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ISMP
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Educating the Healthcare Community About Safe Medication Practices

Pump up the volume: How to prioritize events and analyze error data

PROBLEM: Error reports can be used to identify local system hazards, aggregate analysis of uncommon events, share lessons within and across organizations, and improve patient safety culture.[1] In our January 2022 newsletter (www.ismp.org/node/29217), the main article, *Pump Up the Volume: Tips for Increasing Error Reporting and Decreasing Patient Harm,* focused on how to optimize reporting and the capacity for learning about the human, technical, organizational, and environmental factors that determine the safety of the system as a whole. We believe many of our readers are successfully "pumping up the volume" of reporting errors and close calls within their organizations, but we are concerned some may be relying too heavily on error reporting as the only source of data. Furthermore, some may be using error report volume to calculate an error "rate" and using this as their only or primary measure of safety. Organizations must be mindful of the limitations of using reporting systems to generate error rates. Instead, one focus should be on individual error reports that reveal important actionable system issues, as well as aggregating and prioritizing reported events and investigating them thoroughly so meaningful system changes can be implemented and measured.

Suboptimal outcomes from internal reporting systems. Developing internal systems for reporting and tracking errors within a healthcare organization is the first step toward medication safety and promoting a Just Culture, but it is not enough. In the absence of effective error investigation and analysis, error reporting systems provide little insight into the safety of the medication-use system. Further, if an organization's resources limit its ability to analyze and respond to large volumes of reports, staff attitudes towards reporting can darken, believing that their efforts and concerns are being ignored. We have seen all too often that an organization's investigation and analysis of errors are superficial. As a result, meaningful change occurs infrequently, and outcomes often result in increased education rather than high-leverage system changes.[1] Without contributing to external reporting systems, large-scale tracking and trend analysis are lacking.[2]

Inappropriate use of error rates. Both ISMP and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) recommend that due to differences in culture, definition, patient populations, and the types of reporting and detection systems, medication error rates should not be used to compare one organization to another (www.ismp.org/ext/1057). NCC MERP states, and ISMP fully agrees, that there is no acceptable incidence rate for medication errors and that the number of error reports is less important than the quality of the information collected, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

Large variations in the types of errors reported and what constitutes the threshold to report also exist. Practitioners are more likely to report an event based on severity or the closer to the patient that the event occurred. In addition, some provider types report adverse events regularly (e.g., nurses, pharmacists) while others report less frequently (e.g., physicians). The impact of all these variables on error reporting validates that error rates cannot be used to measure safety over time and should not be used for comparison between health systems, hospitals, and healthcare practitioners.

SAFE PRACTICE RECOMMENDATIONS: While "pumping up the volume" of reporting is an admirable goal, the ultimate measure of success for error-reporting programs is not the number of reports received but rather the learning that occurs, actions taken to improve the safety system, and the amount of patient harm prevented as a result of system changes prompted by the reports. When analyzing error data, consider the following:

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SAFETY wires

Follow Vivitrol preparation instructions to minimize clogged syringes. A nurse prepared a patient's dose of **VIVITROL** (naltrexone) extended-release injectable suspension. The product is an opioid antagonist used for alcohol and opioid use disorders. It is supplied in a carton that contains a 380 mg vial of naltrexone microspheres, a vial of diluent, a 5 mL syringe, a 20-gauge 1-inch needle (to combine the diluent and microspheres), and two sizes of administration needles to accommodate different body sizes (two 20-gauge 1 1/2-inch safety needles, and two 20-gauge 2-inch safety needles). While attempting to inject the dose into the patient's deltoid muscle, the needle became clogged, and the nurse could not expel medication from the syringe. The manufacturer provides extra administration needles of different sizes because the microspheres are known to clog the needles. After replacing the needle, the nurse was able to expel a small amount of liquid to verify patency. But, when the nurse attempted to inject the dose for the second time, the needle clogged again. The patient had to leave but returned the following day to receive the dose of medication.

We reached out to the manufacturer, Alkermes, to notify them of this concern. They told us that, to minimize the chance of clogging the needle, the product must be prepared properly according to the package insert instructions (www.ismp.org/ext/1036).

