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ISMP
An ECRI Affiliate

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Why "benchmarking" error rates is NEVER a good measure of performance or patient safety

Problem: Healthcare organizations often want to know where they stand, in comparison to their peers, in achieving and maintaining an environment that promotes patient safety. Benchmarking is a process that can help meet this goal. The National Institutes of Health defines benchmarking as "a strategic and analytical process of continuously measuring an organization's products, services, and practices against a recognized leader in the studied area for the purpose of improving business performance" (www.ismp.org/ext/1249). Benchmarking requires both performance measurements as well as insights about enablers that help to achieve that performance. It is an ongoing process that is more complex than a direct comparison. Instead, it is a process that provides a systematic method of understanding the specific underlying practices that result in exemplary performance.

While we have written and spoken about the potential dangers of benchmarking error rates many times over the years, unfortunately, there is continued confusion about the term, perpetuating the myth that one can gauge the quality and safety of the medication-use process simply by comparing error rates, both within an organization (e.g., pharmacy-to-pharmacy, employee-to-employee) and externally (e.g., error rates with non-related pharmacies). In fact, ISMP continues to receive inquiries about benchmarking medication error rates. Organizations often want to know if there is a national standard (benchmark) for medication error rates or reported errors to make sure their organization falls below that benchmark. Others want to know statistics on medication error rates per practitioner, or what is the average safe number of prescriptions to fill in a given amount of time. Organizations hoping to demonstrate their commitment to safety often tell us that they have reduced their error rate.

We have also received feedback from healthcare organizations (e.g., specialty pharmacies) who tell us that certain payers or accrediting bodies continue to embrace the practice of comparing error rates for benchmarking. They tell us they are required to track and report error rates to accrediting bodies. For example, URAC's *URAC 2023 Specialty Pharmacy Performance Measurement: Aggregate Summary Performance Report* (www.ismp.org/ext/1393) describes the accrediting body's measure for dispensing accuracy (MP2012-06) as the percentage of prescriptions that the organization dispensed inaccurately, assessed in six parts: incorrect drug and/or product dispensed, incorrect recipient, incorrect strength, incorrect dosage form, incorrect instructions, and incorrect quantity. According to URAC, a lower rate represents better performance.

We are not in agreement that a lower rate represents better performance. And, all the above made us realize it was time to address this topic once again.

Both ISMP (*Pump up the volume: How to prioritize events and analyze error data*; published in the March 2023 issue of this newsletter) and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) (www.ismp.org/ext/1057) recommend that, due to differences in culture, definitions, patient populations, resources, and the types of reporting and error detection systems used, medication error rates based on reported errors should **never** be used to compare one pharmacy to another. The bottom line is that there is no acceptable incident rate for medication errors. The number of error reports is less important than the quality of the information collected, the organization's analysis of the information, and system improvements made to prevent patient harm.

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SAFETY briefs

HIGH-ALERT

Look out for this drug name pair confusion. A patient had been taking **STRIVERDI RESPIMAT** (olodaterol), an inhaled long-acting beta$_2$ agonist, to help manage their chronic obstructive pulmonary disease (COPD). However, when a provider recently intended to prescribe Striverdi for the patient, they inadvertently selected **STIVARGA** (regorafenib), an oral chemotherapeutic agent. Thankfully, a pharmacist intercepted the error when the instructions to "inhale 40 mg daily," included on the prescription, did not make sense for Stivarga. Ultimately, the correct medication, Striverdi Respimat, was dispensed.

Alert pharmacy staff and prescribers about the potential to mix up these medications. Prescribers should include the purpose of the drug in prescriptions. These medication names share a number of letters that appear in similar locations, including the first two letters (i.e., S-t-). Consider the entry of a minimum of the first five letters of the drug name. However, educate staff that it is best to type the entire name or keep typing letters until the intended drug name appears distinct by itself. Educate patients to confirm that the correct medication has been dispensed.

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Large variations exist in the definition of an error, the types of errors reported, and what constitutes the threshold to report. Practitioners are more likely to report an event based on the severity or if it occurred closer to or reached the patient. If an error is intercepted before reaching the patient, the issue may be corrected but never reported. In addition, some practitioners report adverse events regularly while others report less frequently. Other practitioners tell us they do not bother reporting safety issues because it takes too long or the reports in the past did not result in a change to the system. Remember, the easiest way to improve your error rate is to stop reporting – and that is certainly no way for organizations to learn and improve. The impact of these variables on error reporting demonstrates why error rates cannot be used as a valid measure of safety over time, and therefore these invalid metrics should never be used for comparing pharmacies or healthcare practitioners.

