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ISMP
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Community/Ambulatory Care
ISMP Medication Safety Alert!®
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, provide analysis of uncommon events, share lessons within and across organizations, and improve patient safety culture.[1] In the December 2021 issue of this newsletter, 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 have confidence that many of our readers are successfully "pumping up the volume" of reporting errors and close calls within their organizations, but we are concerned that some may be relying too heavily on error reporting as the only source of safety event data. Furthermore, we are concerned that some may use or be required to use error report volume to calculate an error "rate" and then use this value as their only or primary measure of safety. Organizations must be mindful of the limitations of using reporting systems to generate error rates or less than impactful charts and graphs. Instead, the 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 reports, staff attitudes toward 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 also 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 the severity of the event or if the event occurred closer to or reached the patient. In addition, people and practitioner types may report regularly while others report less frequently. 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

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Hyoscyamine tablet labels look alike—verify formulation! The labels for hyoscyamine oral, orally dispersible, and sublingual tablets by Acella Pharmaceuticals are nearly identical (**Figure 1**). To compound this potential confusion, the tablets themselves also look alike with similar green colors and sequential two-digit tablet markings (i.e., 38, 39, 40). We have notified the US Food and Drug Administration (FDA) and the manufacturer of this concern and recommended differentiating the labels. The manufacturer told us that they will escalate our concern.

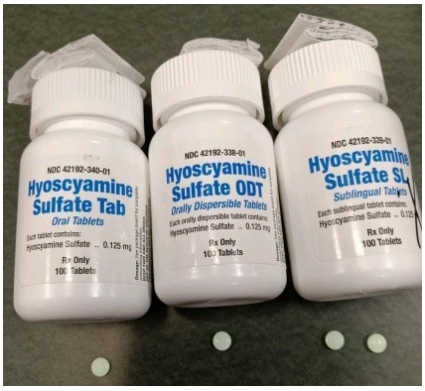

Figure 1. Hyoscyamine oral, orally dispersible, and sublingual tablets have similar labels for all tablet formulations, and the tablets look similar except for the tablet markings, which are hard to see.

Consider purchasing these products from alternative manufacturers to better distinguish the formulations. If you must purchase these products and use counting devices such as those from Eyecon, test whether the device will catch this look-alike drug, especially mix-ups involving the orally dispersible and sublingual tablets. Always use barcode scanning prior to dispensing and administration.

Dispensing the correct quantity of somatropin. Somatropin human growth hormone is available from multiple manufacturers using various brand names (e.g., **GENOTROPIN**, **HUMATROPE**,

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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:

Utilize error reporting as a barometer of safety culture. Organizations should utilize the quantity of errors reported in conjunction with surveys of the organization's safety culture to gauge the psychological safety individuals perceive in regard to error reporting. Rather than simply setting a goal of the number of events reported, take steps to strengthen the organization's culture of safety. Then, measure changes in the number of self-reports and anonymous reports, as increases in self-reports may indicate that staff feel safe sharing experiences that have happened to them to avoid reoccurrence or the potential of the error 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., employee-to-employee, pharmacy-to-pharmacy, district-to-district) and/or external comparisons (e.g., "benchmarking" error rates with other organizations or pharmacies) 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 be fearful to report an error, may not recognize that an error has occurred, or for a variety of reasons may choose not to report. Error rates that are calculated based on error reports reflect only the error "reporting" rate within the organization. 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 understand the risk. Discuss initial plans for process improvements and allow for feedback and questions so that they can all be part of the resolution of risk. Share this information across a variety of sources including with staff (e.g., safety huddles, staff meetings, newsletters), other organizations/pharmacies within your system, and leadership. 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 reporting 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 wrong drug errors, further investigation as to why the increase in reporting is happening is needed. Was there a drug shortage or medication recall due to a manufacturing issue? A recent change in which manufacturer's products are in inventory (e.g., more look-alike containers)? Has there been a change in pharmacy workflow? Have there been changes to the dispensing or barcode scanning systems? 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 errors.

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NORDITROPIN FLEXPRO, **OMNITROPE**, **SAIZEN**, **ZORBTIVE**) and in multiple dosage forms (e.g., pen devices, cartridges to be used with pen devices, vials). The indications for use also vary from product to product. This variety of products, indications, and dosage forms can present challenges to specialty pharmacies. However, specialty pharmacies face several other challenges related to dispensing these products. They must have a process to calculate and verify the appropriate dose and dosing frequency as well as ensure the correct quantity and days supply are dispensed.

Most pharmacy benefit managers limit the quantity of medication that a pharmacy can dispense to a maximum of a 30- or 31-day supply. Depending on the patient's daily dose, this may require dispensing more than one somatropin pen or cartridge. However, the pharmacy must calculate the correct number of pens or cartridges to provide the patient with enough growth hormone for the month without exceeding the 30- or 31-day supply limits. Sometimes this requires dispensing medication amounts that will cover fewer than 30 or 31 days (e.g., a 23-day supply) since the pharmacy cannot dispense partial volumes from the medication containers and may not be able to split cartons containing multiple cartridges or pen devices.

Another factor pharmacies must manage is whether the patient is receiving six or seven doses per week. For example, if a patient is prescribed Norditropin FlexPro 10 mg/1.5 mL pens with a dose of 1 mg per day, three pens will last 30 days. If the patient's dose is 1 mg per day for six days per week, three pens will last 35 days. If the pharmacy cannot bill for a 35-day supply, they may dispense two pens (a 23-day supply). Or the pharmacy could recommend to the provider that the prescription be changed to Norditropin FlexPro 5 mg/1.5 mL pens, as five pens will last 29 days.

