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Educating the Healthcare Community About Safe Medication Practices

Using Just Culture principles to look more closely at active failures and accountability—Part II

In our last newsletter, in the main article, *Another nurse criminally charged—LTC 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 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.

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what's in a Name?

The "-estrant" drug stem name

Medications with the suffix "-estrant" belong to a class of drugs known as estrogen receptor antagonists or antiestrogens. These medications compete with endogenous estrogens by blocking estrogen receptors which inhibit estrogen from promoting cell growth and proliferation. They are used alone or in combination with other drugs to treat women or men with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer.

Currently, there are only two single-agent estrogen receptor antagonists with the "-estrant" stem that are approved by the US Food and Drug Administration (FDA) for use in the United States (**Table 1**). It should be noted that there are other drugs in this class (i.e., tamoxifen) that do not share the "-estrant" stem and are not going to be discussed here.

Table 1. List of estrogen receptor antagonists available in the United States.

Generic Name	Brand Name
elacestrant	**ORSERDU**
fulvestrant	**FASLODEX**

Fulvestrant and elacestrant differ in their available formulations, dosing, and administration. Fulvestrant is available as an injection and comes in a prefilled syringe (250 mg/5 mL). A dose of 500 mg is administered intramuscularly on days 1, 15, 29, and once monthly thereafter. This requires the healthcare provider to administer two 5 mL injections, one into each buttock, slowly over 1 to 2 minutes per injection. Common side effects from fulvestrant include injection site pain, bone pain, hot flashes, and an increased risk of bleeding. The syringes should be stored in their original container, protected from light, and under refrigeration.

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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.

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?*

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what's in a Name?

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Elacestrant is available as an oral tablet that is taken once daily. It should be taken with food to decrease gastrointestinal side effects, such as nausea and vomiting. The dose can be reduced if adverse reactions occur or if it is not tolerated. It should also be taken at the same time each day and should be swallowed whole; it should not be chewed, crushed, or split. If a tablet is broken, cracked, or appears damaged, it should not be taken. Elacestrant has been shown to cause hypercholesterolemia and hypertriglyceridemia; lipid profiles should be monitored prior to starting therapy and periodically thereafter.

SAFETY wires

Possible confusion between Neffy and Narcan nasal sprays. On August 9, 2024, the US Food and Drug Administration (FDA) approved **NEFFY** (**EPINEPH**rine), the first nasal spray for the emergency treatment of anaphylaxis (ARS Pharmaceuticals). A physician reported concerns about the potential for confusion between Neffy nasal spray and **NARCAN** (naloxone) nasal spray, which is used for opioid overdose reversal.

Figure 1. Each single-dose Neffy nasal spray device contains 2 mg of **EPINEPH**rine. It is available in a carton containing two packaged devices.

Neffy is available by prescription only and comes in a carton containing two blister-packaged devices of **EPINEPH**rine 2 mg (2 mg/0.1 mL) (**Figure 1**). It is indicated for adults and children who weigh greater than or equal to 30 kg. Each device provides a single dose of 2 mg of **EPINEPH**rine administered into one nostril. In the absence of clinical improvement after the initial dose, or if symptoms continue to get worse after 5 minutes, a second dose of Neffy may be administered into the same nostril with the second nasal spray device. Patients may need to seek emergency

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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 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.

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medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.

Narcan also comes as a single-dose nasal spray. It is given for opioid overdose reversal for patients of all ages, including infants, children, and adults. If the patient does not respond, or responds and then relapses into respiratory depression, additional doses may be given every 2 to 3 minutes, using a new device for each dose, until emergency medical assistance arrives. Various brand and generic naloxone nasal sprays are available, including over-the-counter (OTC) and prescription products in several strengths (e.g., 3 mg, 4 mg, 8 mg).

Neffy and Narcan come in similar nasal spray devices, and their brand (and generic naloxone) names start with the letter "n." Neffy and Narcan nasal sprays are used for different life-threatening indications (i.e., anaphylaxis versus opioid overdose reversal), so a mix-up could lead to a delay in treatment and patient harm. Unlike the Narcan carton label which, depending on the manufacturer, may include warning statements such as "Use NARCAN Nasal Spray for known or suspected opioid overdose in adults and children," or "Emergency Treatment of Opioid Overdose," the Neffy label does not mention that it is for the treatment of anaphylaxis.

We have reached out to the US Food and Drug Administration (FDA) to notify them of the potential for a mix-up between Neffy and Narcan nasal sprays. If your organization includes either Narcan or Neffy nasal sprays on the formulary, ensure order sentences and discharge prescriptions include the indication. Communicate with staff about the availability of Neffy, and review the packaging, storage location, and other pertinent information. Use barcode scanning when receiving, dispensing, filling the automated dispensing cabinet (ADC), and prior to administration of any medication. Store look-alike products separately. If there is a plan to discharge a patient with a prescription for one of these nasal sprays, educate them about the

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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.

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.

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indication and proper use, and to always read the medication name on the label before use. This is especially important if the patient/family will have both Neffy and Narcan nasal sprays available in their home. Educate them about the importance of storing them separately. Remind patients not to store these in cars that are subject to freezing or excessively high temperatures.

Entire IV insulin infusion administered at fluid rate. A prescriber ordered a 100 unit/100 mL **MYXREDLIN** (insulin) infusion for a patient with diabetic ketoacidosis (DKA). The prescriber also ordered a 0.9% sodium chloride infusion for the patient at a rate of 500 mL/hour as part of the DKA protocol. The nurse labeled both intravenous (IV) lines and programmed each infusion using the smart pump drug library. A second nurse checked the pump programming and labeled lines and the infusions were initiated. Neither nurse traced the lines from the medication/infusion bags, through the pump channels, to the patient or vice versa.

Shortly after, the pump alarmed to signal that the sodium chloride infusion was completed. The nurse returned to the patient's room and found that the insulin infusion had been placed in the pump channel for sodium chloride and the sodium chloride had been placed in the channel intended for the insulin infusion.

The patient received 100 units of insulin in less than an hour. The nurse notified the prescriber and monitored the patient's blood glucose, which was less than 70 mg/dL. The prescriber ordered a dextrose bolus and infusion, and transferred the patient to the intensive care unit (ICU) for monitoring. Fortunately, glucose levels soon returned to normal, and the patient was transferred from ICU to an inpatient unit within 24 hours.

When infusions are started, reconnected, or changed (i.e., new bag/bottle/syringe), trace the tubing by hand from the solution container through the pump channel, and then to the entry site on the patient (or vice versa) to ensure the proper infusion

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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 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. 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.

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.

If Just Culture had 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 had been improved. With that knowledge, leaders could have gotten to work learning and improving the parts of the system that could, indeed, make patients safer.

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is set at the intended rate (pump/channel) and is being administered via the correct route. Confirm the infusion dose and rate are programmed accurately in the pump and verify that the order in the medication administration record (MAR) and the medication label match what is programmed in the pump when performing line tracing and before starting the infusion. During orientation and ongoing training, review the organization's policy and stress the need to trace infusion lines. Practice tracing lines during periodic simulations. Share impactful stories and recognize staff for good catches, including those caught through tracing the infusion line.

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