

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

The differences between human error, at-risk behavior, and reckless behavior are key to a Just Culture

Do you believe your organization operates within a Just Culture? We have asked this question many times while working collaboratively with healthcare organizations and professionals. It is not an easy question to answer. Yet, we often receive hasty affirmative responses assuring us that the organization has, indeed, established a Just Culture, when our direct observations contradict such attestations. One of the key areas of misunderstanding is deeply entangled in how organizations define, differentiate, and respond to human error, at-risk behavior, and reckless behavior, which are the three anticipated behaviors that can lead to risk and patient harm. While organizational leaders may be able to clearly articulate technically correct definitions for these three behaviors, a different story often unfolds in practice and through organizational policies and procedures, particularly human resource-related policies and procedures that establish an unjust disciplinary process that fails to support learning, safety, and improvement.

For example, vague terms, such as “bad behavior” or “poor behavioral choices,” are often used in policies to define the conditions requiring disciplinary action, and all “knowing violations” of policies and procedures are considered reckless behavior while most are likely at-risk behaviors. Thus, if individuals knowingly disregard any policies, procedures, or the usual standard of practice, it frequently results in disciplinary action, even if the breach is widespread due to common system failures or was pursued in good faith due to a mistaken belief that the risk was justified or insignificant.

In a Just Culture, what are the differences between human error, at-risk behavior, and reckless behavior? How do organizations determine if an individual's behavior represents human error, at-risk behavior, or reckless behavior? How are the responses to each type of behavior different? To answer these questions, we provide some basic information about the three types of behavior.

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Table 1. Primary differences between at-risk and reckless behavior

At-Risk Behavior	Reckless Behavior
Perception	
Does not see the risk OR mistakenly believes the risk is insignificant or justified	Always perceives the risk AND understands that the risk is substantial and not justified
Behavior is often the norm within groups	Knows the behavior is not the norm within groups
Risk monitor does not alarm—mistakenly believes the choice is safe	Risk monitor alarms—knows the choice is unsafe
Does not consciously disregard what is known to be a substantial and unjustifiable RISK	Makes a conscious choice to disregard the substantial and unjustifiable RISK
Motivation	
Behavioral choice is often patient-, colleague-, or organization-centric (desire to help others)	Behavioral choice is often self-centered (desire to help oneself)
Puts patients, colleagues, organization first	Puts own needs ahead of others
Decision has social utility	Decision has no social utility

what's in a Name?

The “-fentanyl” drug stem name

Medications with a “-fentanyl” drug name stem are opioid analgesics (anilidopiperidine class) that are primarily used to treat severe pain or as a component of anesthesia by working as an agonist at the opioid receptor. There are four drugs in this class, three of which are derivatives of fenta**NYL** (Table 1). All are schedule II controlled substances and available as a solution for

Table 1. List of “-fentanyl” medications in the US

Generic	Brand
fenta NYL	ACTIQ DURAGESIC FENTORA LAZANDA SUBSYS
remifentanyl	ULTIVA
SUF entanyl	DSUVIA
alfentanyl	none

parenteral administration. Fenta**NYL** is also available as a transdermal patch, sublingual liquid, nasal solution, and a buccal tablet or lozenge (on a handle). **SUF**entanyl is also available as a sublingual tablet.

While “-fentanyl” drugs are used primarily to treat acute pain, fenta**NYL** transdermal is the only formulation used to treat chronic pain in opioid-tolerant patients who require daily, around-the-clock opioids for which other treatments are inadequate. Sublingual **SUF**entanyl, which is used for acute pain severe enough to require an opioid analgesic for which alternative treatments are inadequate, can only be administered by a healthcare provider in a healthcare setting for a maximum of 72 hours. The injectable formulations of fenta**NYL** and **SUF**entanyl are also used epidurally (with bupivacaine and/or **EPINE**phrine) as analgesia during labor and delivery or as a surgical analgesic given intravenously. The general anesthetics

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Human error

Definition. Human error is an inevitable, unpredictable, and unintentional failure in the way we perceive, think, or behave. It is not a behavioral choice—we do NOT choose to make errors, but we are all fallible.

Examples. Most errors can be classified as either an execution failure, which is a skill-based mistake, or a planning failure, which is either a rule-based or knowledge-based mistake. Mental slips and lapses are considered skill-based mistakes. An example of a mental slip is transposing the numbers of a medication dose. Omissions or forgetting to take certain steps in a process are examples of mental lapses. Incorrectly programming a new infusion pump following the directions used for an older pump is an example of a rule-based mistake. Giving an excessive dose of medication due to a knowledge deficit about a patient's recent weight loss is an example of a knowledge-based mistake.

