung the bag on the patient's intravenous (IV) pole, she identified it was actually a bag of magnesium sulfate injection (20 g/500 mL). A pharmacy technician mistakenly stocked the magnesium bag in the heparin bin in the ADC. Both products by Hospira are supplied in clear bags with similar red fonts on the labels (**Figure 1**).

Figure 1. Bags of magnesium sulfate 20 g/500 mL (left) and heparin sodium 25,000 units/250 mL (right) look similar.

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Remembering James Reason

We were saddened to learn of the passing of psychologist and researcher James Reason on February 5, 2025. Reason's many significant contributions to patient safety include his "Swiss cheese" model of accident causation. Healthcare practitioners worldwide have relied on this model for risk analysis. ISMP has often referred to it when describing how latent and active failures lead to preventable adverse events. We shared how this model could be applied to the tragic event described in the February 13, 2025 issue, *Another case of nursing criminalization—LTC must improve systems, not blame nurses—Part I.* Healthcare practitioners worldwide will be forever grateful for Professor Reason's profound impact on risk management and accident prevention.

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terrible loss their family will face. The hallmarks of a strong disclosure and resolution process—transparency, disclosure, apology, and acts to optimize resolution with those who have been harmed—are practiced in a Just Culture.

Outcome bias—in a Just Culture model this means reacting based upon the outcome—is also known as "no harm, no foul." This means people may be punished for providing routine care, often in unstable or destabilizing conditions, when errors and "on-the-spot" decisions made in good faith contribute to a tragic outcome. Equally problematic is that people may be rewarded, or their conduct is seen as tolerable, when culpable acts do not immediately result in a bad outcome. This means individuals who are reckless, those who are willing to gamble with the physical or emotional well-being of another, are not punished as long as they "luck out." Their gambles, by coincidence or a downstream catch by another, are ignored because they do not result in harm.

Both trajectories—tolerating acts that should not be tolerated and punishing for errors and at-risk behaviors—compromise healthy workplaces. They are culture killers; things that undermine psychological safety, trust, belonging, and the sense of shared purpose needed to carry out complex care in a safe way. "No harm, no foul" jeopardizes both the duty to avoid preventable harm and the imperative to nurture a healthy workplace.

In the case analyzed in **Part I**, the nurse who hung the opioid infusion in error was terminated within hours of the patient's death. Based on the analysis of active and latent failures provided in the article, outcome bias appears to have been operative.

ISMP: *If leaders don't respond to outcome, what do they judge? Could this case help leaders appreciate the basis of accountability in a Just Culture?*

Barbara: In a Just Culture, leaders learn to assess and label the quality of the choices of individuals. When acts represent *human error* or are undertaken in good faith but with a mistaken belief that they are acceptable (*at-risk behavior*), Just Culture does not apply disciplinary sanction. Instead, leaders strive to understand the circumstances that led to the error or choice, and why the choice may have made sense to the person at the time. Just Culture draws on the disciplines of cognitive psychology and behavioral economics, and recognizes drift, the notion that people cease to see the risks in workarounds or shortcuts they have developed. This is especially true when two values compete. In the LTC case, a nursing supervisor endorsed storing a high-alert, controlled substance in an unlocked compartment of a refrigerator, next to other drugs that looked similar. On the surface, the nursing supervisor's choice seems like a terrible one. In a Just Culture, we would strive to appreciate why the supervisor made this choice, appreciating the overall mission—to deliver the medications—and considering other drug storage options that were reasonably available. Did the nursing supervisor appreciate that her choice opened the possibility of substantial and unjustifiable risk to the safety of the patients she and her team were caring for?

This analysis is helpful because you've identified all deviations, or failures, in the way care was imagined and designed and categorized them as *active* failures or *latent* failures. Active failures are the errors and choices individuals proximate to the event made that contributed to the tragic outcome. Most preventable adverse events, including this one, happen when multiple latent failures in the organization align with, or precipitate, the active failures of individuals. In a Just Culture, we identify all active failures, what the law would term a "breach," and evaluate each one.

