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

Psychologically safe workplace enhances root cause analysis interviews—Part II

Problem: In a psychologically safe environment, practitioners are more likely to proactively share medication safety concerns, which can lead to enhanced learning and quality improvement. In **Part I**, we discussed the use of insightful questions through leadership walk arounds, such as the Institute for Healthcare Improvement's patient safety leadership WalkRounds process, to foster open communication founded on mutual trust. Similarly, the likelihood of openly discussing medication errors is highly dependent on the degree of psychological safety felt by healthcare workers. Staff may be less likely to share details with organizational leadership in a punitive environment where they lack psychological safety. In **Part II**, we describe how to approach staff interviews *after* an event occurs, by conducting a root cause analysis (RCA) in a psychologically safe space.

RCA is one type of event investigation—an analytical approach to problem solving that seeks to identify why medication errors happen and how to prevent them. In our April 22, 2010 article, *Building patient safety skills: common pitfalls when conducting a root cause analysis* (www.ismp.org/node/803), we discussed how many practitioners learn the science and skills associated with quality improvement and patient safety—including RCA—through informal on-the-job training. Most would agree that not enough training has been done to prepare leaders to anticipate, identify, analyze, and resolve patient safety problems, while simultaneously approaching staff interviews in a manner that promotes psychological safety. Skills in these areas are pivotal to patient safety and quality improvement. Unfortunately, common pitfalls are still encountered while conducting an RCA, as described below, often rendering the process less useful than intended.

Failure to conduct "at-risk" behavior assessment

RCAs often omit a critical step of the event investigation by failing to closely examine the behavioral components of an error. Unfortunately, leaders rarely investigate contributing factors that lead to "at-risk" behaviors and workarounds where staff cut corners, breach policies, or do not follow procedures. In a Just Culture, at-risk behavior is when staff do not see the safety risk of the action they are taking or may mistakenly believe the risk is insignificant or justified (see our June 18, 2020 article, *The differences between human error, at-risk behavior, and reckless behavior are key to a Just Culture* [www.ismp.org/node/18533]). Their behavior is often the norm within their working groups (others do the same). Their "risk monitor" does not alarm and they mistakenly believe the choice they make is safe. Stopping the investigation with the identification of those risky behaviors is not enough, and often inappropriately results in punitive action for the involved individuals. Instead, it is crucial to uncover incentives that encourage risky behaviors, reasons behind the decreased perception of risks associated with such behaviors, and unintended consequences that discourage safe behaviors. Each at-risk behavior should always be investigated further to determine its causes, which most often reside in the organization's culture or design of systems.

Stopping the investigation when human error is identified

The investigation of an event sometimes ends when "human error" has been identified as the cause. However, once a human error is identified, the investigation should always continue to try to uncover any preexisting performance shaping factors (e.g., task complexity, workflow, time

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HIGH-ALERT

Proactive assessment uncovered look-alike calcium gluconate and tranexamic acid bags. A pharmacy technician was evaluating a new product, calcium gluconate 1,000 mg/50 mL, which had recently been purchased due to a shortage of supply from their typical manufacturer. They noted that the calcium gluconate injection bags looked very similar to tranexamic acid injection bags and escalated this concern to pharmacy leadership. Both products, made by Amneal, come in similar size bags and have nearly identical outer wrappers with similar colors, fonts, and designs (**Figure 1**, page 2). This was a great example of completing a safety analysis to proactively consider product characteristics that might cause confusion and lead to medication errors. The pharmacy is now purchasing calcium gluconate from a different manufacturer to prevent mix-ups.

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IMPORTANT! Read and utilize the Acute Care Action Agenda

One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, selected items from the **April – June 2024** issues of the ***ISMP Medication Safety Alert! Acute Care*** newsletter have been prepared for use by an interdisciplinary committee or with frontline staff to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue number to locate additional information.

The **Action Agenda** is available for download as an Excel file. **Continuing education** credit is available for nurses at: www.ismp.org/nursing-ce.

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availability/urgency, process design, experience, training, fatigue, stress) or other environmental conditions, system weaknesses, or equipment design flaws that allowed the error to happen and reach the patient.[1-4] The investigation is incomplete if it ends with human error as the root cause because it fails to uncover how human errors get through the system and reach patients—information that is critical when planning the redesign of systems.