Causes. Human error is either endogenous (random human error), which arises within an individual from a random and unpredictable cognitive event, or exogenous (system-based human error), in which some feature of the environment contributes to a failure in cognitive processes. The risk of endogenous errors is increased by negative personal performance shaping factors such as anxiety and stress, fatigue, preoccupation and distractibility, fear and dread, sensory deficits, and other psychosocial factors. The risk of exogenous errors is increased by negative system or environmental performance shaping factors, such as low lighting, excessive noise levels, interruptions and physical distractions, fatiguing staffing patterns, technology glitches, the absence of job aids (e.g., calculators, labels), and unlimited access to medications. As negative performance shaping factors increase in scope and intensity, the probability of human error increases significantly.

Perceptual biases also contribute to both endogenous and exogenous errors. Examples of perceptual biases include confirmation bias (seeing what you believe), change blindness (inability to detect changes in plain view), and inattention blindness (inability to see information because attention is focused elsewhere). Cognitive biases may influence how individuals respond to an error. Examples of cognitive biases include hindsight bias (tendency to see past events as predictable), normalcy bias (it will never happen here), and severity bias (tendency to base the severity of the response on the outcome).

Management. Since human errors are inevitable, they are best managed within a Just Culture through system redesign to make the system human error-proof or error-resistant. System redesign often requires the integration of high-leverage strategies (e.g., forcing functions, fail-safes, barriers, automation and technology, standardization and simplification) that increase system reliability and reduce or eliminate the risk of errors and/or patient harm. Discipline, including counseling, is not warranted or effective to address human error because erring individuals did not intend the action or any undesirable outcome that resulted. In a Just Culture, the only just option is to console the individual who made the error and to redesign systems to prevent future errors.

Furthermore, the potential or actual severity of the error outcome should play no role in determining how individuals are treated, even when patients are harmed. Individuals should know that they will be treated fairly when they report their mistakes, and that they will be accountable for the quality of their choices, not the human error itself or the severity of its outcome. Also, a severity bias often results in a “no harm, no foul” approach, with missed opportunities to redesign systems and console individuals for human error.

At-risk behavior

Definition. At-risk behaviors are different from human errors. They are behavioral choices that are made when individuals have lost the perception of risk associated with the choice or mistakenly believe the risk to be insignificant or justified.

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alfentanil and remifentanil are only indicated to induce and maintain anesthesia.

All of these drugs have a high risk of addiction, abuse, and misuse. The package inserts have several warnings, including respiratory depression and an increased risk of profound sedation, respiratory depression, coma, and death from concomitant use with benzodiazepines (e.g., diazepam, LORazepam) or other central nervous system (CNS) depressants. Both fentanyl and sufentanil carry a boxed warning for serious, life-threatening, or fatal respiratory depression. The transdermal, sublingual, and buccal formulations are part of a Risk Evaluation and Mitigation Strategy (REMS) prescribing program to reduce the risk of respiratory depression from accidental exposure. Recently, the US Food and Drug Administration (FDA) issued a warning to the manufacturer of DSUIVA (sufentanil sublingual tablet) regarding misleading marketing materials which down-play the strong limitations for use and administration (www.ismp.org/ext/649).

Common adverse effects of “-fentanyl” drugs include headache, nausea, vomiting, dizziness, hypotension, fatigue/sedation, constipation, and diarrhea. Alfentanil and remifentanil carry a greater risk of neuromuscular side effects, such as muscle rigidity. Buccal formulations may also cause mouth tingling. It is important to note that all patients react differently to opioid medications. Specific prescribing, administration, and monitoring guidelines need to be established for these medications.

SAFETY wires



Dispense unit dose syringes using the most appropriate concentration.