For practitioners, the term *breach* is often associated with wrongdoing. But all breaches do not signal bad intent or recklessness; they simply mark a point in time when conduct was not as desired. Some breaches are inadvertent, some are insignificant or justifiable, while others represent poor choices. Just Culture provides a means to differentiate breaches relative to the quality of the choice. This process assures the organizational response is fair, just, and replicable.

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>SAFETY brief

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Upon investigation, the hospital found that a pharmacy technician had scanned the barcode on one of the heparin bags to access and refill the heparin ADC bin (following their pharmacy's restocking process to only scan one product) and then placed a magnesium bag in the heparin bin in error. The products also come in similar-looking boxes that were stored side-by-side in the pharmacy storage area. A second hospital reported a close call after a pharmacist found these same bags mixed together on the pharmacy shelf.

We reached out to the manufacturer to recommend differentiating these infusion bags by making the labels less similar. When pharmacy receives a new product, conduct a review to identify potential risks with the product's design, including look-alike labeling and packaging. If risks are identified, consider purchasing the product (or one product of a problematic pair) from a different manufacturer. Store look-alike products separately, and consider the use of signage or other warnings on the infusion bags and in storage locations.

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. Ensure each individual product is checked. Segregate and secure all medications designated for an individual ADC during transport. Those loading the ADC should use barcode scanning to confirm the accurate placement of medications and confirm each product is in the correct drawer or pocket. Determine if your ADC has the functionality for practitioners to scan each individual product when refilling the ADC, and consider requiring scanning of each medication container/packaging before placing it in the ADC. Review the ISMP ***Guidelines for the Safe Use of Automated Dispensing Cabinets*** (Core Safety Process #6). Employ bedside barcode scanning technology to confirm that medications selected for administration match those included on the patient's medication administration record. Educate nurses to carefully review individual product labels after removing the medication from the ADC, when spiking an IV bag, prior to administration, and when discarding or replacing it in storage.

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ISMP: *Let's talk about the errors and choices of the individuals in this case. Starting with the nursing supervisor, who after learning that a nurse could not secure the* ***HYDRO****morphone infusion in the locked compartment due to space limitations, instructed the nurse to place it on an unsecured shelf in the refrigerator. How can we approach accountability when reviewing the nursing supervisor's decisions?*

Barbara: The nursing supervisor's choice to direct staff to store an infrequently used high-alert medication in an unlocked area of the refrigerator, adjacent to other IV medications in similarly packaged containers, is the first breach we would evaluate. We would ask questions to determine why the nursing supervisor made this choice and what other choices, if any, she contemplated. Foundational to this inquiry is the nursing supervisor's ability to perceive the risk. Did she appreciate the increased risk of inadvertent medication selection this decision set in motion? This would include assessing the individual's knowledge about high-alert drugs and safe storage practices. Running out of storage space in a small refrigerator serving 60 patients is a problem that could reasonably be anticipated, so we would strive to understand the degree to which the organization managed risks associated with medication storage. To what extent did the organization provide resources, guidance, and education to individuals who might need to make "just in time" decisions about medication storage?

A second breach on the part of the nursing supervisor would be the failure to inform other nurses about the atypical storage of this medication or to flag it in a way that would differentiate it from others. Medication safety specialists would see placing a large volume infusion of **HYDRO**morphone, a medication and formulation not normally present in this setting, next to a similar-looking antibiotic bag as akin to placing a hand grenade, in disguise, in the refrigerator. The more important issue here is, "How did the *nursing supervisor* perceive the risk associated with this act? Did *she* see the risk?" Again, asking specific questions in a steady, stepwise fashion assures organizations respond to individuals based on the quality of their choices.

The fact that the nursing supervisor did not act to communicate the risky situation to others could suggest that she did not appreciate the risk. Efforts to prevent a similar mishap from occurring again would focus on safe medication storage, under routine conditions and when conditions destabilize or become unexpectedly risky, as happened when a **HYDRO**morphone infusion bag was brought into the facility. It is possible the nursing supervisor's choices were made in good faith, without appreciation of the substantial risk her directive set in place. It is also possible she saw the choice as justifiable, given the limited options for safer storage that were available.

