

ASHP Medication Safety Section Advisory Group 2020-2021

Just Culture Toolkit

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Introduction

As a health system, patient care and safety are the focus of our everyday cadence. Do no harm; heal the sick and wounded; improve the quality of life of our patients - these are straightforward, right? If you are like most healthcare workers, the tenets of patient safety are second nature, but the reality is that the vast landscape of “patient safety” can be overwhelming and infinitely more complex. At the end of the day, our hospitals, clinics, and other care sites are staffed by humans – us! We walk through the healthcare institution’s doors each day with the intention of doing the right thing, but as Kohn, Corrigan, and Donaldson point out – *To Err is Human*.¹ If human error is inevitable, how can we protect our patients from harm without penalizing workers who do their best on a daily basis? The first step is to aim for a Just Culture within your institution.

What is a Just Culture? According to Professor Sir Norman Williams, “a just culture considers wider systemic issues where things go wrong, enabling professionals and those operating the system to learn without fear of retributions.” This report later adds, “just culture in healthcare recognizes both systemic factors and individual accountability.”² More simply stated, Just Culture empowers staff to focus on understanding why an error occurred (or almost occurred), and guides administrators to shift their focus away from *outcomes* and towards system design and optimization.³ The Just Culture approach facilitates this paradigm shift, creating space for these systematic changes and improving quality of care across the healthcare landscape.

How do you promote a Just Culture? It is a straightforward concept but remains nebulous in terms of its implementation. A central tenet is to create an environment of learning, and to encourage staff to report freely to minimize outcome bias. Eliminating outcome bias leads to improved reporting and allows health systems to

benchmark their data year over year. Reporting enables health systems to optimize processes, especially those with low cognitive burdens that have an overreliance on human performance.^{1,4}

Throughout this toolkit, you will find the resources you need to create, and maintain, a Just Culture framework at your institution to promote a strong culture of safety.

Core Concepts

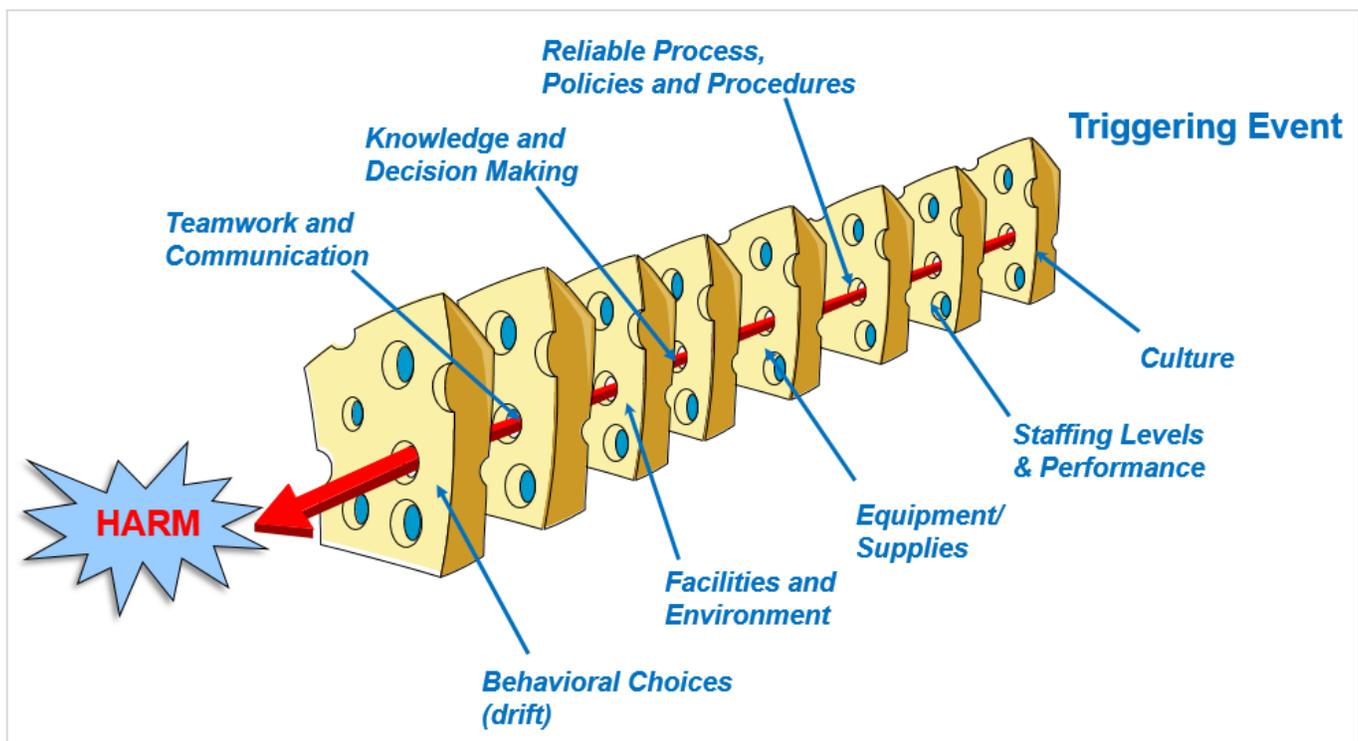
Culture is defined as how we do things - our morale, customs, behaviors, beliefs, and even the way we develop trust. As it pertains to medication safety, culture also affects the way we respond to potential errors and approach the problem-solving process.⁵

A Just Culture governs our response to errors within the healthcare setting. Below, we review the core concepts that lay the foundation for a fair and just culture.

I. LEARNING SYSTEMS

- a. Creating a culture of reporting is essential. To understand how best to construct a system, first we must be able to recognize and acknowledge its flaws.
 - i. In a reporting/learning system, staff want to report errors, and leaders engage staff to develop process improvements.
- b. Learning systems acknowledge that many errors stem from both active and latent failures⁶; approach to errors should focus on opportunities for improvement rather than ‘fixing’ the singular occurrence.
- c. Just Culture strives to create a learning environment in which staff and administrators focus on the “holes” in the system – a concept dubbed the “Swiss Cheese Model” (see Figure 1)^{6,7}.

FIGURE 1. The “Swiss Cheese” Accident Causation Model



II. SYSTEM DESIGN

- a. How an organization is designed and run its business
- b. Organizational structure, components, processes, procedures, tools, environment, interfaces, staff and data work in tandem to achieve specific goals.

III. SYSTEM RELIABILITY

- a. The probability that the system will perform without failure under normal conditions for a defined period of time.
- b. Reliability will ideally compensate for anticipated failures.
- c. Culture eats strategy for breakfast. Even the most well designed, reliable system will be overcome, or eaten, by a punitive culture.

