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Acute Care ISMP Medication Safety Alert!®

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 belie 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

SAFETY briefs

HIGH-ALERT

Double concentration (2%) propofol now available. As mentioned in our May 14, 2020 newsletter (www.ismp.org/node/17746), Fresenius Kabi received an emergency use authorization (EUA) from the US Food and Drug Administration (FDA) to allow importation of **Fresenius PROPOVEN** 2% (propofol 20 mg per mL) emulsion in 100 mL vials. The product is now available in the US. Propoven 2% emulsion contains double the concentration (20 mg per mL) of **DIPRIVAN**, which is a 1% (10 mg per mL) emulsion. The company is providing key information about how the product differs from Diprivan 1% along with additional materials, such as alert stickers to place on vials (**Figure 1**);

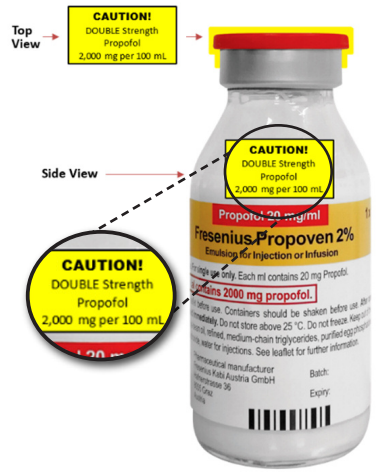

Figure 1. Propoven 2% comes with yellow alert stickers, 2 per vial, for placement as depicted above.

wall charts to display in key areas such as pharmacies, intensive care units (ICUs), and emergency departments (EDs); and healthcare provider and caregiver fact sheets (www.ismp.org/ext/502). Please review additional recommendations for safe use of this product published in our May 14 newsletter, including modifications in smart pump libraries since flow rates will be halved compared to propofol 1%. Although the product is meant for ICU patients only, anesthesia and ED personnel outside the ICU also need to be aware of its availability.

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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. Prescribing 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, 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 inattentional 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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HIGH-ALERT

FDA removes syringe administration from vinCRIStine labeling. At the request of the US Food and Drug Administration (FDA), Pfizer has revised the prescribing information and product packaging for vinCRIStine sulfate injection. FDA recommended the revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission. The labeling of vinCRIStine now states: **To reduce the potential for fatal medication errors due to incorrect route of administration, vinCRIStine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated "FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES."** Furthermore, administration of the drug via syringe has been totally removed from the package insert.

ISMP specifically called on FDA to eliminate syringe administration of vinCRIStine in official product labeling in our March 14, 2019, issue of the *ISMP Medication Safety Alert!* (www.ismp.org/node/1492). More than 130 deaths are known to have occurred from accidental intrathecal injection of the drug via syringe. No cases of accidental intrathecal administration have been reported with dilution of the drug in a flexible plastic container or minibag.

BD will not market an ISO 80369-3 compliant enteral syringe. BD announced earlier this month its decision to no longer pursue an ISO 80369-3 compliant enteral syringe system. BD was in the process of developing a male enteral syringe system to help avoid the risk of administering oral/enteral liquids via Luer connectors, such as those used for vascular devices and neuraxial lines. The BD system would have served as an alternative to the ISO 80369-3 compliant ENFit system. However, a recent evaluation of its program identified some technical challenges with the syringe that would impact the company's ability to bring it to market in a timely manner. The design met the ISO standard but had a male-to-female rather than a female-to-male connection, as does ENFit. ENFit is the only ISO 80369-3 compliant line of enteral devices and enteral tubes on the market for this purpose. BD said that it will continue to offer BD oral/enteral legacy syringes, as before.

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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.

For example, if you are an experienced pharmacist, you may rush past drug interaction messages with barely a notice, rely on a historical weight to verify a weight-based drug dose, and scan the barcode on the first container several times when multiple containers are required to prepare an admixture. 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 pharmacist who dispenses a "missing" medication quickly is more likely to receive positive reinforcement from the awaiting nurse than a pharmacist who fully investigates the reason for the request, thus delaying receipt of the missing medication. 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 and many others 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. 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

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GEDSA members delay phase out of legacy enteral systems. As a result of the coronavirus (COVID-19) pandemic, the Global Enteral Device Supplier Association (GEDSA) recently announced (www.ismp.org/ext/500) that member manufacturers will continue to support customers as needed, instead of strictly sticking to the original transition schedule (www.ismp.org/ext/501) for phasing out the manufacturing of legacy feeding tubes, administration sets, and transition adapters. What this means is that each GEDSA member has its own schedule, some with the capability to be flexible with conversion schedules and others not; therefore, GEDSA's strong recommendation is to contact your specific manufacturer or supplier. Manufacturing of legacy devices was planned to be phased out beginning July 1, 2020, with transition adapters no longer manufactured beginning January 1, 2021. Simply put, legacy devices and connectors will not suddenly disappear; instead, manufacturers' inventories will be used up until only ISO compliant inventory is available.

