Community/Ambulatory Care
# ISMP Medication *Safety Alert!* ®

Educating the Healthcare Community About Safe Medication Practices

Implement high-leverage and layered risk-reduction strategies using ISMP's hierarchy of effectiveness

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Healthcare is a complex and multifaceted field where some level of risk is ever-present. The groundbreaking 1999 Institute of Medicine report, "To Err is Human," rocked the world by estimating that as many as 98,000 deaths occur each year due to preventable medical errors, underscoring the unavoidable reality of human error in healthcare.[1] Acknowledging this, we must recognize that even the most dedicated among us are prone to lapses and mistakes. The inherent complexity of healthcare systems, coupled with the unavoidable potential for human error, creates a significant challenge to patient safety.

In order for organizations to minimize preventable errors, they must actively seek out and mitigate inherent, pervasive risks in the system. To achieve this, we must focus on enhancing both system and human reliability. This includes prioritizing error prevention, ensuring errors are reported when they occur, and diligently mitigating harm to patients if an error reaches them. Creating a truly safe healthcare system typically requires multiple strategies, balancing system and human reliability with ease of implementation, categorized by those that are high-, medium-, and low-leverage.
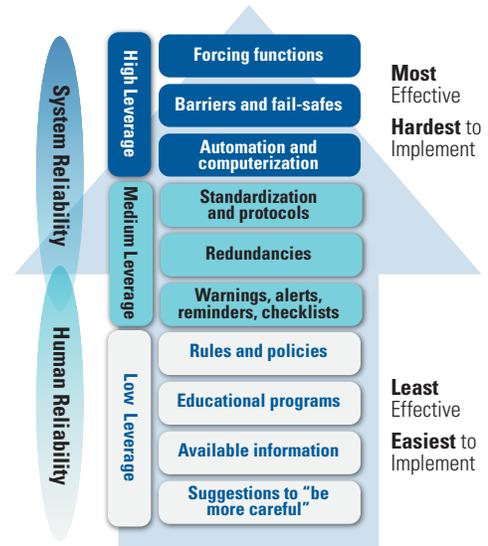
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Figure 1. ISMP's Hierarchy of Effectiveness of Risk-Reduction Strategies.

ISMP's Hierarchy of Effectiveness of Risk-Reduction Strategies (**Figure 1**) is a model that provides a multifaceted approach to risk reduction. High-leverage strategies are the most effective because they can eliminate the risk of errors and associated harm by designing out hazards, although they often require complex implementation plans and significant resources. Medium-leverage strategies are easier to implement and help reduce the likelihood of errors and minimize patient harm. However, on their own, they may need periodic updating and reinforcement and will not guarantee 100% patient protection. Certain medium-leverage strategies also pose a risk to workflow and alert fatigue if they do not have governance around them (e.g., having multiple checklists or electronic health record [EHR] alerts may have untold consequences if too many are implemented and then become burdensome). Low-leverage strategies aim to improve human performance and are generally easy and quick to implement. However, they are the least effective strategies for error prevention, but, unfortunately, they are frequently relied upon as the sole means to mitigate risk.

Since low-leverage strategies rely heavily on modifying human behaviors and habits, they prove to be the least effective overall. Conversely, high-leverage strategies focus on systemic changes and are more challenging to implement, but they offer a more robust and sustainable approach to minimizing risk within the organization. Medium-leverage strategies are situated between these two extremes, offering a moderate level of effectiveness with a corresponding level of implementation difficulty. So, using multiple strategies with varying leverages is essential for mitigating risks and improving patient outcomes.

SAFETY briefs

⚠️ HIGH-ALERT **Safeguards needed when linking new prescription to old.** A community pharmacy technician entered into the pharmacy software system a new prescription for oxy**CODONE** and acetaminophen with the directions "Take one tablet by mouth every 8 hours as needed for pain." As part of the pharmacy's standard process, the technician approved the system to link the new prescription to one that was previously filled for the same medication. The pharmacy established this process to ensure continuity of the patient's medication history, prevent duplication, and allow the system to monitor filling frequency. However, during the process of linking the prescriptions, the pharmacy software system automatically carried forward the directions from the previous prescription. The problem was that the directions were not an exact match. The directions on the new prescription were changed to "Take one tablet by mouth every 8 hours as needed for pain. May take 1 extra tab up to 4 times in 4 weeks for breakthrough pain." The system did not alert the technician of the change, but thankfully the error was caught during pharmacist verification.