These situations result in additional workload for pharmacists and pharmacy technicians or liaisons as they must contact the provider to suggest different products to maximize the days supply, and then they have to contact the patient more frequently to coordinate

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While the safety report trend might be the initial call to action, collecting information from multiple sources gives meaning to the data and may point 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), ISMP, the manufacturer, or standards or accrediting organizations? 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 process, organizations must collect and analyze data beyond that gathered through voluntary error reporting. Whether they are included in your safety reporting system or not, issues identified during pharmacist verification can be a valuable data source, and organizations should not miss proactive opportunities and wait for an error to be reported to improve systems. Include errors detected and/or averted by automation (e.g., barcode scanning data, alerts generated in order entry systems). Monitor, if possible, medication-related triggers including patients needing to be seen by their providers or seeking treatment in an emergency department or hospital. 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). 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 communications with leadership.

Proactively identify risks. Use tools such as the ***ISMP Medication Safety Self Assessments*** (www.ismp.org/node/34) to assist your team in proactively identifying 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! Community/Ambulatory Care*** newsletter is critical. Since these events are often rare, but can happen again elsewhere, 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. Establish a process for review of external medication safety-related resources and include the following in the regular review:

- ***ISMP Medication Safety Alert!*** publications (www.ismp.org/node/1003), *Ambulatory Care Action Agendas* (www.ismp.org/node/646), and ISMP guidelines, including our ***Targeted Medication Safety Best Practices***
- 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)
- ECRI (www.ecri.org)
- Centers for Medicare & Medicaid Services

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refills. And, given the variable quantity often required for these medications, there is an increased risk that the refill call with the patient or actual refill dates will be set incorrectly, potentially leaving patients without medication for days. There is also the potential for increased costs for the patient if they must pay their regular monthly copay but only receive a 23-day supply. Also, if a patient is enrolled with a copay card that has a limited number of charges per year (e.g., 12 charges for 12 months), they will expend all charges before the end of the year if they need more medicine before 30 days. So, at the end of the year, they may need to pay higher out-of-pocket copays.

Evaluate your pharmacy workflow and the potential for errors when dispensing growth hormone products. Leverage technology to help standardize work and calculations. This may be possible within your pharmacy dispensing and/or clinical patient management software platforms. The pharmacy that reported the above concerns developed a spreadsheet-based growth hormone calculation tool that allows pharmacy staff to type in the product and daily dosage prescribed. The tool then calculates the correct number of pens or cartridges needed to fulfill the order with the correct day supply. This pharmacy has also educated staff on growth hormone challenges and risks and requires a pharmacist to double check and document all growth hormone dosing calculations. Finally, one of our newsletter reviewers mentioned that they often see drug names truncated and carton contents difficult to decipher when selecting products during order entry. They suggested that pharmacies work with their pharmacy dispensing software vendors to provide a hyperlink to images of the product cartons on data entry and verification screens to enable staff to more easily identify the number of devices or doses contained in the selected product.

Diluent from omeprazole kit given by itself. Omeprazole, a proton pump inhibitor used to reduce stomach acid in conditions such as gastroesophageal reflux disease, is available from Azurity Pharmaceuticals as **FIRST-OMEPRAZOLE** compounding kit

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- Peer-reviewed journals
- ISMP's consumer website, ConsumerMedSafety.org, for errors impacting your patients and ways to help them prevent errors

Create a strategic plan. Develop a strategic plan to advance the following error-reduction strategies:

- Maintaining a robust medication error reporting system
- Analyzing medication risks and errors with your interdisciplinary team
- Carefully planning technology implementation
- Using effective and timely measurable assessments to evaluate the impact of selective error-reduction strategies
- Using a proactive approach to risk identification and analysis
- Using external information to improve medication safety
- Annually reviewing the strategic plan to reduce medication errors

Share errors with external entities. Organizations should collaborate with a Patient Safety Organization (PSO) to share adverse drug events or hazards and learn from other organizations. If more than one organization completes a root cause analysis (RCA) on the same issue and this information is aggregated, the outcome will have a larger impact that may otherwise have gone unnoticed. For more information about the ECRI and the ISMP PSO, please visit: www.ecri.org/pso.

Enhance event reporting systems. Work with information technolgy staff and/or 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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Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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which contains a bottle of omeprazole powder for oral suspension and a bottle of diluent co-packaged in a carton. Prior to use, the contents of the drug powder in one of the bottles must be properly reconstituted with the diluent from the other bottle. Although the manufacturer indicates that the powder must be reconstituted, sometimes this step may be missed prior to dispensing the medication to patients. This is what happened in a recent case. A patient received multiple doses of the diluent alone. The bottle of diluent was not mixed with the bottle of omeprazole powder and was dispensed to the patient. The patient thought that they had received the actual medication.

This situation is similar to events involving **FIRVANQ** (vancomycin) compounding kits that we wrote about in our December 2018 and May 2021 newsletters. Keep the First-Omeprazole kit intact prior to use or when supplying to long-term care or other facilities; do not store the drug powder and diluent bottles separately. Both bottles (diluent and reconstituted powder) should be presented to the pharmacist for final verification. The manufacturer has a video (https://youtu.be/CSRzvXfWFq0) showing how to reconstitute the omeprazole powder. Please note that the adapter cap included with the kit is not child resistant. See the article *Worth repeating…Ensure medications are properly reconstituted* in the January 2023 issue of this newsletter for recommendations to help ensure medications are properly reconstituted before dispensing.

Special Announcement

Virtual MSI workshops

Don't miss the opportunity to register for one of our unique 2-day, virtual ***ISMP Medication Safety Intensive (MSI)*** workshops. Learn how to identify risks before they cause harm and how to use data for continuous improvement. Our next workshop is scheduled for **April 13-14, 2023**. For more details about the program and more dates in 2023, please visit: www.ismp.org/node/127.