IV. HUMAN PERFORMANCE and ERROR TOLERANCE

- a. Errors can be attributed to one of the following modes of human performance: (1) skill-based, (2) rule-based, or (3) knowledge-based (Table 1).⁵

TABLE 1. Human Performance and Associated Failure Modes

Performance Mode	Description	Estimated Error Rate ⁸	Failure Modes	Error Example
Skill-Based	Familiar, routine tasks, carried out using internal skill patterns	1 in 10,000 decisions	<u>Slip</u> – error without intention	Putting milk in the pantry instead of the fridge Placing magnesium 2 g bag in a bin meant to hold magnesium 4 g bags
			<u>Lapse</u> – unintentional failure to do a task; error of omission	Forget to put milk in the fridge and leave it sitting on the kitchen table Omitting a “high alert” auxiliary sticker when dispensing 23.5% NaCl
Rule-Based	Responding to a situation by recalling and using a previously established rule; may use an ‘internal’ flowchart or algorithm to make decision	1 in 1,000 decisions	<u>Wrong rule</u> – taught or learned the wrong response	When asked the capital of Massachusetts, many people answer Worchester instead of Boston A pharmacy technician is taught to override certain scanning alerts which are not meant to be overridden
			<u>Misapplied Rule</u> – know the right rules, but knowingly select another response; thinking becomes confused (a critical thinking problem)	When asked for rhyming words, the first three words are correct, but then the person says “bread”, which does not fit. MOST.... COAST.... BOAST.... BREAD! Using actual body weight for heparin infusion dosing instead of adjusted body weight in obese patients
			<u>Non-Compliance</u> – choose not to follow a rule	Short-cutting seat belt use because you’re in a hurry Choosing not using Closed-

				System Transfer Device while compounding hazardous drugs
Knowledge-Based	Requires problem-solving, typically in a new or unfamiliar situation that requires trial-and-error, extrapolation, or application of a different rule	1 in 2 decisions	<u>Mistake</u> – come up with wrong answer or course of action	An EMT administers the wrong drug to a patient because she did not know pertinent information about the medication Recommending an incorrect anticoagulation reversal agent or its dose

V. **RECOVERY**

- a. Catch errors downstream, mitigating patient harm.
- b. Examples: patient-monitoring, antidotes, error alerts within the Electronic Health Record

VI. **BARRIERS**

- a. Prevent or stop errors from progressing downstream
- b. Examples: limiting access/externalize/centralize, differentiate/affix warnings, forcing functions

VII. **REDUNDANCY**

- a. Adding a parallel element to avoid single cause failure
- b. Examples: automated redundancies, independent double checks (IDC), read back

VIII. **BEHAVIOR CATEGORIES**

- a. Proper application of the Just Culture approach requires event evaluators to understand the behaviors that resulted in error. The type of behavior dictates the approach to management and resolution.
- b. Human behaviors that contribute to error include: (1) Human Error, (2) At-Risk Behavior, and (3) Reckless Behavior.

TABLE 2. Categories of Human Behavior³

Behavior	Description	Approach to Offending Individual	Actions for Management
Human error	Inadvertent action (slip, lapse, mistake)	CONSOLE – offer support	Change in processes, procedures, training, design, environment, behavioral choices
At-risk behavior	Choice or action that increases risk (shortcuts, workarounds)	COACH - change the perception of risk and change the consequences	Addressing at-risk-behavior requires staff to report the issues to management and to practice second order problem solving for long term remedies Add barriers to prevent noncompliance (create incentives for healthy behavior choices), reduce barriers that prevent compliance (remove incentives for at risk behavior), examine the system for additional improvement opportunities such as increase situational awareness (e.g., technology workarounds, rushed communication during shift change/handoff, skipping process steps)
Reckless behavior	Conscious disregard of	DISCIPLINE - remedial	Administer disciplinary action, re-

	a substantial and unjustifiable risk; willful decision to disregard safety procedures	action	education, etc.
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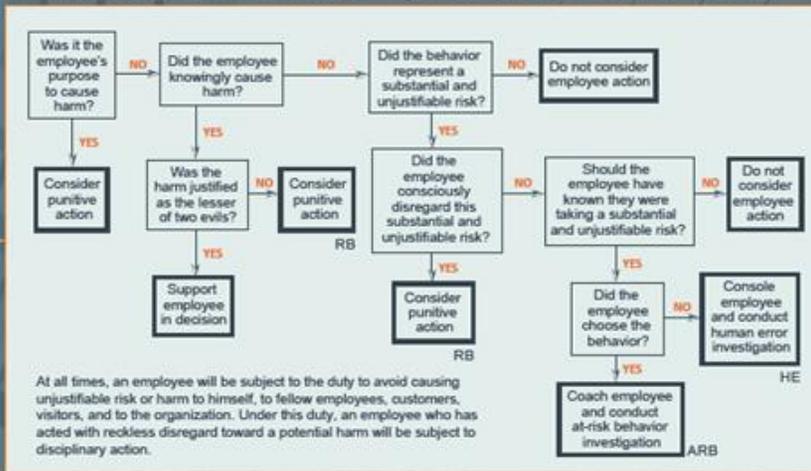
IX. THE JUST CULTURE ALGORITHM

- a. The Just Culture Algorithm is a valuable tool that helps entities establish a non-punitive approach to patient safety, incorporating core concepts described above. The algorithm may be applied to realized errors or near-miss events alike. The algorithm asks a series of questions that help administrators and staff identify areas for system optimization.
- b. Before applying the algorithm:
 - i. Ask the following questions:
 1. What happened?
 2. What normally happens?
 3. What does procedure require (if applicable)?
 4. Why did it happen?
 5. Is our system currently set up to prevent these types of events? If so, what is in place to prevent these types of errors?
 - ii. Apply the following tests:
 1. Substitution test: Would a competent employee with the equivalent level of training have done the same thing? Would you have committed the same error?
 2. Test of intention: Did the employee knowingly violate standards of care?
 3. Impaired practices: Was the employee impaired due to substance abuse or health issue?
- c. The Just Culture Algorithm^(TM)
 - i. The below algorithm offers unbiased guidance to evaluate human behaviors and guide leadership response to an error.⁹

Did an employee put an organizational interest or value in harm's way?