GEDSA members will continue to monitor the situation and respond accordingly, but to minimize disruption to patient feeding and care in the foreseeable future, members are committed to providing a continuous supply of the enteral products that are currently being utilized worldwide. GEDSA remains committed to ENFit, supports its use, and acknowledges it is the ISO-compliant option when the potential for a misconnection is high. According to GEDSA, about 25% of US hospitals have adopted the ENFit system.

The KIDs List. To create a standard of care for the safe use of medications in pediatric patients, the Pediatric Pharmacy Association (PPA) commissioned a group of pediatric pharmacists to evaluate the literature and compile a list of potentially inappropriate drugs for pediatric patients. This "KIDs List" is the first list of drugs that should be "avoided" or "used with caution" in all or a subset of pediatric patients. It is akin to the well known *Beers Criteria* for older adults but for pediatric patients. ISMP served as a reviewer for the project. The list was published in March 2020 in the *Journal of Pediatric Pharmacology and Therapeutics* (Meyers RS, Thackray J, Matson KL, et al. Key potentially inappropriate drugs in pediatrics: the KIDs list. *J Pediatr Pharmacol Ther.* 2020;25[3]:175-91; www.ismp.org/ext/459).

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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.

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

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ISMP now accepting nominations for Cheers Awards

In an ongoing effort to improve patient safety, ISMP takes great joy in recognizing others who share this same vision. Each year, ISMP celebrates individuals, organizations, and groups that have demonstrated exemplary commitment to the science and study of medication safety through innovative and creative projects, standards setting, research, or educational efforts. The winners will receive an ISMP Cheers Award, which will be presented during a ceremony in early December—more to follow.

Nominations for this year's Cheers Awards will be accepted through **September 11, 2020**. ISMP accepts external nominations, including self-nominations. The prestigious Awards spotlight efforts from all healthcare disciplines, and winners have included representatives from hospitals, health systems, long-term care, ambulatory care, community pharmacies, professional associations, federal and state agencies, as well as individual advocates. To submit a nomination, visit: www.ismp.org/node/1036.

Special Announcements

FREE international ISMP webinar

ISMP is presenting a **FREE** international webinar on **June 23** (7:00 a.m. EDT), ***Medication Safety During the COVID-19 Pandemic: What Have We Learned in the United States?*** The program is intended for an international audience. During the pandemic, numerous medication safety compromises were made in the US. Independent double checks during medication preparation and administration were abandoned or abbreviated. Pharmacists were processing orders online from home, not in the hospital. Unproven medications for prophylaxis and treatment of COVID-19 were used, sometimes sickening patients unnecessarily. Infusion pumps were kept outside of patients' rooms in critical care units to reduce nurse exposure and conserve personal protective equipment. Learn how and why these and many other changes were made, and where we go from here. To register, visit: www.ismp.org/node/18044.

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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 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 inaction 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 actions 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.

Special Announcements

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FREE FDA webinar—with ISMP

The US Food and Drug Administration's (FDA) Division of Drug Information is presenting a **FREE** webinar on **June 30**, ***FDA Drug Topics: Role of FDA and ISMP in Preventing Medication Errors***. FDA and ISMP speakers will illustrate how FDA collaborates with ISMP and uses information shared from the ISMP National Medication Errors Reporting Program (MERP) to benefit overall drug safety. The role of pharmacists in identifying, preventing, and mitigating medication errors will also be explored. For details, visit: www.ismp.org/ext/30, and to register, visit: www.ismp.org/ext/31.

FREE FDA course on oral anticoagulants

The US Food and Drug Administration (FDA) is offering a **FREE** 1-hour continuing education course, ***Practitioners' Guide for Improving Oral Anticoagulant Use***, which will be available online until June 2023 at: www.ismp.org/ext/503. The course serves as a quick guide for reducing risks with oral anticoagulants, covering common misconceptions about proper use; the prevalence, types, and prevention of adverse drug events; and situations when oral anticoagulation therapy outweighs bleeding risk. The course material includes printable tools that providers can use with their patients, including **ISMP High-Alert Medication Learning Guides for Consumers** for **PRADAXA** (dabigatran), **XARELTO** (rivaroxaban), **ELIQUIS** (apixaban), and warfarin.

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