A wrong route error happened after an order for 2 mg of oral morphine was dispensed using a commercially available 15 mL bottle containing a 100 mg/5 mL (20 mg/mL) oral solution. The oral syringe that accompanies the 20 mg/mL morphine solution bottle has a mark for 5 mg as the lowest dose on the syringe scale (Figure 1, page 3). Because the 2 mg (0.1 mL) dose was not measurable using the provided syringe, a nurse prepared

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Why we drift. It is human nature to drift away from strict procedural compliance and to develop unsafe habits for which we fail to see the risk. Human behavior runs counter to safety because the rewards for risk taking (e.g., saved time) are often immediate and positive, while possible adverse outcomes (e.g., patient harm) are often delayed and remote. As a result, even the most educated and careful individuals will learn to master dangerous shortcuts, particularly when faced with an unanticipated system problem (e.g., technology glitches, time urgency). Over time, the risk associated with these behaviors fades and the entire culture becomes tolerant to these risks. Individuals are not choosing to put patients in harm's way; instead, they feel they are still acting safely. In fact, the more experienced you are at what you do, the less likely you are to recognize that you are in a risky situation when engaging in at-risk behavior.

If you are an experienced nurse, you may not think twice about programming an infusion pump outside the drug library, preparing intravenous (IV) admixtures instead of waiting for pharmacy to dispense them, and removing medications via override from an automated dispensing cabinet (ADC) outside of an emergency. Successful outcomes foster continuance and tolerance to the risks, particularly when colleagues look the other way or begin imitating the at-risk behavior.

Upside down consequences. When organizational tolerance to risk is high, safe behavioral choices may actually invoke criticism, and at-risk behaviors may invoke rewards. For example, a nurse who takes longer to administer medications may be criticized, even if the additional time is attributed to safe practice habits and patient education. But a nurse who can handle six new admissions during a shift may be admired, and others may follow her example, even if dangerous shortcuts may have been taken to accomplish the work. In fact, shortcuts like these could even be labeled as “efficient” behavior.

Underlying system causes. Most at-risk behaviors are precipitated by large and small system failures that individuals must work around, often daily, to get the job done. A medication needed for a patient is missing on the unit; access to the ADC is crowded and time-consuming; the new barcode scanner has a high rate of scanning failures. The list of system failures is varied and long, often making it difficult or impossible to execute tasks as designed. We expect individuals to use critical thinking skills to navigate around systems or processes when they do not work well in the moment, and we praise and reward individuals when they do this. Thus, individuals are often satisfied, even proud, with their abilities to deliver patient care despite obstacles, even when it means taking shortcuts, breaching procedures, or working around the system as designed. Unfortunately, individuals responding to dysfunctional systems by failing to follow a policy or procedure are often inappropriately disciplined, especially if an error happens.

Subconscious decisions and silent risk monitor. Another reason that humans drift is that we are illogical decision makers. The human brain is capable of subconscious and conscious reasoning. Our subconscious brain manages about 80% of all human endeavors. It operates automatically and quickly, eager to solve problems but not unhappy when wrong—it comes with the territory of making decisions on the fly (Marx D. *Dave's subs: a novel story about workplace accountability*. Plano, TX: By Your Side Studios; 2015). The conscious brain operates very slowly to solve more complex problems, deferring to the subconscious brain for all but the most complex problems. Thus, humans make most decisions subconsciously, formulating choices they do not even realize they are making. Humans also have an internal risk monitor running in the background of both our conscious and subconscious brain, quietly watching our world and constantly looking for hazards. If the risk monitor becomes aware of a serious hazard, a little voice knocks on the door of our conscious thoughts and lets us know we are in danger. Keep in mind, only the conscious brain is alerted if the risk monitor alarms. When individuals engage in at-risk behaviors, their internal risk monitor is silent—they do not see the hazard created by their behavioral choice, or they mistakenly believe it is insignificant or justified.

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the dose using a 1 mL parenteral syringe. That allowed for the accidental connection of the parenteral syringe to the patient's intravenous (IV) line, and unfortunately, the oral solution was administered IV.

The practitioner who reported this event linked the error to not having a way to measure and administer doses under 5 mg using the accompanying oral syringe. He asked ISMP to advocate for adding “smaller markings” on the syringe. However, morphine 20 mg/mL solution is intended only for opioid-tolerant patients who would be receiving doses in line with the syringe markings or greater. For lower doses, an oral solution is available in a 2 mg/mL (10 mg/5 mL) concentration. Thus, we will not be advocating for changes to the morphine 20 mg/mL syringes.



Figure 1. The lowest dose marking is 5 mg on the oral syringe that accompanies the morphine oral solution 100 mg/5 mL (20 mg/mL).