- Potential or actual harm to persons
- Potential or actual harm to property

Duty to Avoid Causing Unjustifiable Risk or Harm



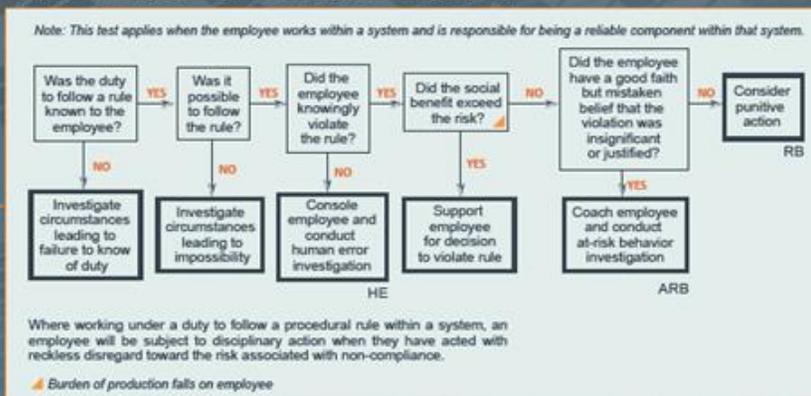
Actions

	With System	With Employee
Human Error (HE)	Modify system performance shaping factors	Console employee Remedial action
At-Risk Behavior (ARB)	Modify system performance shaping factors	Coach employee Remedial action
Reckless Behavior (RB)		Punitive action Remedial action

Did the employee breach a duty to follow a procedural rule in a system designed by the employer?

- Rule specifies *how* to perform the job
- System largely controlled by employer

Duty to Follow a Procedural Rule (system largely controlled by the employer)



Actions

	With System	With Employee
Human Error (HE)	Modify system performance shaping factors	Console employee Remedial action
At-Risk Behavior (ARB)	Modify system performance shaping factors	Coach employee Remedial action
Reckless Behavior (RB)		Punitive action Remedial action

(continued)

Duty to Produce an Outcome (system largely controlled by the employee)

Did the employee breach a duty to produce an outcome?

- Rule specifies the outcome to be achieved
- System largely controlled by employee

* If unsure, default to duty to follow a procedural rule

Note: This test applies when the employee is aware that he or she controls the system and is responsible for the output of the system.



Where working under a duty to produce an outcome, an employee will be held accountable as directed by the code of conduct and individual policies. These policies put the employee on notice to the duty, and prescribe acceptable outcomes attached to each duty (e.g. time and attendance, dress code).

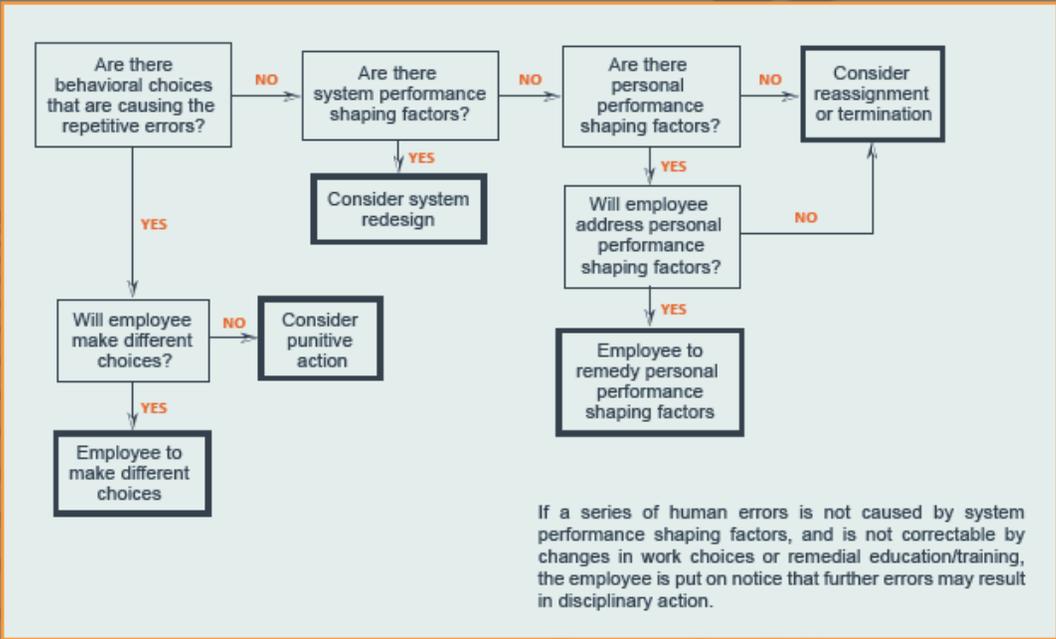
▲ Burden of production falls on employee

Actions

	With System	With Employee
Duty to Produce Outcome	Modify system performance shaping factors	Help employee produce better outcomes Punitive action

(continued)

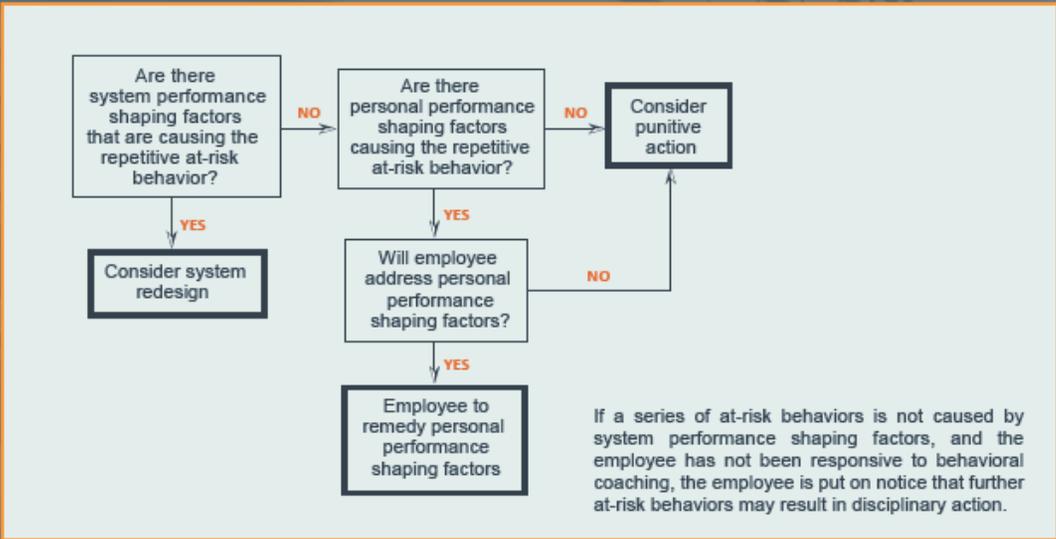
Repetitive Human Errors



Actions

	With System	With Employee
Repetitive Errors	Modify system performance shaping factors	Employee to address personal performance shaping factors Employee to make better behavioral choices

Repetitive At-Risk Behaviors



Actions

	With System	With Employee
Repetitive At-Risk Behaviors	Modify system performance shaping factors	Employee to address personal performance shaping factors Employee to make better behavioral choices