Safe Practice Recommendations: To ensure continuous performance improvement, it is important for self-comparison of organizational medication safety metrics over time. As an alternative to attempting to compare unreliable "benchmarking" error report data with other organizations, consider the following recommendations to ensure your organization is maximizing its opportunities as a learning organization and discovering opportunities to reduce patient harm.

Create a psychologically safe environment. Promote and implement a fair and Just Culture (www.justculture.com) where safety is a primary focus within the organization, and staff continually look for risks that pose a threat. Develop and disseminate nonpunitive policies about event reporting.

Strive for increased actionable reports. The goal of error-reporting programs is not to reduce the number of reports received, but rather, increase the learning that occurs, along with actions taken to improve the safety of the system. Educate practitioners and leadership, including corporate leaders and the board of directors, that the goal is to increase reporting, a clear descriptor of a learning culture, so actions can be taken to improve system reliability.

Improve reporting of close calls (good catches). Measure changes in the number of errors that are caught prior to reaching the patient (e.g., good catches, with a higher number of reports being better). An increase in the number of times a practitioner stopped and escalated an unsafe situation demonstrates the development of a learning culture, where individuals see value in sharing safety issues and trying to proactively address them.

Encourage self-reporting. Those who receive and act on error reports must earn the trust of reporters and prove that the program is sensitive to reporters' concerns, particularly fear of punishment or undue embarrassment for making and reporting errors. Use reports of errors and close calls to assess system performance, not staff performance. An increased number of self-reports may indicate that staff feel safe sharing experiences that have happened to them to avoid reoccurrence or the potential for the error reaching a patient the next time.

Educate reporters to include contact information. Anonymous reports can be a barrier to understanding root causes, contributing factors, and behavioral choices since communication with the reporter for additional information is not possible. Coach managers and staff about how anonymous reports can represent a missed opportunity. Explain to managers and staff how the organization learns from errors to improve systems and processes and encourage them to include their contact information to ensure a thorough event investigation is completed. An increase in anonymous reporting might indicate staff are afraid to report due to fear of a punitive response from leadership. Organizations that operate within a Just Culture have created an open and learning reporting environment in which staff are comfortable in raising their hand when they have observed a hazard or cut a corner to achieve an organizational goal, or will self-report when a mistake has been made.

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Look-alike oral liquid bottles. Bottles containing 473 mL of hydr**OXY**zine 10 mg/5 mL oral solution and hyoscyamine 0.125 mg/5 mL elixir, both made by Chartwell Rx (**Figure 1**), look nearly identical. Both products have similar looking names and use the same colors and design elements (e.g., the same curved dark and light blue bands) on the primary display panels. To prevent mix-ups between these products, explore ordering one of them from a different manufacturer. Consider using shelf dividers to keep stock separated and neatly organized. If you separate storage of these products, post signage or shelf stickers to direct pharmacy staff to the location of the product that was moved. Implement barcode scanning during the filling stage of the dispensing process to help identify if the wrong product is selected from the shelf.

Figure 1. Look-alike bottles of hydr**OXY**zine 10 mg/5 mL oral solution (left) and hyoscyamine 0.125 mg/5 mL elixir (right), both made by Chartwell Rx.

Vaccine registry not checked before administration. A nurse administered **TYPHIM VI** (typhoid vi polysaccharide vaccine) 0.5 mL injection to a clinic patient. When documenting the vaccine administration in the state registry, the nurse saw that the patient had previously received **VIVOTIF** (typhoid vaccine live oral Ty21a) capsules. Therefore, the patient should not have been reimmunized against typhoid fever for five years. The prescriber and patient were notified, and no harm was reported.

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Enhance safety culture survey participation. Use results from surveys of the pharmacy, clinic, and/or medical office's safety culture to gauge the level of psychological safety perceived regarding error reporting. Take the time to understand staff's perceptions and identify an appropriate organizational response to improve the culture. Focus efforts on increasing safety culture survey response rates and improving scores.