Prior to use, the microsphere and diluent vials must be at room temperature for at least 45 minutes. To ease mixing, firmly tap the microsphere vial on a hard surface to ensure the free flow of powder prior to injecting the diluent. Once the diluent is added, vigorously shake for approximately one minute. After thorough mixing, the product should be milky white without

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FRESENIUS KABI IVENIX INFUSION SYSTEM

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Utilize error reporting as a barometer of safety culture. Organizations should utilize the quantity of errors reported in conjunction with surveys of the hospital's safety culture to gauge the psychological safety individuals perceive regarding error reporting. Rather than simply setting a goal of the number of events reported, take steps to strengthen the organization's culture of safety. Measure changes in self-reports, as increases often indicate that staff feel safe sharing experiences that have happened to them to avoid reoccurrence or the potential of the event actually reaching a patient. Anonymous reports might indicate the opposite and can be a barrier to understanding root causes since communication with the reporter for additional information is not possible. Similar to self-reports, an increase in reported close calls demonstrates the development of a learning culture, where individuals see value in sharing safety issues and trying to proactively solve them.

Avoid error rate comparison. Eliminate attempts to create medication error rates from reports for purposes of internal (e.g., unit-to-unit, employee-to-employee) and/or external comparisons (e.g., benchmarking error rates) to measure medication safety within the organization. Recognize that "error rates" are grossly inaccurate, because they are only based on voluntary reporting in an environment in which staff may not recognize that an error has occurred, be fearful to report an error, or for a variety of reasons may choose not to report. If error reports are "counted," educate practitioners that the goal is to elevate the "reporting" rate, not keep it low. In addition to sharing stories with staff, highlight the system-based problems that have been uncovered and the corresponding efforts and strategies employed to reduce the risk of errors and patient harm. Consider using ISMP's conceptual model, the ***Key Elements of the Medication Use System™*** (www.ismp.org/node/895), to guide you through this process. While it may be difficult to measure risk avoidance and a reduction in patient harm, a reasonable alternative is measuring the number of system changes as a result of information shared through the error-reporting system.[1]

Share system changes and error report outcomes. When events are reported, be transparent with staff about the error that occurred without identifying individuals. Ask questions and talk freely with staff to learn if the circumstances related to the error still exist and help them to identify the risk. Discuss initial plans for process improvements and allow for feedback and questions so that they can all be part of the risk resolution. Share this information across a variety of sources including with departmental staff (e.g., safety huddles, staff meetings, newsletters), cross-departmental colleagues (e.g., interprofessional huddles, committee meetings, interdepartmental newsletters), other hospitals/facilities within your health system, and leadership including the board of directors. If staff have input into the process and observe changes based on their reports and feedback, they will be more willing to take the time to report hazards and errors and participate in other performance/safety improvement projects. Sharing details of implemented system changes will also facilitate the spread of lessons learned and will help others to improve their systems.

Understand the significance of a trend. The information may show a trend of similar reports, but it may not necessarily reveal what is truly happening within your organization. For example, if you identify an increase in reports of adverse reactions to a chemotherapy medication, further investigation as to why the increase is happening is needed. Was there a medication recall due to a manufacturing issue? A recent change in prescribing practices for oncology patients? Use of new care plan or protocol? Has there been a change in pharmacy workflow during chemotherapy compounding, or a change in administration practices? Have the devices used in these processes changed? Ask staff for feedback including if there were any deviations in the process (e.g., products, equipment, technique) to gain insight into what might be contributing to this uptick in reports. Learn too about the identification of the adverse reaction. Were there changes in monitoring practices? While the safety report trend might be the initial call to action, collecting information from multiple sources gives meaning to the data and often points to system variability that needs attention.

Investigate rare events that could lead to harm. When prioritizing error reports for further follow-up, consider if the hazard or error is new and if it has caused or could cause harm. Does it require action by the US Food and Drug Administration (FDA), manufacturer, or standards organizations such

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clumps and move freely in the vial. After withdrawing the suspension into the syringe using the same preparation needle, replace the preparation needle with the appropriately sized administration needle.

The preparation must be administered immediately. Even with a few minutes delay after suspension but before transfer into the syringe, the medication needs to be resuspended. The vial can be inverted a few times to resuspend and then transferred into the syringe for immediate use. Educate all practitioners involved that this is a time-sensitive process. Only administer Vivitrol as a deep intramuscular gluteal injection, and not into the patient's deltoid muscle. We are unsure why the nurse in this case was administering the drug into the patient's deltoid muscle.

The needles provided in the carton are designed for the administration of Vivitrol and practitioners should not use other needles. If both needles become clogged, contact Alkermes to initiate a replacement request. Alkermes notified us that some organizations save unused, unopened needles left over from other patients to have a backup supply.