X. EVENT FOLLOW-UP

- a. To mitigate outcome/severity bias, leadership involved in event reviews and follow-up should not allow severity of the outcome/level of harm to drive the response
 - b. Discuss Findings
 1. Follow up with *involved* individual(s) to identify:
 - a. Sources of error (i.e., human, at-risk behavior, reckless behavior)
 - b. Circumstances surrounding the error (e.g., time of day, staffing ratios, patient characteristics)
 - c. Potential mitigating factors (things that kept it from being worse)
 - d. Potential exacerbating factors (things that contributed to severity)
 - e. Expected vs. realized outcome
 2. Follow up with all entity staff to discuss:
 - a. Systematic improvements to the medication-use or patient-care processes
 - b. Additional sources of error (i.e., things that did not go wrong in this situation but are related and/or could result in a similar outcome)
 - c. Provide Support
 1. Second Victim¹⁰ - A second victim is a health care provider involved in an unanticipated adverse patient event, medical error and/or a patient-related injury who become victimized in the sense that the provider is traumatized by the event.
 - a. Frequently second victims feel personally responsible for the unexpected patient outcomes and feel as though they have failed their patients, second-guessing their clinical skills and knowledge base.
 - b. Emotions experienced by Second Victim, which may result in error, for example: guilt, depression, sleep disturbances, anxiety, suicidal ideation, burnout/turnover, post-traumatic stress disorder, distraction, and lack of confidence.
 2. Care for the Caregiver resources
 - a. New terminology used for Second Victims Programs > Care for the Caregiver
 - b. Benefits: right thing to do, reduces turnover, reduces distraction that may lead to error
 - c. Consult your local Human Resources department to inquire if any related programs are available at your institution
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Implementing a Just Culture

Just Culture adoption goes beyond understanding of the Core Concepts. Establishing a valuable Just Culture framework requires consistent engagement, self-reflection, and improvement. The following section discusses important considerations for implementing Just Culture at your entity.

I. **STAKEHOLDER BUY-IN & BUILDING A TEAM**¹¹⁻¹³

- a. When implementing Just Culture, stakeholder (including senior leadership) engagement is the key to building a sustainable and functional system for all. Development of materials and processes is dependent on assembling a team that is actively involved and committed to building and maintaining a culture of safety.
- b. A key first step will be identifying 'key players' in the Just Culture landscape.
 1. Consider the following concepts when selecting team members to initiate this process:
 - a. Start local
 - i. While leadership engagement is key (see below), Just Culture will not be successful without buy-in from the frontline and support staff across different departments and services.
 - ii. Consider the different areas of your hospital, identify locations with unique processes and/or populations, and ensure that representatives from each of these areas are included.
 - b. Include varied perspectives
 - i. Team members should represent a spectrum of skill sets and levels of experience.
 - c. Make sure members are engaged
 - i. Development of a Just Culture is an iterative process. Team members should be invested and available for regular meetings and should make it a priority to garner feedback from their areas of practice.
 - d. Provide resources
 - i. Team members will require access to internal and external resources to build a functional system.
 - ii. Team members should have access to the following internal resources:
 - i. Time and attention of key leaders and administrators
 - ii. Internal medication-use data and relevant safety metrics
 - iii. Established reporting systems and assessment tools, if applicable
 - iii. Team members should have access to the following external resources:
 - i. Training materials (e.g., CUSP Toolkit¹¹, TeamSTEPs toolkit¹⁴)
 - ii. External data from entities that have established Just Culture processes

- c. Once the above concepts are accounted for, you can assemble your team. The following individuals are frequently involved in the Just Culture process, but this is by no means comprehensive. Depending on your reporting structure and workplace culture, additional members may be useful or required.
 1. Nursing, including nurse educators and nurse managers
 2. Providers, (mid-level prescribers, residents/fellows and attending)
 3. Pharmacists, including specialists, generalists, and operations pharmacists
 4. Leadership, including area managers, Medication Safety Officers
 5. Senior executives, including Director of Pharmacy
 6. Quality, Standards, Risk Management and/or Accreditation representatives
 7. Ancillary and support staff from multiple units across the hospital

II. LEADERSHIP BUY-IN^{11,12,15}

- a. While staff engagement and open reporting are key tenets of Just Culture, the process will not be successful without comprehensive and meaningful engagement from leadership. In Just Culture, leaders are accountable for creating an environment that supports error disclosure, open communication, learning from mistakes, and fair discipline. To be a 'good' leader with respect to Just Culture, administrators need to understand all aspects of the medication use process and be sensitized to barriers.
 1. Available data demonstrate that when leaders are involved in the development and implementation of Just Culture, their perceptions and understanding of safety events more closely mirror those of frontline staff.
 2. By aligning the awareness of leadership and staff, you can create a more functional and accessible medication safety process.
- b. The Joint Commission (TJC) acknowledges the role of leadership in the development and maintenance of safety cultures as an essential component.¹³
 1. In an analysis of the TJC Sentinel Event Database, TJC found that inadequate leadership frequently contributes to adverse events in multiple ways, including:
 - a. Insufficient support for reporting
 - b. Lack of feedback or response to staff and others who report safety concerns
 - c. Allowing or participating in intimidation of front-line staff
 - d. Not prioritizing safety changes and recommendations
 - e. Ignoring staff burnout and associated implications
 2. It is the view of TJC that institutions where leaders make patient safety a visible and meaningful part of their everyday actions are the most successful in maintaining a culture of safety. TJC recommends the following actions to build and continuously improve safety culture at your institution:
 - a. Adopt a transparent, non-punitive approach to event review and follow-up

- i. Have an accessible reporting system in which unsafe conditions are identified in a way that allows anonymity
 - ii. Evaluate and implement trigger tools to pre-emptively catch errors
 - b. Establish a clear and just process for recognizing human error vs system error
 - i. Communicate near misses to the larger group, acknowledge and gather feedback on System fallibilities
 - c. Eradicate intimidating behavior
 - i. Demonstrate respect in all interactions; acknowledge and act on safety-related feedback
 - d. Establish communication (see **Standardizing Communication**, below)
 - e. Recognize safety leaders within your department and reward those who actively engage in the Just Culture process
 - i. Acknowledge 'good catches' and gather regular feedback

III. **POLICY INTEGRATION** ¹⁶⁻¹⁸

- a. Policies are used by hospitals and health-systems to reinforce expectations and actions as they relate to quality and safety. Developing a policy to support Just Culture may be an effective tool in communicating the value of cultivating a Culture of Safety, and in providing staff with the appropriate tools to empower open and honest reporting. Policies not only support staff, but help leadership emphasize their commitment to Just Culture practices through official processes and documentation.
 - 1. A Just Culture policy may be useful at your institution, regardless of if Just Culture is a new or established practice. Most accrediting bodies consider policies to be binding which makes institutions committed to enforcing its content. See below for details on specific sections you may consider.
- b. Individual policy statements are often tied to specific rules, regulations, or accreditation standards, which offer protection against liability. TJC maintains standards related to Safety Culture that may be integrated into a policy on Just Culture. The standards in Table 3 have been identified by TJC as components of Safety Culture.