Adopt multiple approaches to identify risks and errors. Pharmacies, clinics, and medical offices should establish systems to learn about errors or unsafe conditions/acts in other ways in addition to error reporting. For example, engage in proactive staff interviews to identify safety risks and any barriers leading to workarounds. This could happen during huddles or focus groups with frontline staff. Periodically conduct proactive risk assessments (i.e., self assessments, failure mode effects analyses [FMEA]). Define and monitor organizational expectations as it relates to data collection for technology utilization, such as monitoring barcode scanning compliance and alert overrides. Periodically perform quality control checks by directly observing the processes and workflows in your practice setting. Implement a post-fill audit program as a manual redundancy to ensure prescription accuracy and identify errors before they reach patients.

Quantify system changes. Keep track of the system-based problems that have been uncovered and the corresponding efforts and strategies employed to reduce the risk of errors and patient harm. While it may be difficult to measure risk avoidance and a reduction in patient harm, a reasonable alternative is highlighting the system changes that have been made as a result of increasing information shared through the error-reporting system. Develop a process to regularly inform staff of actions taken to make the systems safer as a direct result of reporting.

Build a medication safety dashboard. Build your pharmacy, clinic, and/or medical office's targets into a medication safety dashboard to expedite the processes for analysis and to self-evaluate your medication-use system. When presenting dashboard information, identify actions that supported progress and those challenges that still exist.

Monitor and share performance improvement. Establish a cadence for reviewing internal metrics (e.g., monthly, quarterly). Report findings to frontline staff, committees, and leadership, including corporate leaders and the board of directors. Gather feedback for further improvements. Help committee members and corporate leadership who are seeking error rate comparisons to understand why there is no national comparison and what can be done instead to demonstrate the movement to a safe and reliable medication-use system. Communicate the meaningful impact of implemented changes that resulted from error reporting.

Many adalimumab biosimilars may look similar

In the ***Safety brief***, *Confusion among the many Humira products*, published in our November 2022 newsletter, we shared concerns one specialty pharmacy had about the look-alike packaging with the multiple **HUMIRA** (adalimumab) products. Humira is used for nine different autoimmune indications in both pediatric and adult populations, and the manufacturer produces many different prefilled syringe and pen carton configurations. Since publication of the ***Safety brief***, 10 biosimilar and/or interchangeable adalimumab products have become available, each with 1 or more dosage forms and concentrations. As payors begin to select different biosimilar products for their formularies, pharmacies will need to stock more and more of these products. And, with all of the adalimumab products having overlapping strengths/concentrations, and nonproprietary names that only differ by the added biosimilar suffix (some even have similar letters), the opportunity for mix-ups is high.

We have learned from a number of specialty pharmacies that the packaging of many of these products may also lead to product mix-ups. For example, a pharmacy shared that the cartons of **AMJEVITA** (adalimumab-atto) 40 mg/0.4 mL and Amjevita 40 mg/0.8 mL autoinjectors look similar and can be

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To help safeguard against errors with vaccines, verify the patient's immunization status in the state or local immunization information system, and the pharmacy computer system and/or electronic health record [EHR] prior to providing vaccines. Provide vaccinators with ongoing education and competency assessments including the need to verify immunization status in information systems prior to administration, as this can identify wrong timing and extra dose errors before reaching the patient. Encourage staff to report vaccine errors, and share close calls so that the organization can learn from events and improve processes.

Some products continue to present risks of needlestick injuries. In the August 2022 and June 2023 issues of this newsletter, we reported the potential for accidental needlestick injuries with the use of manufacturer prefilled syringes that do not come with a needle safety guard. The products mentioned included **EVENITY** (romosozumab-aqqg), **KINERET** (anakinra), **HUMIRA** (adalimumab), and **LEQVIO** (inclisiran).

We recently learned of another product that poses the same risk. This time it is a kit—the leuprolide acetate 14 mg/2.8 mL kits which are used in the palliative treatment of advanced prostate cancer. The kits come with a vial containing 14 mg/2.8 mL of leuprolide acetate,14 syringes with affixed needles, and 28 alcohol swabs. The needles do not have a safety device. In the case reported to ISMP, a nurse accidentally stuck herself with the needle attached to the included syringe after administering the medication to a patient.

These injectable products have been designed to be administered by patients or their caregivers after receiving proper training. However, they are also administered by practitioners in the inpatient and long-term care settings where the use of needles with safety mechanisms is common and expected. Also, if the patient does not have a proper sharps container, these syringes, with their exposed needles, may make their way into garbage bins and other forms of common waste, exposing children, animals, and others to unintended needlestick injuries.