ISMP: *Let's discuss the choices made by the evening shift nurse who hung the* ***HYDRO****morphone in error.*

Barbara: In the analysis of active failures described in **Part I**, it appears the nurse removed a medication in error from the refrigerator. (She believed she had retrieved the patient's ordered antibiotic but instead had the **HYDRO**morphone in hand.) The nurse had removed the medication from the refrigerator but had to return it when the infusion cap needed for administration was missing. We cannot know with certainty if the medication carried to the bedside the first time was the correct one, nor how much the nurse's standard checking processes were disrupted by the need to stop the normal sequence of care while a critical supply was located. We would strive to understand what the nurse normally did when removing medications and what she did in this case. Equally important, we would learn about the practice norms of her peers, through observations and inquiries. Did this nurse's choices look different from what others routinely did and would recognize as normal while working under similar conditions?

We would say the first breach to be evaluated would be the evening shift nurse's failure to verify the medication in hand at the point of retrieval. It is possible the nurse misread the medication label one

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Worth repeating...

Patient developed methemoglobinemia after administration of Hurricaine spray

A practitioner administered **HURRICAINE** (benzocaine) spray 20% to a patient's throat prior to nasogastric tube placement to ease discomfort during the procedure. The patient became acutely hypoxic and developed methemoglobinemia requiring methylene blue to reverse the effects. Methemoglobinemia is a serious and potentially fatal adverse effect associated with topical benzocaine products. The risk increases with the number and duration of sprays administered outside of the prescribing information, which states that the dosage should be a half second spray, which may be repeated once. However, from a human factors perspective, no one can estimate fractions of seconds reliably or visualize how thick or widespread the actual deposition of the spray really is. The hospital reported that it is too easy for practitioners to unknowingly exceed the dose.

ISMP first warned about topical anesthetic-induced methemoglobinemia in our June 4, 1997 newsletter, and we have written about it many times since. But it is still a risk, so we think it is ***Worth* repeating**.

Alert practitioners and patients to the proper dosing of benzocaine-containing topical anesthetics and the possibility of methemoglobinemia when these products are used. These drugs should not be used in high doses, especially in patients who may be predisposed to methemoglobinemia. Predisposing factors include age (e.g., older patients with cardiac problems may be sensitive to even low methemoglobin levels, it should not be used in children less than 2 years old); the status of the area that is being sprayed (e.g., inflamed areas absorb more drug); concomitant use of other drugs which have been implicated in causing methemoglobinemia (e.g., phenazopyridine, sulfamethoxazole, dapsone, nitroglycerin); and the genetic make-up of the patient (e.g., autosomal recessive variants in the CYB5R3 gene, autosomal dominant variants in the globin genes).[1] Patients who may receive

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or both times she removed the IV bag from the refrigerator. That is, she made an error—her brain did not accurately appreciate the data transmitted after visual inspection occurred. It is also possible the nurse did not visually inspect the label.

A second breach by the evening shift nurse would be a failure to accurately verify the medication in hand was the intended one at the point of administration. A Just Culture analysis would consider factors that could impact the accuracy of a visual check and the nurse's ability to detect and correct the original error. While we lack sufficient data to fully assess this breach, the matching doses of the two medications (1,250 mg), delivery methods (IV bags), and storage (both bags would be cold to the touch) could be contributory. Also, the deliberate low lighting at the bedside would be investigated. We would want to know if nurses routinely perform visual checks of IV medications under low lighting. Are the bedside conditions described in this case typical? Were the steps taken by the nurse at the bedside to verify the accuracy of the medication commensurate with what other nurses do and what the organization expects or tolerates?

The absence of barcode scanning of IV medications in the facility and the broken scanner (that was intended to be used when nurses administered non-injectable medications) are also noteworthy. This suggests the organization was willing to rely solely on human performance to deliver complex care. In these cases, leaders may hope or expect the performance of nurses to be flawless, something science tells us is not possible. It's a faulty belief that often contributes to leadership decisions that forgo the opportunity to deploy and manage technologies that would more reliably detect and correct predictable human flaws. The degree to which leaders of the facility appreciated the increased risk of patient harm resulting from these choices would also be considered in a Just Culture.