TABLE 3a. Select Joint Commission Standards for Patient Safety

Assessment	Strengthening Systems	Trust/ Intimidating Behavior	Identifying Unsafe Conditions	Accountability/ Just Culture
LD.03.01.01, EP 1: Leaders regularly evaluate the culture of safety and quality using valid and reliable tools.	LD.03.01.01, EP 2: Leaders prioritize and implement changes identified by the evaluation [of safety culture]. LD.03.01.01, EP 5: Leaders create and implement a process for managing behaviors that undermine a culture of safety.	LD.03.01.01, EP 4: Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.	LD.04.04.05, EP 3: The scope of the safety program includes the full range of safety issues, from potential or no harm errors (sometimes referred to as close calls ["near misses"] or good catches) to hazardous conditions and sentinel events.	LD.04.04.05, EP 6: The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment. (See also LD.03.04.01, EP 5; LD.04.04.03, EP 3; PI.01.01.01, EP 8)

TABLE 3b. Select ISO 9001:2015 Accreditation Standards

Context of Organization	Strengthening Systems	Environment	Management
4.1: The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.	4.4.1d: The organization shall determine the processes needed for the quality management system and their application throughout the organization and shall determine the resources needed for these processes and ensure their availability.	7.1.4: The organization shall determine, provide, and maintain the environment necessary for the operation of its processes and achieve conformity of products and services.	9.3.2b: The management review shall be planned and carried out taking into consideration changes in external and internal issues that are relevant to the quality management system.

- c. Regardless of if your institution ties policy statements to specific rules or standards, a formal policy can go a long way in assuring staff that leadership is invested in the continued development of safety culture. In establishing a policy, consider the following components:
1. Rationale/Purpose – this section describes the intention behind policy development and lays groundwork for current and future state of operations at your site.
 - a. Definitions – may consider including definitions of behavior types, safety event causes, or classification of medication safety events (e.g., prescribing, verifying, administering, monitoring, etc.)

- b. This section should emphasize that all healthcare workers are accountable for their actions, with an acknowledgement that Systems have a role in Safety Culture
 - c. This section should also include language on protecting staff from punitive action by leadership
 - 2. Responsibilities – this section outlines responsibilities of key personnel in the reporting and disciplinary process. This section may address the roles of various individuals, including:
 - a. Front-line staff (e.g., nursing, physicians, pharmacists)
 - b. Medication Safety Officer
 - c. Pharmacy/Nursing/Provider Administrators
 - d. Senior Hospital leadership
 - e. Risk Management / Patient Safety and Quality / Regulatory and Accreditation representatives
 - 3. Process – this section outlines standard key actions that make up the Just Culture Process. It may include an outline of:
 - a. *Event Reporting* – this section may outline how to access the event reporting portal, how to categorize events, or a procedure to assess and escalate events.
 - b. *Event Review* – this section outlines institution-specific practices and standards for reviewing a report, including scoring tools for ranking severity (e.g., Safety Assessment Code Matrix) or guides for assessing and escalating serious Adverse Drug Events. This section may also discuss the scope of different departments and/or specific individuals' (e.g., MSO) responsibilities.
 - c. *Follow-up Actions* – this section may discuss potential follow-up actions following event review, including processes by which your institution may modify system performance (e.g., EHR optimization, procedure changes, etc.), and modify employee performance (e.g., re-education or remedial action, corrective action).
 - 4. Other – additional relevant appendices / resources may be added as part of this policy:
 - a. Diagram of the Just Culture Algorithm
 - b. Institution specific flow-charts outlining reporting structure
 - c. Institution specific outline flow chart of chosen scoring system for medication-related events
 - d. Important contact information for MSOs, Regulatory and Accreditation representative or Risk Stakeholders, or Employee Conduct hotlines
- d. As with any new policy or procedure, implementation of a Just Culture policy will require accessible and comprehensive education. Refer to the section on **Standardizing Communication**, below.

IV. **Standardizing Communication** ^{11,14,19–21}

- a. Sites must establish open lines of communication to not just promote and disseminate materials that support a culture of safety, but these lines of communication must remain open in order to engender an open and non-punitive reporting environment. Communication from hospital or department leadership should be clear and consistent across all departments to ensure that staff members understand new or adapted processes.
- b. Effective communication should include the following components regardless of where your hospital is in the Just Culture process.
 1. It is complete – it communicates all relevant information, avoiding excessive details or ‘noise’.
 2. It is clear – it uses plain, accessible languages that can be understood by all departments.
 3. It is timely – new processes or changes are communicated as soon as possible, allowing staff time to acclimate to changes in reporting requirements, review structure, or other aspects of the Just Culture process.
 4. It is quick - written communications should look simple so it does not overwhelm the reader and thereby encourages everyone to review it. Try to use bullet points or tables vs. paragraphs.
- c. Remember that different departments within the health system may have different venues for communication. Effective communication across departments is dependent on solid relationships with the **Stakeholders** you identified as part of the Just Culture process.
 1. To establish communication between departments or across specialties, be aware of common barriers and take steps to identify and correct areas of concern. Common barriers across or within any given department include:
 - a. Lack of coordination or follow-up
 - b. Misinterpretation of established expectations or processes
 - c. Impact of hierarchies or weak leadership
 - d. Resource constraints (lack of time, lack of technology, excessive workloads)
 - e. Complacency or desensitization
- d. Effective communication largely depends on finding the right ‘style’ for your institution.
 1. Communicating from Leadership to Staff –
 - a. While there are many ways to organize or display information, the most common in the health care setting is the **SBAR** (Situation, Background, Assessment, and Recommendation).
 - i. This format of communication is a simple framework that provides an easy-to-remember framework for framing critical conversations. It is focused and straightforward, allowing you to accomplish complete, clear, and timely communication.