Although lack of a smaller dose marking on the syringe scale may have contributed to the nurse preparing the dose with a parenteral syringe, the way to minimize the risk of an error and patient harm is to use the most appropriate concentration of oral solution available. The hospital pharmacy investigated obtaining the lower concentration from their wholesaler. More to the point, nurses should receive patient-specific, ready-to-administer doses in labeled oral or ENFit syringes from the pharmacy, rather than a 15 mL bottle that contains 150 doses (2 mg each). The hospital is adding an “ORAL USE ONLY” comment on the medication administration record. Barcode scanning could verify the drug and concentration and prevent errors, particularly if both concentrations are available.

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Management of at-risk behaviors. To effectively manage at-risk behaviors, honesty about our propensity to drift is required. While it is one thing to publicly admit that individuals make errors, it is wholly another to admit that individuals frequently choose to violate rules, even if they are working around system failures and are rewarded for their “effective” behavior. Admitting that at-risk behaviors exist is messy and taboo, but it is the first crucial step in effectively and justly managing the behavior. While it has traditionally been easier to harshly judge these behavioral choices, incorrectly label them as reckless conduct, and inappropriately discipline all who knowingly violate the rules, in a Just Culture, the solution is not to punish those who engage in at-risk behaviors. Instead, managing at-risk behaviors requires removing the barriers to safe behavioral choices, removing the rewards for at-risk behaviors, and coaching individuals to see the risk associated with their choices.

Coaching. Coaching involves helping an individual see the risk associated with a behavioral choice that was not seen or was misread as being insignificant or justifiable. It is a productive conversation between individuals about the risks vs. rewards of certain behaviors and the decision-making process for behaviors under the control of the individual. The purpose of the conversation is to raise awareness of the risk associated with an individual’s behavior, uncover the reasons for engaging in the behavior so they can be remedied, and to align expectations for the individual to make a safer behavioral choice in the future. This may be as simple as telling an individual that a particular choice may have more risk than he or she might see. Occasionally, the conversation requires more depth if the individual is unconvinced about the risk associated with their behavioral choice.

Coaching is different than counseling. Coaching is a positive verbal conversation to increase situational awareness of the risk associated with behavioral choices while uncovering any underlying causes of behavioral drift. In contrast, counseling is often the first step in the disciplinary process, when individuals are put on notice, often verbally and in writing, about certain behaviors or outcomes required for their continued employment.

Coaching conversations should be part of a manager’s daily routine whenever they observe an individual or group engaging in at-risk behavior. Managers should not wait for an event to occur before addressing at-risk behavior; instead, they should be proactive in sharing their perceptions of risk with the workforce and their expectations to make safe behavioral choices. Additionally, coaching should never be accomplished by merely publishing or reiterating a policy, procedure, or usual standard of practice. In most cases, individuals already know about the policy, procedure, or standard and have been trained to carry it out. At-risk behaviors are not usually associated with a lack of knowledge about the rule, but rather a lack of awareness of the risk associated with the task or not following the prescribed process. Choosing not to coach at-risk behavior because it is uncomfortable or may not be well received by the individual or group allows the risk to continue unchecked until harm occurs. What is not corrected is condoned.

Once managers are comfortable with coaching at-risk behaviors, they should encourage individuals to conduct peer-to-peer coaching when they see others engaging in at-risk behaviors, particularly when they do not believe colleagues see the risks they are taking. This is more than a willingness to lend a hand; it requires both the willingness to approach a peer in a productive manner in the moment when at-risk behavior is observed (not during a peer review session), as well as the willingness to be coached by others.

System redesign and rewards. Addressing at-risk behaviors also requires remedying the system failures and tacit rewards that are driving that behavior. For example, if syringes that are prepared on the unit are unlabeled because there are no blank or preprinted labels available, the system must be redesigned to make syringe labels readily available so staff have the right tools to make the safest behavioral choice. If medications are frequently being removed via override from an ADC in preparation

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Silicone-free syringes required. A hospital alerted us to an issue with dose preparation of **BERINERT**, a concentrate of C1 esterase inhibitor (human) indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks. HAE is a rare condition, and dose preparation of this drug was a new process in this hospital. Pharmacy and nursing staff had been educated about proper dosing, preparation, and administration; however, a crucial piece of information in the product labeling was missed: the manufacturer requires silicone-free syringes for reconstitution and administration of the drug.

The product, packaged as a kit, contains a single-use Berinert vial, a 10 mL vial of sterile water for injection, a **Mix2Vial** filter transfer set, and an alcohol swab; however, a silicone-free syringe is not included. Since the drug is very expensive and must be protected from light, it was kept in the original packaging and was not opened prior to use. Staff assumed a syringe was in the carton, as it is with other kits requiring silicone-free syringes, such as **ORENCIA** (abatacept). Since the required use of a silicone-free syringe was not known, the product was prepared using a syringe with silicone, and the drug was administered to the patient.