Unjust punitive action

Some RCAs have been weakened by unjust punitive action taken against involved practitioners shortly after the event. This is largely due to hindsight bias and a prevailing but unfair outcome bias, in which the harm the patient incurred dictates the degree of punishment. The RCA investigation may be more inclined to focus on the shortcomings of the individuals (as determined by organizational leadership often before the RCA begins) and less inclined to uncover underlying system causes of the event. Further, due to punitive action, individuals involved in the event may be unwilling to attend or provide important details during the RCA, often leading to inaccurate assumptions.

Lack of probing questions to identify latent failures

Many RCAs do not dig deep enough to uncover the deep system-based causes of events, or latent failures. To learn about latent and active failures, ISMP has provided a webinar, *Lessons learned about human fallibility, system design, and justice in the aftermath of a fatal medication error* (www.ismp.org/ext/1398) which can be found in our on-demand education library. Probing questions must be systematically asked about how the organization was managing information, the environment, human resources, equipment/technology, and associated human factors at the time of the event. The process of asking "why" when human factors or a system have been identified as contributory leads to uncovering more deep-seated latent failures in the system.

Safe Practice Recommendations: When conducting the interview component of an RCA process, be sensitive and ensure that staff understand that the purpose of the investigation is not to place blame but to learn from the event and improve safety. Reinforce why staff play an important role in providing helpful facts to promote safety.

Focus event investigation on understanding the following:[1]

- What happened that particular day? How did the event occur?
- Why did it happen?
  - ☐ Are there system-based causes of the event or unsafe conditions/hazards (including latent failures or things that could have/should have been better controlled upstream)?
  - ☐ What made that particular day different?
  - ☐ What usually happens? What are the norms?
  - ☐ What should have happened according to policy and procedure?
  - ☐ Conduct a substitution test: What would three colleagues with similar training have done in the same situation? While this is one tool to consider, understand that human nature is to drift away from strict procedural compliance and develop unsafe habits (at-risk behavior).
- Conduct a Just Culture assessment: Determine if the event involved human error, at-risk behaviors, or reckless behaviors. Each at-risk behavior should always be investigated further to determine its causes, which most often reside in the organization's culture or design of systems.
- What will prevent it from happening again?
  - ☐ How can systems or processes be changed to prevent similar events or reduce or eliminate the event or unsafe condition?

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Figure 1. Calcium gluconate 1,000 mg/50 mL (left) and tranexamic acid 1,000 mg/100 mL (right) injection bags by Amneal look nearly identical.

We contacted the US Food and Drug Administration (FDA) and the manufacturer and recommended altering the outer wrapper labels (e.g., using color differentiation). When the pharmacy receives a new product (e.g., new product added to formulary, drug shortage), conduct a review to identify potential risks with the product's design including look-alike labeling and packaging concerns with other products in use within the organization (www.ismp.org/node/71460). When problems are recognized, consider purchasing the product (or one product of a problematic pair) from a different manufacturer. Use barcode scanning when receiving, dispensing, filling the automated dispensing cabinet (ADC), and prior to administration. Store look-alike products separately, and consider the use of signage in storage locations or auxiliary labels on the infusion bags.

Do not confuse eye wash solution with an enema. Three different hospital pharmacies have reported the potential for mix-ups between an eye wash solution (eye irrigating solution containing purified water) and an enema product ("saline laxative" containing sodium phosphate) that come in nearly identical packaging. Both products, made by Rugby, come in similar size cartons with the same colors, fonts, and designs (**Figure 1**, page 3). We have previously shared a separate concern, that some Fleet Enema products are referred to as a "saline enema," which implies the products only contain normal saline or sodium chloride 0.9% when they actually contain sodium phosphate (See our March 21, 2024 newsletter article, *Fleet enemas, not as benign as they seem,*

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- ☐ What actions need to be taken?
- ■ How will outcomes be measured?

The interview process can be summarized in five phases: Preparation, Engagement, Account, Closure, and Evaluation.[3-8]

1) **Preparation Phase:** Prior to the RCA interview, collect and review background information, determine who to interview, and schedule in-person interviews in a non-threatening private place without distractions. Based on the event that occurred, select from a list of probing interview questions that address the ***Key Elements of the Medication Use System*** (www.ismp.org/node/895), such as:

Was critical information about the patient missing or unknown?

Examples: age, measured weight (e.g., kg), height, allergies, vital signs, laboratory values, pregnancy status, patient location and identity, diagnosis, chronic conditions (e.g., renal/liver impairment)

Was critical information about the drug missing or unknown?

Examples: rarely used medication, maximum dose, typical dose, complex dosing instructions, route, contraindications, special warnings, drug interactions, availability of drug references, pharmacists not accessible to provide drug information, availability/use of protocols/order sets, inaccurate or incomplete medication reconciliation

Was information miscommunicated or not communicated?