- ii. The SBAR tool is endorsed by a number of healthcare quality and accreditation bodies, including the Institute for Healthcare Improvement and The Joint Commission.
 - b. Other effective communication tools that may help open lines of communication:
 - i. Daily check-ins or check lists, updating teams on overnight events and following-up on action items
 - ii. Check-Backs, as described by TeamSTEPPS, which promotes closed-loop communication to ensure messages are received by end users and that responsible parties fulfill obligations
 - iii. Shadowing different departments or roles within your department to gain understanding of workflows and how your team interfaces with others
 - iv. Case Studies or Large-Group Event Review to get staff invested in the process and help them understand nuances or changes in how leadership approaches review and follow-up
 - 2. Communicating from Staff to Leadership –
 - a. AHRQ endorses use of the CUS Tool¹¹ to help staff communicate unsafe or uncomfortable situations quickly and concisely. This tool is less popular but may be helpful in empowering staff if your site is not familiar with Just Culture or if implementation is slow-going. Components are described below.
 - i. **C – Concerned**
 - i. Staff member describes the specific behavior that is currently, or has potential to, create an unsafe situation
 - ii. **U – Uncomfortable**
 - i. Staff member describes potential consequences of the unsafe action they are describing
 - iii. **S – Statement of safety issue**
 - i. Staff member makes request of leadership, provides potential mitigation or management strategies
 - e. When implementing Just Culture, the first method of communication may not be effective. Continue to gather feedback on communication and engage with frontline workers regarding their awareness of relevant updates and changes. Communication is an iterative process; the most successful programs will adapt as their Safety Culture continues to grow.
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Maintaining A Just Culture

After a successful implementation of the Just Culture program, it is vital to sustain the program effectively. Engaging staff at the time of hiring, providing structured communication, developing unit-based safety programs, and sharing patient safety data can help meet this goal.

Introducing staff to Just Culture during orientation can be vital in creating and maintaining a robust environment of safety. This can be accomplished by incorporating didactic and interactive onboarding or training modules and by enlisting senior leadership to help share the philosophy of Just Culture and set expectations early on. Institutions can also develop and share standard systems change reports with the frontline staff. This delivers a message to the frontline staff that the institution believes in addressing system level issues instead of blaming individuals. Additionally, the institution can develop and utilize a standardized targeted communication to communicate system changes to the frontline staff to connect them with the change and pass the ownership of implementing the change to them. See Appendix I.

It is essential to engage frontline staff to ensure the continued success of both nascent and established Just Culture programs.^{11,22} Developing a Comprehensive Unit-based Safety Program (CUSP) can help achieve this goal. It provides frontline staff with the support and tools to identify and handle the unsafe conditions for their patients at the clinic or unit level. An interdisciplinary CUSP team can consist of the following core team member:

- I. CUSP coordinator: The CUSP coordinator acts as an expert who guides the patient safety and quality improvement initiatives for the CUSP teams and helps various CUSP teams to connect to meet the institutional goals.
- II. CUSP facilitator: The CUSP facilitator acts as a subject matter expert to apply CUSP standards. He/she works closely with outside team members and other administrators (e.g., Patient Safety Officer) to identify and address safety opportunities.
- III. CUSP champion: The CUSP champion works closely with the CUSP facilitator to develop leadership skills to implement targeted interventions and motivates frontline staff to remain motivated and engaged. He/she acts as a project manager for the CUSP projects.
- IV. Unit manager: A nurse manager of the unit usually fills this role. He/she actively mentors and empowers frontline staff to identify unit/clinic-based safety issues and support quality improvement and patient safety projects.
- V. Provider champion: A physician usually fills this role. He/she works closely with the CUSP facilitator and CUSP champion to actively participate in the CUSP projects by providing input on the patient-related safety/quality factors and strengthening the interdisciplinary collaboration. He/she helps to get other providers' buy-in with the CUSP safety/quality initiatives.

- VI. Senior executive: The senior executive helps connect frontline staff with other senior executives. Also, he/she provides necessary resources to implement CUSP projects and support the team in understanding the institution's strategic goals.

An interdisciplinary CUSP team focuses on patient safety by identifying and preventing potential gaps in the system that can lead to patient harm using a 5-step approach.

- I. Firstly, CUSP creates a culture of safety based on science, which engages unit/clinic staff to routinely think about patient safety. This helps target issues causing systems to change and prevent patient harm.
- II. Secondly, it also encourages frontline staff to engage in identifying gaps proactively that can cause patient harm and encourages them to work on solutions to prevent events from occurring or reaching the patients.
- III. Thirdly, senior executives should participate in CUSP efforts when possible. This helps them connect with the frontline staff and develop shared accountability, shared understanding of the safety opportunities, and consensus amongst all to mitigate patient risks and improve the safety culture.
- IV. Steps one through three helps develop the basis for the fourth and the most important step in this 5-step approach. The frontline staff focuses on learning from the events by answering questions such as "What happened?", "Why did it happen?", "What did we do to reduce risk?", and "How do we know risks were reduced?".
- V. Steps one through four, with time, help inculcate improved awareness amongst frontline staff members, promote open communication between various disciplines, emphasize the importance of collaborative work effort, and develop a culture of safety and accountability.

Agency for Healthcare Research and Quality's (AHRQ) Surveys on Patient Safety Culture™ (SOPS®) can be used to understand an institution's patient safety culture at a given time.²³ This information can then be evaluated to identify opportunities to determine targeted actions. This in turn helps improve staff's patient safety awareness, trend changes in the patient safety culture over time, and analyze the impact of interventions and initiatives on the patient safety culture.

Case Studies

Case Study #1

A patient is admitted to pre-op for surgery. During intake, the patient reports a history of hives with Keflex. She is ordered cefazolin 2g IV x1 prior to incision. The orders are entered into the CPOE system by the surgeon (prior to allergy information entry into the EMR) to be verified by a pharmacist. The pre-op area has a non-

profile ADC, with all medications available for dispensing without order approval by the pharmacist. The ADC does not display allergy information.

As is the practice in this hospital, the RN removes the medication from the ADC prior to approval by the pharmacist and tapes to the IV bag hanging for administration by the CRNA. The CRNA removes the dose in the OR and administers to the patient. In the PACU, the nurse notices a diffuse rash, with beginning formation of hives. The anesthesiologist is paged, and diphenhydramine 25 mg IV is administered. The patient recovers without sequelae.

During event investigation, the pre-op nurse admits she did not know that Keflex was related to cefazolin. Upon polling other pre-op nurses, this was a consistent finding: drug class identification was not common knowledge. The CRNA reports assuming there were no problems with the medication because the nurse had provided the dose. He did not check the patient's chart for allergies prior to administration, as is policy. He did know the class relationship between Keflex and cefazolin.

Discussion: This case provides opportunity to utilize the Just Culture principles and algorithm for both the pre-op nurse and the CRNA. Let's work through the decisions of the pre-op nurse first.