ISMP: *How would Just Culture evaluate the choices of the night shift nurse who assumed care of the patient receiving an IV infusion and later responded to a pump alert and restarted the infusion?*

Barbara: We would evaluate the choices of the night shift nurse similarly, identifying and evaluating any deviations from expected care. During the nurse's initial patient assessment, she did not detect the error made on the evening shift. It is possible she did not visually inspect and confirm the medication infusing was the ordered one. It is also possible she did not read the label accurately. The nurse's first-person account would help us understand what happened and why.

Relative to how the organization managed the risk, we would strive to understand the policy expectations related to change of shift handoffs for residents who have medications infusing via a pump and how behavioral norms reflected these. It does not appear bedside shift report or a nursing handoff at the bedside occurred in this case. This is a practice that allows errors to be detected and corrected but is not universally deployed in all organizations or care settings.

At the point when care is transferred from one nurse to another, we would want to understand organizational expectations related to the nature and timing of inspections of medications infusing via a pump. This would include pump settings, tubing connections, visual inspection of medication and tubing labels, and the condition of the insertion site. A Just Culture analysis would also consider the degree to which nurses adhered to this policy guidance and any circumstances or conditions that prevented them from doing so.

The nurse's second breach—troubleshooting and restarting the occluded infusion pump without detecting the original error—follows the same process. The information available today is insufficient to determine whether a visual inspection of the medication label occurred or whether the nurse's visual inspection was faulty. As with all breaches, Just Culture would determine the degree to which this nurse's actions differed from organizational expectations, her normal practice, and how the nurse's actions reflected the norms of her peers on the night of this event.

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topical anesthetics should be asked about their past medical history to determine if any of these risk factors are present. If cyanosis develops after the application of topical anesthetics, methemoglobinemia should be considered as a cause.

Evaluate the use of benzocaine products in your organization, including Hurricaine spray. Consider using alternative topical anesthetics such as a unit dose non-aerosol spray (e.g., **HURRICAINE ONE**) or the use of a benzocaine spray that comes packaged in a metered-dose formulation (e.g., **TOPEX**) to make it easier to control the amount of drug being applied. However, even a metered-dose product will not prevent an overdose if multiple sprays are used. Build clinical decision support (CDS) in the electronic health record (EHR) when prescribing topical anesthetics including Hurricaine spray (e.g., spray for a half second, dose range checking [DRC] alert to avoid in patients less than 2 years old). Create an institutional protocol to treat methemoglobinemia that includes stopping the agent precipitating methemoglobinemia, and when to initiate intravenous (IV) hydration and oxygen supplementation.[1] Build an order set in the EHR with treatment options (e.g., methylene blue, ascorbic acid, blood transfusion, hemodialysis). Ensure reversal agents are stored in automated dispensing cabinets (ADCs) on units where benzocaine spray is administered (e.g., cardiology, emergency department, operating room). Use CDS when prescribing methylene blue including guidance when methylene blue may be contraindicated or precautions are warranted (e.g., avoid in patients with glucose-6-phosphate dehydrogenase [G6PD] deficiency; screen for the possibility of precipitating serotonin syndrome in individuals receiving selective serotonin reuptake inhibitors; use with caution in pregnant women, patients with renal failure, and in anesthetized patients).[1] Consider applying auxiliary labels to topical anesthetic spray bottles to alert staff to avoid excessive use.

Reference

1. Iolascon A, Bianchi P, Andolfo I, et al. Recommendations for diagnosis and treatment of methemoglobinemia. *Am J Hematol.* 2021;96(12):1666-78.

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ISMP: *Why is the question "How was the organization managing the risk?" so important if Just Culture is about individual accountability?*

Barbara: The outcomes an organization produces are the result of two distinct inputs: the design of the system and the errors and choices of people operating within that system. Individual accountability, as you point out, is about evaluating errors and choices made by people. The identification of breaches—the undesirable errors, choices, and missteps that routinely occur in complex trajectories of care—is how a Just Culture analysis begins whether the choice results in harm or not.