HYDROmorphone administered via the wrong route. A prescriber ordered **HYDRO**morphone 4 mg injection but was able to select the oral route of administration in a Cerner electronic health record (EHR). The pharmacist did not identify the oral-parenteral product type mismatch, so they did not contact the prescriber to recommend oral tablets or liquid. The computer system also allowed the pharmacist to verify the order since there were no alerts. Later, the nurse did not notice the oral route of administration, removed a 4 mg/2 mL injectable vial from an automated dispensing cabinet (ADC), and administered the 4 mg dose of medication intravenously (IV). The patient lost consciousness and required naloxone to reverse the opioid's effect.

We reached out to Cerner about this event, and a representative mentioned that the Cerner recommended settings would help

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as USP or The Joint Commission? Can patients, vendors, standards organizations, and regulators take specific actions to prevent or reduce the risk of similar errors or mitigate potential patient harm? For these instances, we cannot wait for a trend to occur, and the individual report is enough to escalate and prompt further action.

Detect errors through other means. To generate a more complete picture of the safety of the medication-use processes, organizations must collect and analyze data beyond that gathered through voluntary error reporting. Include errors detected and/or averted by automation (e.g., barcode scanning data, smart pump data, alerts in order entry and verification systems). Monitor medication-related triggers including the use of reversal agents (e.g., naloxone, flumazenil), abnormal laboratory results, procedure or treatment complications, and patient transfer to a higher level of care. While time consuming, you can learn a lot about process variation through observational studies of critical or complex parts of the process (e.g., pharmacy compounding, medication administration). Staff are often very willing to suggest at what points in the process they are feeling vulnerable; all you have to do is ask. Develop frontline staff safety round-table discussions for staff to discuss common issues seen in day-to-day practice to identify potential system improvements that may help prevent errors, and include these discussions in leadership rounding.

Proactively identify risks. Use tools such as the ***ISMP Medication Safety Self Assessments*** (www.ismp.org/node/18) to assist your team in proactively identify opportunities for reducing patient harm.

Learn from external reports. Reviewing and acting upon external reports such as those published in the ***ISMP Medication Safety Alert!*** is critical. Since these events are often rare, but can happen again somewhere else, they need to be shared and addressed proactively to protect patients. Not reviewing these reports and taking the recommended actions is one reason why we continue to see deaths from medication errors when we already know what to do to prevent them. Identify individuals, such as a Medication Safety Officer (MSO) or members of an interdisciplinary medication safety committee, to regularly review external medication safety-related resources, including the following in the regular review:

- ***ISMP Medication Safety Alert!*** publications (www.ismp.org/node/1003), *Action Agendas* (www.ismp.org/node/645), and ***Targeted Medication Safety Best Practices for Hospitals*** *(Best Practices)* (www.ismp.org/node/160)
- The Joint Commission Sentinel Event Alert newsletters (www.ismp.org/ext/1015)
- US Food and Drug Administration (FDA) drug alerts and statements (www.ismp.org/ext/1016)
- National Alert Network (NAN) alerts (www.ismp.org/ext/1017)
- National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) recommendations and statements (www.ismp.org/ext/1018)
- Medication Safety Officers Society (MSOS) list serve (www.medsafetyofficer.org)
- American Society of Health-System Pharmacists (ASHP) Compounding Connect Community list serve (www.ismp.org/ext/1020)
- ECRI (www.ecri.org)

Create a strategic plan. Use a model like the California Medication Error Reduction Plan (CA MERP) framework (www.ismp.org/node/46487) as a foundation for developing a strategic plan to advance the following error-reduction strategies:

- Maintaining a robust medication error reporting system

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prevent this wrong route error. However, the organization where this error occurred was not using Cerner's recommended settings. In the organization's search configuration, the first five order sentences (how the drug is listed on the medication selection screen) for **HYDRO**morphone have the IV route linked to the injectable product. But after prescribers select one of these order sentences, they can modify the route field to any route from the drop-down list. For this order, the prescriber changed the route from IV to oral, intending to prescribe an oral formulation. However, the system had automatically assigned the 4 mg/2 mL injectable vial based on the order sentence. If the hospital had configured the Cerner preferred setting, once a prescriber selects an order sentence linked to an injectable product, only appropriate parenteral routes will be available in the drop-down list. If prescribers select "more," they can choose an oral route, but the system no longer automatically assigns an IV product since it is not compatible. Instead, a filter option displays the route/dosage form compatible products for the pharmacist to dispense.