1. What Just Culture Duty was violated?
 - a. Duty to Produce an Outcome
 - b. Duty to Follow a Procedural Rule
 - c. Duty to Avoid Causing Unjustifiable Risk or Harm
2. Intent is an important part of Just Culture. It helps establish if human error or a poor decision are implicated in the event. Our first question should be: was there intention to cause harm?
 - a. Yes
 - b. No
3. If this is determined to be human error, what are the next steps? Choose all that apply.
 - a. Console the employee
 - b. Coach the employee
 - c. Complete a record of conversation and place in the employee's personnel file
 - d. Look for any system improvements to help make a human error difficult to commit in the future
 - e. Send an email communication to all department staff to be more careful with allergies

4. If the investigation reveals at-risk behavior, where the risk was recognized but intentionally disregarded, what actions would be taken? Choose all that apply.
 - a. Console the employee
 - b. Continue with algorithm to determine intent (benefit outweigh the risks, good faith that the violation was insignificant or justified)
 - c. Coach the employee if the benefit did not outweigh the risk and conduct at-risk behavior investigation
 - d. Remediation or punitive action if the employee believed the risk was insignificant or justified
 - e. Remediation or punitive action if the employee knew the risk was not justified but chose to proceed.
5. How would you classify this event?
 - a. Human error
 - b. At-risk behavior
 - c. Reckless behavior
6. Return to question 1 and answer the same questions for the CRNA.
7. What system targets do you see in the pre-op process?
8. What system targets can be identified for the CRNA/OR process?

Case 1: Answer key and discussion

1. C (pre-op nurse), B (CRNA)

A guiding principle for all healthcare is to avoid harm. In this case, the CRNA would be responsible for this as well, but the primary violation was in choosing to ignore a policy and procedure in place to support avoidance of harm. If the CRNA had followed the rule, he would have seen the allergy, applied his knowledge of drug class cross-sensitivity, and prevented the adverse reaction. The nurse followed the rule (procedure) for her unit but lacked a piece of knowledge that resulted in an inability to sustain safe practice.

2. A (both employees)

Though their errors were different, neither person intended harm based on the information provided.

3. A, D

The difference between console and coach is intent. It is impossible to “coach” human error out of a situation. There was no conscious decision to diverge from the prescribed process, but a lapse. Consoling an employee is empathizing with the trauma inflicted when a person is involved in a mistake, particularly one that results in harm.

Consolation conversations do not belong in an employee personnel file; that is reserved for coaching, remediation, and punitive actions resulting from poor decisions made during a process.

System weaknesses allow human error to reach a patient more easily. By constantly reviewing and improving our systems, we can render it difficult for a human error to occur, or to reach a patient.

Blanket communications without context are generally ineffective, as are reminders to “be more careful” or processes reliant on memory. Communications should be actionable and specific.

4. **B, C, E**

At-risk behavior most commonly occurs when the staff member mistakenly believes that the risk is minimal by breaking the rule or skipping steps. This can be an example of *normalization of deviance*.^{24,25} It can also represent a mistaken belief that the benefit of the action outweighed the associated risks. It is important to identify this intent to determine subsequent steps with the employee (coach or remediate/punitive).

If the employee mistakenly believed the risk was justified or failed to recognize the inherent risk, coaching is the appropriate action. Malicious intent is not present, and the employee did not recognize the harm of their actions. Conducting an “at-risk” behavior investigation can help determine if this is a pattern for the employee or an isolated event. Coaching should include going through the proper process with explanations regarding the decision path, and an honest discussion involving reasons for deviation and any potential improvements in the process to eliminate the desire to deviate.

Sometimes an employee does knowingly ignore a risk with no compelling reason. This more often is classified as reckless behavior and determination comes after a full investigation. This is rare and certainly not the norm but should result in punitive action and potentially remediation.

5. **A (pre-op nurse), B (CRNA)**

The pre-op nurse followed the process as per unit policy. The process has many inherent flaws, leading the nurse to make a mistake. Additionally, there is a knowledge deficit regarding cephalosporin drug class and a *substitution test*³ failure with other unit staff nurses reveals it would be a common mistake. These findings point to human error, and consoling the nurse is the correct action.

The CRNA engaged in at risk behavior evidenced as bypassing part of a safety procedure (failure to check the chart for allergies). This occurred because he assumed availability of the dose meant the nurse knew the antibiotic was appropriate and safe. While there are likely system flaws present (performance of a substitution test would be beneficial for the CRNA process as well) the CRNA knowingly operated outside standards without a benefit to risk evaluation. Further evaluation should be conducted to determine if this is a pattern of behavior.

6. See answers for CRNA above.

7. There are many safety systems available but not utilized in the pre-op process. Some ideas are presented below.

Review of all orders by a pharmacist prior to administration is a Joint Commission standard and best practice, but some areas in hospitals are given an exemption. The pre-op area historically operated in this fashion, but with today’s technologies this should no longer be standard practice. CPOE and links between EMRs and ADCs allow for quick pharmacist review and can prevent this type of human error by blocking access to a

medication before pharmacist review. Changing the ADC in pre-op to a profile station ensures pharmacist review and approval prior to removal from the ADC.

Emergency situations may necessitate an override of the profile setting, or system downtime may result in the station being changed to override. In these instances, working with the ADC manufacturer to display allergy alerts on the ADC would be a safety net for staff removing medications prior to review by a pharmacist.

Change the process of antibiotic removal from the pre-op nurse to the CRNA. Since the pre-op nurse is not administering the dose, they should not hold this responsibility. For hospitals with anesthesia ADCs in the operating rooms, this transition can be easily accomplished for most antibiotics. If no intra-op ADCs are present, this would force review of the patient's EMR by the CRNA prior to removal of the dose, presenting an opportunity for allergy review.

Education is a lower tier on the intervention effectiveness hierarchy but can still be an effective tool when combined with more effective interventions. Providing class review education for pre-op nursing with commonly used pre-op antibiotics combined with a quick to read poster on the ADC machines could be helpful for pre-op RNs.

8. In addition to coaching the RNA for policy and procedure violations, there are some targets that could be pursued in the OR setting.

Change the process of antibiotic removal from the pre-op nurse to the CRNA. Since the pre-op nurse is not administering the dose, they should not hold this responsibility. For hospitals with anesthesia ADCs in the operating rooms, this transition can be easily accomplished for most antibiotics. If no intra-op ADCs are present, this would force review of the patient's EMR by the CRNA prior to removal of the dose, presenting an opportunity for allergy review.

Ensure allergy check and antibiotic review are included in the Time Out checklist.

Case Study #2

Emergency Department team notified of an incoming STEMI patient. In preparation for patient arrival, pharmacist removed STEMI medications (heparin, aspirin and ticagrelor) from the automated dispensing cabinet (ADC) along with medications for rapid sequence intubation (etomidate, succinylcholine and rocuronium). All medications were placed on the medication preparation area in the trauma room. Upon arrival, the patient was coding and required emergent intubation. Airway medications were requested by the provider, prepared by the pharmacist, and administered. Based on recommendation of Cardiology in consultation with the patient's family; treatment was not pursued, and STEMI medications were not necessary. Upon patient transfer, it was discovered that the heparin and etomidate vials were the same size and had similar labeling. In the rush to care for the patient, it was discovered that heparin rather than etomidate had been drawn up and administered to the patient.