According to the company, it is important to use silicone-free syringes because particulate matter or visible protein flakes may appear when siliconized syringes are used. Since the syringe is not part of the Berinert kit, pharmacies and patients must purchase silicone-free syringes from one of four companies that sell this product:

- Air-Tite Products Co (HSW NORM-JECT Syringes)
- B. Braun (Injekt Syringes)
- West Pharmaceutical Services (Daikyo Crystal Zenith Luer Lock Syringes)
- Thomas Scientific (HSW NORM-JECT Luer Lock Syringes)

CSL Behring, the manufacturer of Berinert, does not recommend the use of a specific silicone-free syringe, and they have not tested the syringes listed above with

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for a procedure *before* they are prescribed, the incentives to engage in this at-risk behavior—perhaps requests from prescribers and praise for patient readiness—must be addressed.

Reckless behavior

Definition. Reckless behavior is the conscious disregard of a substantial and unjustifiable risk. In comparison to at-risk behaviors, individuals who behave recklessly always know the risk they are taking and understand that it is substantial. They behave intentionally and are unable to justify the behavior (i.e., do not mistakenly believe the risk is justified). They know others are not engaging in the behavior (i.e., it is not the norm). The behavior represents a conscious choice to disregard what they know to be a substantial and unjustifiable risk. Key to this concept is that the individual must recognize the substantial and unjustifiable risk in order to disregard it. Therefore, they must reasonably foresee that their actions or inactions will or could create a substantial and unjustifiable risk.

Causes and examples. The reasons for engaging in reckless behavior are as varied as the conduct, but no reason can excuse recklessness towards the safety of others. While reckless behavior is hopefully rare, examples include drug diversion, retaliatory breaches in patient confidentiality, or performing surgery under the influence of drugs or alcohol.

Differentiating between at-risk and reckless behavior. Some organizations have difficulty distinguishing between at-risk and reckless behavior. To be clear, when determining whether the behavior is reckless, the question to ask yourself is whether the individual consciously disregarded what he or she knew to be a substantial and unjustifiable **RISK**. This question is associated with the conscious disregard of a known substantial and unjustifiable **RISK**, not the conscious disregard of a policy, procedure, or usual practice standard. Policy, procedure, and practice standard violations are often at-risk rather than reckless choices, where the **RISK** is not seen or mistakenly believed to be insignificant or justified. Reckless behavior requires the conscious disregard of a perceived significant **RISK**. Most often, the person making a reckless choice is motivated by a self-centered desire to put their own needs ahead of others; thus, their behavior has no social utility to benefit others, particularly the patient, the organization, or their colleagues. Differences between at-risk and reckless behaviors are summarized in **Table 1** (page 1).

Management. In a Just Culture, reckless behavior is blameworthy behavior. As such, swift and appropriate remedial or disciplinary sanctions should be considered according to the organization's human resources policies to correct the undesired conduct. The level of corrective action is typically determined by the organization's disciplinary procedures and often ranges from counseling or reprimand to more punitive actions such as termination of employment. Additionally, system redesign may be helpful to protect against future reckless behavior. For example, drug diversion can be curbed with robust system enhancements.

Conclusion

Among the three types of behaviors that can increase risk and harm, at-risk behaviors, along with any necessary system redesign, should be the primary focus of a patient safety program. At-risk behaviors are an organization's greatest safety challenge, as well as its greatest opportunity for improvement. While inexperienced individuals are prone to human error as they learn new tasks and skills, the inescapable human error is less of an issue, as is the rare reckless behavior. However, at-risk behaviors are typically rampant as more experienced individuals drift away from rules, policies, and procedures, no longer seeing the risks in the workarounds or shortcuts they have developed over time. Managing these at-risk behaviors proactively and justly through coaching, system redesign, and a reward system that encourages safe behavioral choices is vital.

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Beriner. We believe the manufacturer should include a silicone-free syringe with the drug. Also, with this drug, the intention is for the patient/caregiver to prepare doses for self-administration at the onset of an HAE attack. Thus, pharmacies that dispense this drug should provide one of the four syringes mentioned above for use in the hospital. It is also important to educate patients and provide these special syringes to the patient upon discharge. Discharge planning/care management staff should ensure these syringes are available for patients after discharge.



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