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easily mixed up (**Figure 1**). While the Amjevita 40 mg/0.4 mL concentration is highlighted in yellow on its carton, the size and prominence of the 40 mg part of the concentration for both the 40 mg/0.4 mL and the 40 mg/0.8 mL cartons compared to the font size of the different volumes makes them look similar. Another pharmacy reported that the cartons containing one **YUFLYMA** (adalimumab-aaty) 40 mg/0.4 mL autoinjector look nearly identical to cartons that contain two autoinjectors (**Figure 2**).

Figure 1. A pharmacy reported that the cartons containing Amjevita 40 mg/0.4 mL autoinjector (left) look similar and can be confused for cartons containing Amjevita 40 mg/0.8 mL autoinjector (right).

Some manufacturers are also producing both branded and unbranded versions of their adalimumab product. For example, Sandoz produces **HYRIMOZ** (adalimumab-adaz) and the unbranded (i.e., no brand name) product adalimumab-adaz. While the products have different national drug code (NDC) numbers and pricing strategies, they both share the same nonproprietary name, adalimumab-adaz. The cartons for both the branded and unbranded 40 mg/0.4 mL prefilled pen devices look identical except for the different names and NDC numbers which are easy to miss given the rest of the cartons are exactly the same (**Figure 3**). Dispensing the wrong NDC could result in billing errors as well as mislabeling.

Figure 2. Yuflyma cartons containing two autoinjectors (top) look similar to Yuflyma cartons containing a single autoinjector (bottom) and may easily be confused for one another.

To help intercept selection errors when retrieving one of these products from the refrigerator, it is critical to scan each carton during fulfillment. Ideally, pharmacy computer systems will prompt or require scanning of each carton to be dispensed. Avoid scanning one carton multiple times when dispensing more than one carton. Enhance the computer system to alert the pharmacist during product verification if barcode scanning was bypassed during fulfillment. Clearly label storage bins, and if space permits, use separate storage locations for the different adalimumab products. Make sure staff are aware that the medications have been separated and where to locate them. Explore ways to differentiate the products to highlight critical information when they are received from the supplier. Educate staff on the different products and the potential to mix them up. At the point-of-sale, open the bag and have the patient check what has been dispensed to make sure it is correct. If the product is shipped to the patient, instruct them to carefully inspect the product upon receipt, comparing the product name and quantity to what is listed on the pharmacy label. Encourage patients to contact the pharmacy if they have any questions or concerns.

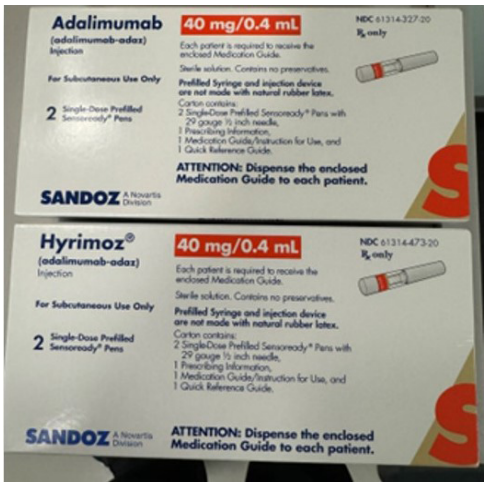

Figure 3. The cartons for Hyrimoz (bottom) and its unbranded version adalimumab-adaz (top) look identical, which could lead to dispensing the wrong NDC, billing errors, and mislabeling.

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We will continue to communicate with the US Food and Drug Administration (FDA) about the issue of manufactured syringes that do not have safety needle guards. When dispensing these products, provide patient counseling and make sure patients have the information and supplies necessary to dispose of the products properly and safely. FDA has published advice for consumers about the best ways to dispose of needles and other sharps (www.ismp.org/ext/1396).

Special Announcements

Nominations open for CHEERS AWARDS

Nominations for this year's **CHEERS AWARDS** are now open and will be accepted through **August 2, 2024**. Please refer to the information provided on our website when submitting a nomination. For details, visit: www.ismp.org/node/123.

MSI Workshop for Outpatient Pharmacy

Join us for our ***ISMP Medication Safety Intensive (MSI)*** workshop designed for those working in community, mail order, and specialty pharmacies. Learn how to identify risks before they cause harm and how to use data for continuous improvement. This program will take place on **Friday, September 20** and **Friday, September 27, 2024**, from **7:30 am - 4:30 pm ET**. To register, please visit: www.ismp.org/node/127.

To subscribe: www.ismp.org/ext/1369

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