1. What type(s) of errors occurred?
 - a. Skill based
 - b. Rule based
 - c. Knowledge based

2. Was there intention to cause harm?

- a. Yes
- b. No

3. Following discussion with staff involved, it is determined that there are aspects of both human error (mistakenly using the wrong vial) and at-risk behavior (not carefully reading the label). What next steps may be appropriate? Choose all that apply.

- a. Console the employee
- b. Coach the employee
- c. Complete a record of conversation and place in the employee's personnel file
- d. Look for any system improvements to help make a human error difficult to commit in the future
- e. Discuss the case in a confidential manner at a team M & M or Performance Improvement conference

Case 2: Answer key and discussion

1. **A**

The pharmacist, in her second year of residency training, mistakenly used the incorrect vial when preparing the requested etomidate dose in an urgent and chaotic code situation.

2. **No**

There was no intent to cause harm to this patient

3. **A, B, D and possibly E**

Consoling an upset staff member for a human error of drawing up the wrong medication is an important place to start the conversation.

Coaching and reminding the staff member on the importance of reading the label before drawing up the medication and completing a verbal handoff to the person administering the medication, is key safe practice that needs to be followed, even in an emergent situation.

Identifying opportunities for improvement with staff involved is valuable. In this case, opportunities for improvement included better organization and prioritization of medication preparation in the trauma room. Specific practice recommendations may include not pulling all medications at once or improved separation of medications in the crowded medication preparation area.

Discussing aspects of the case and potential system improvements in a confidential and safe manner may be of value with team members beyond those involved in the specific. The decision to discuss more broadly will depend upon the situation and organizational culture. With an emphasis on learning and improving.

Case Study #3

Confusion and mental status changes were noted on a patient on the medicine unit of the hospital just before shift change. It was identified that the patient was severely hypoglycemic with a blood glucose value of 27. The provider ordered 25 Grams of Dextrose 50% to be administered as an IV push stat. The pharmacist for the medicine floor was not expected to arrive for another hour so the nurse decided to remove the Dextrose 50% on override from the automated dispensing cabinet (ADC). The nurse signed the Dextrose 50% out of the ADC; however, he selected a vial of 1% lidocaine from the open matrix drawer that opened. The nurse recalled hearing that overrides for the ADC were discouraged due to patient safety risk and mistakenly thought that he could not use barcode scanning for medication administration for medications removed on override. He was worried about the patient and quickly administered the vial of medication. Another nurse joined him in the patient's room shortly after the medication had been given and clarified the need to barcode scan all medications prior to administration, including those removed on override. Upon scanning the medication, it was discovered that 25ml of 1% lidocaine had just been administered to the patient. The provider was contacted, and care was provided to the patient.

1. What types(s) of errors occurred?
 - a. Skill based
 - b. Rule based
 - c. Knowledge based

2. Was there intention to cause harm?
 - a. Yes
 - b. No

3. Following discussion with staff involved, it is determined that there are aspects of both human error (mistakenly selecting the wrong medication from the ADC) and at-risk behavior (not reading the label and not scanning the medication prior to administration). What next steps may be appropriate? Choose all that apply.
 - a. Console the employee
 - b. Coach the employee
 - c. Complete a record of conversation and place in the employee's personnel file
 - d. Look for any system improvements to help make a human error difficult to commit in the future
 - e. Develop an audit tool to monitor barcode scanning compliance by individual nurse
 - f. Post barcode scanning rates for each nurse (including name) on the wall in the nursing locker room

4. After further review, it was discovered that this nurse has a medication scanning compliance rate of 78% while the hospital average is 97.3% and his peers on the medicine floor average 98.8%. How does this impact next steps?

Case 3: Answer Key and Discussion

1. **A and B**

The nurse inadvertently selected the incorrect medication from the automated dispensing cabinet (ADC) which is a skill-based error. The nurse was aware that there were practice recommendations in place surrounding overrides from an ADC but misunderstood and incorrectly applied the barcode scanning expectations - this is more of a rule-based error.

2. **No**

3. **A, B, D and E**

Caring for the caregiver and consoling a distraught staff member is important in any situation where a human error is made.

Coaching the nurse on the importance of barcode scanning medications prior to administration is a critical component for the at-risk behavior. Clearing up the confusion about inability to barcode scan and appropriate use of override from the ADC are necessary here as well. Given the urgency of the situation, this was likely an appropriate time to use the override function.

Looking for system improvements such as placement within the ADC of the dextrose and lidocaine and monitoring of override rates should be considered.

Monitoring of barcode scanning compliance rates are an important component to creating a high reliability organization. While there may be a benefit in having each nurse be aware of their compliance rate in comparison with the average, identifying rates for each nurse by name in a public manner is not an appropriate strategy.

4. This is a tricky situation. In the ideal world, barcode scanning compliance rates would be monitored on a regular basis which would have allowed the poor compliance rate for this nurse to be identified and handled in a prospective manner. Routine bypassing of safety expectations warrants monitoring, coaching and at times, disciplining for non-compliance. If it was not routinely monitored or issue was not previously discovered, this would be an appropriate time to re-establish expectations and set up monitoring from this point forward.

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Appendix I. Sample Process Change Communication Template

Process Change Communication	
Subject	
Type of Pharmacy Communication Check all that apply	<input type="checkbox"/> Operational/Policy Change workflow or orderset changes, restrictions, drug shortages, BPAs <input type="checkbox"/> Formulary update monthly updates on formulary completion and go-live dates <input type="checkbox"/> Medication Safety e.g. LASA, HAM, Pyxis, Alaris, ISMP <input type="checkbox"/> General Education useful info with indirect pharmacy impact e.g. changes affecting nursing
Owner	
Contact information	
Description and Rationale Include approving committees, decision and date	
When is it changing?	Go-Live: Click or tap to enter a date.
Who will be impacted? Select all that apply	<input type="checkbox"/> Pharmacy <input type="checkbox"/> Nursing <input type="checkbox"/> Medical Staff <input type="checkbox"/> Ancillary Teams specify Click or tap here to enter text. <input type="checkbox"/> Inpatient <input type="checkbox"/> Outpatient specify Click or tap here to enter text.
What do I need to know? Include information on Pyxis, Alaris if applicable	
What do I need to do?	
How to procure product? Include manufacturer, CIN, NDC, package quantity, as applicable. Contact the Central Buyer Team for questions	
CPOE-associated number	
Automated Dispensing Cabinet ID	
References if applicable	

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