Examples: incorrectly dictated or misheard verbal order, misunderstood order on the medication administration record (MAR), nonstandard documentation/communication, intimidation, teamwork issues, failure to communicate, incomplete handoff communication, warnings bypassed, or error-prone abbreviations

Was there a drug name, label, or packaging problem?

Examples: look-/sound-alike names, look-alike packaging, confusing or missing labeling information, label that obscures information, label not visible, warning labels missing/inconsistently applied

Was there a problem with how the drug was stored, dispensed, or delivered?

Examples: pharmacy turnaround time, automated dispensing cabinet (ADC) override, pharmacy delivery issue, dose missing or expired, strength or dosage form that is inappropriate per patient's age (e.g., adult versus pediatrics), unauthorized access to drugs

Was there a drug delivery device problem?

Examples: device design flaw, unsafe default settings, availability of devices, maintenance of devices, failure to engage available technology (e.g., smart pumps), misprogramming, free-flow, line mix-ups/misconnections

Were there problems in the physical environment, staffing patterns, workflow, or supervision?

Examples: lighting, noise, clutter, organization of unit, physical barriers, foot traffic, interruptions, staffing levels and skills, work schedules, inadequate supervision, supervisory support issue, inadequate breaks, workload and shift patterns, inefficient workflow and bottlenecks, employee safety

Did lack of staff education play a role in the error?

Examples: inexperience, inadequate orientation, lack of competency assessment validation, new or unfamiliar drugs/devices, failure to provide feedback about safety/hazards/errors/prevention, widespread knowledge deficit, non-compliance with mandatory education or required certification, lack of support for advanced certification and education

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www.ismp.org/node/128165). The sodium phosphate enema is not sterile and could cause harm if used in the eyes, and the eye wash would not have a therapeutic effect in treating constipation.

Figure 1. Rugby's "Eye Wash" (left) and "Enema" (right) cartons look nearly identical.

We contacted the US Food and Drug Administration (FDA) and the manufacturer and recommended altering the product cartons (e.g., using color differentiation). If your pharmacy purchases these products, consider purchasing one from a different manufacturer. Store look-alike products separately, and consider the use of signage, shelf talkers, or other warnings such as auxiliary labels on the cartons and in storage locations (e.g., eye wash station).

Oral hydration products could be mistaken for IV use. A pharmacist reported the potential for a wrong route error due to the brand name of an oral hydration product, LIQUID I.V. (**Figure 1**, page 4), which is not for intravenous (IV) use (www.liquid-iv.com). It is an over-the-counter (OTC) powder intended to be mixed with water for oral use and is available at retail stores. The pharmacist was reviewing a drug database update in their electronic health record (EHR) and found LIQUID I.V. listed as an orderable item.

This is not the only oral product with a naming

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Coming soon: Applications for the **Judy Smetzer Just Culture Champion Scholarships** open **August 1, 2024**. Visit: www.ismp.org/node/30840.

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Did lack of patient education play a role in the error?

Examples: missing patient labeling information, lack of patient counseling, non-adherence, not encouraged to ask questions, lack of investigating patient inquiries, incomplete discharge instructions, complex drug regimen, medication reconciliation problem, health literacy, language barrier or other communication problem, intimidated by staff

Were there issues related to quality control or independent verification systems?

Examples: equipment quality control checks, barcode technology

Did elements of the culture contribute to the error?

Examples: fear of retribution for errors, management of behavioral choices, focus on productivity and volume, lack of feedback about errors, regulatory conditions, financial resources/constraints, organizational structure/priorities

Other human factors issues (staff and patient)?

External examples: task and information complexity, ergonomics, time urgency, familiarity with task/product/equipment

Internal examples: mental/physical health of staff/patient, fatigue, fitness for duty/self-administration, stress, motivation

Other technology issues?

Examples: technology workarounds, technology malfunction, design flaw, misinterpretation, user error, technology and devices not meeting needs, information access and drug security issues

2) **Engagement Phase:** To engage and build rapport, the interviewing leaders should introduce themselves, greet the person being interviewed, and explain the purpose and process of the interview. Be clear about the intentions, such as "I wanted to discuss a recent event with you so that we can better understand how it happened, share lessons learned with staff, and make changes to improve our systems and processes." Use a conversational and non-confrontational tone while remaining objective and compassionate (i.e., fact-finding, not placing blame).