Our focus on the system allows organizations to determine the degree to which they are accepting risk along a given trajectory of care. Systems are weakly designed when it's easy for errors to be set in motion and where there's limited opportunity for critical missteps to be detected and corrected. Systems that rely on human performance without safety nets are not reliable. This does not mean that practitioners who work in these systems are less caring or less competent than other healthcare workers. It simply means they work under conditions with more latencies—conditions more likely to give rise to a highly undesirable outcome than better-designed, more error-resistant systems.

In thinking about the breaches attributed to the nursing supervisor and the two nurses who provided direct patient care in this case, it becomes clear that the likelihood of preventing a recurrence is rooted in the system response. Irrespective of the organizational response to the nurse in this case—just or unjust—there will always be tired practitioners and people staying over to provide care when a colleague is tardy; people who will misread, incompletely read, or skip reading important information. People who will make choices in good faith to address seemingly simple, immediate problems that confer substantial and unjustifiable risk.

Organizations that intend to reduce the likelihood of a tragedy like this one will laser-focus on hardwiring processes and technologies that more reliably prevent, detect, and correct human flaws. Focusing on the system allows organizations to see how harm can be prevented. This remains true even if the predictable, active failures you've identified were to happen again. This is how Just Culture helps organizations move to a more proactive way of thinking about and responding to risk as well as assuring a steady, predictable, just response to individuals.

ISMP: *What could have happened had Just Culture been applied in this case?*

Barbara: In as much as we don't have a complete analysis, it is impossible to say what the specific organizational response to each of the three nurses would have been if Just Culture had been applied. A Just Culture investigation would have demanded a complete investigation, with errors and choices (active failures) and system-shaping factors (latent conditions) fully identified and vetted. Nothing in this case suggests conduct that would align with a decision to terminate a nurse "on-the-spot."

When organizations practice Just Culture, they have an opportunity to build psychological safety among their team. This occurs when it becomes expected to speak up to disclose one's errors, workarounds, and the choices that could have, but did not, lead to harm. To nurture the desirable behavior of "speaking up," organizations must be clear about what's culpable and what's not. When practitioners know they will not be punished for being human (making a mistake) or being in the wrong place at the wrong time, it becomes safe to disclose circumstances and conditions, things often only known to people who perform complex tasks. The opportunities to learn and improve become richer. These positive findings are reflected in culture of safety and employee engagement surveys. And when people proximate to tragic events are supported—through second victim support or other employee assistance programs—the organization sends a powerful message about their commitment to practitioners' well-being.

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Special Announcements

Virtual MSI workshop

Join us for our first ***ISMP Medication Safety Intensive (MSI)*** workshop in 2025. This unique 2-day virtual program will be held **March 13 and 14, 2025**. For more information and to register, please click here.

ISMP announces 2025 Just Culture Scholarship winners

Congratulations to this year's ***Judy Smetzer Just Culture Champion Scholarship*** recipients! The scholarships are provided by ISMP in cooperation with The Just Culture Company and include enrollment in a certification course. This year, three outstanding leaders were selected: **Jamie Flower**, RN, MS; **Renee Miller**, RN, MSN, CPHQ, CPPS; and **Jennifer Wright**. In addition to the full scholarship recipients, six other healthcare leaders will receive a partial scholarship. For more on the scholarship and winners, visit: ISMP Announces 2025 Just Culture Scholarship Recipients.

Ensure medication safety with PN

Will you be at the ASPEN 2025 Nutrition Science and Practice Conference? Attend our symposium on **March 25, 2025**, and learn about risks and error-prevention strategies related to compounding parenteral nutrition (PN) as well as the role of multi-chamber bags and alternative lipids. For more information and to pre-register, click here.

ISMP Symposia: Applying Best Practices for Injection Safety

Join us this spring to learn about vulnerabilities in the preparation and administration of intravenous (IV) medications and innovative solutions for preventing errors! Our experts will compare ready-to-administer (RTA) products and traditional methods, discuss how to enhance the safety of bedside injection procedures, and provide practical strategies for better patient outcomes. Click the links below for more information:

- **April 3, 2025:** TSHP Annual Seminar 2025 in Irving, TX
- **April 5, 2025:** NYSCHP 2025 Annual Assembly in Saratoga Springs, NY

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Relative to the nurse who was fired, surrendered her license, and was later charged with second-degree reckless manslaughter, I would say that the application of Just Culture would have ensured that she, and the other on-duty nurses whose choices would have been evaluated, were judged based on the quality of their choices. System-induced factors and the degree to which the organization managed these predictable risks would have been considered.