Cerner plans to notify all clients about the importance of the recommended configurations for route-form compatibility. Cerner will also let clients know about audits they may apply to ensure they are using the recommended configuration. Consider reviewing your EHR functionality to determine if a wrong-route mismatch can occur and update your system as needed.

There are situations, usually off-label, in which a different route of administration is needed. And while injectable products are sometimes administered orally, organizations should restrict the ability to select routes that are not intended for certain products (e.g., only IV route should be allowed for vinca alkaloids).

In addition, nurses should question doses of IV **HYDRO**morphone over 2 mg. As a reminder, 2 mg of IV **HYDRO**morphone is equivalent to approximately 12 to 14 mg of IV morphine, which is an exceedingly high dose, especially for someone who is opioid naïve.

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- Interdisciplinary teams analyzing medication risks and errors
- Carefully planned technology implementation
- Effective and timely use of measurable assessments to evaluate the impact of selective error-reduction strategies
- A proactive approach to risk identification and analysis
- Use of external information to improve medication safety
- Annual review of the strategic plan to reduce medication errors

Share errors with external entities. Organizations should collaborate with a federally protected Patient Safety Organization (PSO) (i.e., ECRI and the Institute for Safe Medication Practices [ISMP] PSO, www.ecri.org/pso) to share adverse drug events or hazards and learn from other organizations. Reporting to a national confidential database such as ISMP can have enormous impact on reducing global patient harm through the identification of risk and latent contributory factors (www.ismp.org/MERP).

Enhance event reporting systems. Work with vendors to modify internal reporting systems to meet end user needs including the ability to generate useful and customizable reports. Systems should be agile so that staff responsible for overseeing the reports can enter follow-up information at a later time pending a more time-intensive investigation. Developers of reporting systems should be flexible in their inclusion of new information technology, reflect advances in patient safety research, and be responsive to user feedback.[3]

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Misprinted label on sodium chloride bag

An organization that purchased 0.9% sodium chloride injection USP (NDC 0264-5802-00) 1,000 mL bags (lot number 0061852531, expiration 2025-02-28) by B. Braun received product that appeared to be labeled as 9% sodium chloride injection USP (**Figure 1**). Apparently, the left side of the label plate did not make proper contact during the printing process. We are uncertain if other lot numbers are impacted.

We reached out to the manufacturer to notify them of this issue. They told us they are still investigating this, but it appears that the ink did not properly adhere to the bag. For now, inspect your supply of 1,000 mL B. Braun 0.9% sodium chloride injection USP bags and notify the manufacturer if you have or receive impacted product. Although this may be alarming to see, bags of 9% sodium chloride are not manufactured or used.

Figure 1. A B. Braun 1,000 mL infusion bag of 0.9% sodium chloride injection USP (NDC 0264-5802-00) appears to be labeled as 9% sodium chloride.

Special Announcements

Monthly video series on healthcare issues with our affiliate — ECRI

A new monthly video series featuring healthcare insights from experts within ECRI and ISMP premiered January 11, 2023. Each month, ***ECRI Now*** features interviews with representatives from our team who discuss their experiences and perspectives on some of the biggest issues facing healthcare today. In the first episode, ISMP's Michael Gaunt, PharmD, discussed best practices for safe vaccine administration (www.ismp.org/ext/1107). New episodes are posted the first Wednesday of each month. Each episode includes topics of relevance to healthcare leaders and staff across the continuum. These videos are **FREE** to the public and can be viewed by going to: www.now.ecri.org.

FREE drug diversion 2-part webinar

Drug diversion is a serious problem that affects patients' and health professionals' safety. Patients may suffer from suboptimal therapy, substandard care, or be at risk for adverse reactions or infections. Join us on **March 15, 2023**, for ***Part II: Reducing the Risk and Infection Outbreaks from Drug Diversion***, as our speakers present drug diversion from a risk management and an infection control perspective. For details and to register, visit: www.ismp.org/node/61022. If you missed ***Part I: The Pursuit of Prevention—Confronting Drug Diversion***, you can view the recording at: www.ismp.org/node/61019.

To subscribe: www.ismp.org/node/138

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Editors: Ann Shastay, MSN, RN, AOCN; Jennifer Gold, MSN, RN; Shannon Bertagnoli, PharmD; Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Kelley Shultz, MD. ISMP, 5200 Butler Pike, Plymouth Meeting, PA 19462. Email: ismpinfo@ismp.org; Tel: 215-947-7797.