3) **Account Phase:** The interview should avoid any accusatory statements. It should be based on a systems approach to learn how people experience errors due to system breakdowns. Inform the practitioner that you will be taking notes to review with them at the end of the interview.

Encourage practitioners to report all details even those that seem trivial. Start by asking, "Can you tell me what happened in your own words?" to allow the practitioner to recreate the event in an open-ended narrative. Ask for additional details, such as "What happened after you….?" "Can you expand on that?" "What specific times?" "What specific words were communicated?" Ensure a collaborative open dialogue without interruptions. Ask focused follow-up questions (see probing question examples above) for clarification, focusing on one fact at a time. Use memory joggers such as reverse order recall (ask to tell what happened again but starting from the end back to the beginning) and change perspectives (ask to tell the story again but from the perspective of another staff member).

Use non-verbal cues (e.g., head nods) to acknowledge your understanding. Allow the interview to go slowly, do not interrupt, and resist the urge to fill silence and pauses. Before closing, allow the practitioner to correct any inaccuracies and add any other details by reviewing the notes together.

4) **Closure Phase:** To close, thank the staff member for helping you learn from the event so that the organization can prevent similar events from reaching a patient. Address questions and

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Figure 1. Despite its name, LIQUID I.V. is for oral use, not IV use.

convention that could be misinterpreted. There is another product, BIOLYTE (www.drinkbiolyte.com), that includes the phrase "the IV in a bottle" on the label (**Figure 2**). The product website states, "BIOLYTE is the only medical grade hydration drink to contain the same amount of electrolytes as an IV bag, plus natural ingredients that help the body get back in balance." The names and labeling of these products could certainly suggest to someone that they can be administered parenterally.

Figure 2. Although this magazine advertisement and the product label state, "the IV in a bottle," BIOLYTE is for oral use.

We have notified the US Food and Drug Administration (FDA) and the companies that make LIQUID I.V. and BIOLYTE about this concern. Check your EHR database and remove these items if listed.

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concerns, convey the next steps, and provide your contact information. Encourage them to reach out if they think of anything else that might be helpful or that they want to discuss.

5) Evaluation Phase: Without the interviewee, reflect on the interview to determine what went well and what could be done better next time.

Conclusion

Leaders must cultivate a collaborative and thorough RCA investigation and commend staff who openly discuss errors. The use of purposeful interview questions asked in a manner that intentionally supports psychological safety can help leaders better determine what happened so that contributing factors and especially root causes can be identified. Through this process, the robust actions taken will have buy-in from the process owners (e.g., frontline staff) so meaningful system changes can be implemented and measured to prevent reoccurrence.

References continued to the right >

Special Announcements

Virtual MSI workshop

You still have time to join us for one of our ***ISMP Medication Safety Intensive (MSI)*** workshops before the end of the year. Upcoming sessions will be held on: **August 8 and 9**; **October 3 and 4**; and **December 5 and 6, 2024**. There is also a workshop scheduled specifically for practitioners who work in the community or specialty pharmacy settings on: **September 20 and 27, 2024**. For more information and to register, please visit: www.ismp.org/node/127.

Last call for CHEERS nominations

Nominations for this year's **CHEERS AWARDS** will close **August 2, 2024**. Please refer to the information provided on our website when submitting a nomination to ensure the required packet is received before the deadline. For details, visit: www.ismp.org/node/123.

ISMP's on-demand library

Educational programs available on ISMP's on-demand library webpage are a convenient way for practitioners to stay ahead of new trends in medication safety and access ISMP's collection of webinars and symposia. Some programs provide continuing education (CE) credits for pharmacists and technicians. For additional details, please visit: www.ismp.org/ext/1404.

New in-person human factors course

Our colleagues at ECRI are offering a new program entitled, ***Human Factors Engineering: Systems Thinking to Enhance Patient Safety***. During the two-day, live training, ECRI's human factors engineers will provide the foundational knowledge to understand and conduct proactive assessments and reactive near miss and adverse events assessments from a true systems perspective. Applications for continuing education (CE) credits have been made. The course will be held at ECRI headquarters in Plymouth Meeting, PA, on: **September 24 and 25, 2024**. For more information and to register, please visit: www.ismp.org/ext/1403.

ASHP USP Chapter <797> Activities

The American Society of Health-System Pharmacists (ASHP) is offering six **FREE** on-demand activities including webinars, *Frontline Conversation* sessions, and podcasts centered around the revised USP Chapter <797> requirements in different healthcare settings. Continuing education (CE) credit is available with the webinars for pharmacists and technicians. For more information and to participate in the activities, go to: www.ismp.org/ext/1405.

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