The tenure of the nurse and her willingness to stay late and to "double-back" for the morning shift suggests a person who was a hard worker, someone who contributed to the organization's mission and who cared about her patients. The number of destabilizers—things we might have called curveballs if they hadn't led to the death of a patient—the nurse faced while completing routine duties are compelling. Nevertheless, had her choices been found to be reckless, undertaken with knowledge that they would lead to harm, or with purpose to cause harm, the nurse would have faced the possibility of disciplinary sanction.

One final thought about what would have happened had Just Culture been applied in this case. The organization, and perhaps the State, could have set aside any false notion that by removing one individual, the safety of other residents in the facility or in similarly run facilities had been improved. And with that knowledge, leaders could have gotten to work learning and improving the parts of the system that could, indeed, make patients safer.

Danziten and Tasigna are NOT interchangeable nilotinib formulations

On November 14, 2024, Azurity announced the approval of **DANZITEN** (nilotinib tartrate), indicated for adults with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in the chronic phase (CP) and accelerated phase (AP) of Ph+ CML resistant to or intolerant to prior therapy that included imatinib. Danziten is available in blister packs of 71 mg or 95 mg tablets, which must be swallowed whole and may be taken with or without food. Danziten is NOT approved for pediatric use.

TASIGNA (nilotinib hydrochloride), manufactured by Novartis, is approved for the same indications as Danziten but for both adult *and* pediatric patients 1 year of age and older. Tasigna is available in different strengths—bottles containing 50 mg capsules or blister packs containing 150 mg or 200 mg capsules—and a different formulation and salt form than Danziten. Due to Tasigna's increased bioavailability when taken with food, it has a *boxed warning* to avoid food 2 hours before and 1 hour after taking the medication, or it may significantly prolong the QT interval. However, according to the Tasigna prescribing information, the capsules may be opened and dispersed in one teaspoon of applesauce. Both products have a *boxed warning* for QT prolongation and sudden death with specific monitoring recommendations and the need to avoid additional QT prolonging agents or strong CYP3A4 inhibitors.

It is critical to note that these products are not interchangeable and have very different dosing recommendations (**Table 1**). Because of this, there is a risk of under- or overdose and patient harm if the wrong product is selected for the ordered dosing regimen. The risk of a selection error may be increased

Table 1. Recommended adult dosing for Danziten and Tasigna.

Approved indications for adults	Danziten dosage (with or without food) *	Tasigna dosage (on an empty stomach) *
Newly diagnosed Ph+ CML-CP	142 mg every twelve hours	300 mg every twelve hours
Resistant or intolerant Ph+ CML-CP and CML-AP	190 mg every twelve hours	400 mg every twelve hours

*Doses may be modified or reduced based on organ function, cardiac monitoring, laboratory values, or concomitant medications.

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if practitioners order the drug only by the generic name without the salt form. For example, if the prescribed nilotinib dose is 300 mg every twelve hours by mouth, there may be some who think they can use three of the Danziten 95 mg tablets, round the dosage strength, and get close enough to the 300 mg dose. This would result in an overdose of Danziten.

ISMP has notified the US Food and Drug Administration (FDA) of these concerns and recommends drug information vendors and electronic health record (EHR) vendors state that these products are not interchangeable. Organizations should evaluate if it is possible to have only one of these products on the formulary. If both products are available, review how these medications are ordered in your EHR, and if possible, ensure that a specific brand name is part of the selection process. Build clinical decision support with dose range checking and warnings (e.g., avoid food 2 hours before and 1 hour after administering Tasigna), and ensure order sentences are automatically linked to the appropriate formulation. Store these products separately and use barcode scanning when receiving, dispensing, and prior to administration. Educate staff and patients that these products are not interchangeable and to confirm it is the correct brand product prior to dispensing and administration. During patient education, explain whether it should be taken with or without food, and reinforce the correct dosing instructions, especially if the patient is directed to take a reduced or alternate dose than what is included in the blister pack.

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