Evaluate your pharmacy computer system's prescription linking functionality. Some systems may prompt the user to link the new prescription to an old prescription already on the patient's profile. If this functionality is utilized, review the workflow, processes, and prompts when linking to old prescriptions. System vendors should explore ways to allow the linking of prescriptions in the computer system without copying forward information from an old prescription that differs from the new prescription. If copying of information is allowed (should not be automatic), the system should provide prompts during order entry and verification for staff to verify that each piece of information (e.g., drug name, drug strength, quantity, directions) on the new prescription matches the one already on the patient's profile before accepting any copying. Even if your computer system cannot

> **Hierarchy of effectiveness** — continued from page 1

In our June 2020 article, Education Is "Predictably Disappointing" and Should Never Be Relied Upon Alone to Improve Safety, we cautioned against relying solely on education as a risk-reduction strategy. While fundamental for knowledge and skill development, education is less effective in our risk-reduction hierarchy than system-focused strategies like forcing functions and automation. Education does not guarantee that the new information has been learned, will be correctly applied in the right circumstances, and will lead to the desired skills. Additionally, knowledge and skills may erode over time, especially if they are not needed or not reinforced through routine activities. The most impactful strategies do not rely on human memory and make it difficult to make mistakes, while also making it easy to do things right. Education alone simply cannot achieve this level of inherent safety.

The real power of this model comes from a layered and comprehensive approach, leveraging interdisciplinary medication safety expertise in the building of the risk mitigation strategies to maximize their quality and effectiveness at each level. A single risk-reduction strategy is rarely enough. Actions must be broad, influencing as many steps of the medication-use process as possible, from procurement and storage to prescribing, dispensing, administration, and disposal. For instance, staff education (a low-leverage strategy) combined with forcing functions and fail-safes (high-leverage strategies) creates a more robust system. This layered approach addresses vulnerabilities at multiple points, and by integrating both human and system reliability enhancements, organizations create a more resilient safety net, minimizing the chances of errors reaching the patient.

When developing and designing risk-reduction plans, we encourage organizations to use this model and refer to **Table 1** (page 4) for descriptions and examples of the strategies listed, from most to least effective based on the science of human factors engineering.

High-Leverage

Forcing functions are high-leverage system strategies offering the greatest effectiveness in mitigating risks. These are design features, procedures, or tasks that compel specific actions and prevent undesirable outcomes by ensuring predetermined conditions are met, enforcing proper usage, highlighting errors, and preventing unintended consequences. Constraints eliminate the opportunity for error by making a critical step unavoidable. By making certain actions prerequisites, forcing functions create a necessary safeguard in the system where the proper sequence of actions is actively enforced, ensuring a more reliable and predictable outcome.

Barriers and fail-safes represent another highly effective strategy for reducing risk. Barriers place limitations or restrictions that are designed to prevent unintended actions, reduce access to dangerous process steps, and minimize potential harm. Fail-safes employ procedures or equipment design features to prevent malfunctioning or unintentional operation by automatically reverting a system to a predetermined safe state in the event of a failure.

Automation and computerization represent the last high-leverage strategy for enhancing system reliability and mitigating risks. This includes taking a look at the whole process and identifying ways to simplify it by removing unnecessary steps, while providing technological support. Automation can decrease variability in practice, thereby improving consistency, reliability, and efficiency. Computerization uses technology to replace manual systems and prevents communication failures, which enhances accuracy and streamlines workflows. This integrated approach reduces the potential for human error and creates a more robust and interconnected system.

Medium-Leverage

Medium-leverage risk-reduction strategies include standardization and protocols; redundancies; and warnings, alerts, reminders, and checklists. These strategies rely on both systems and human vigilance for their reliability, requiring consistent application and monitoring.

incorporate this change, the manual process used to verify prescriptions should include these additional steps. Educate practitioners about the importance of verifying each piece of information.

⚡ **MethylPREDNISolone dose pack label error.** A patient reported to their pharmacy that the printing of the methyl**PREDNIS**olone dose pack (national drug code 59762-4440-2, lot LG7675), manufactured by Greenstone, was incorrect. The printing on the foil backing of the dose pack did not align with the blisters containing the tablets (**Figure 1**). The printing appears to be rotated in relation to the tablets. As this foil backing contains instructions guiding patients to the correct dose each day, the error could lead to patient confusion and contribute to dosing errors.
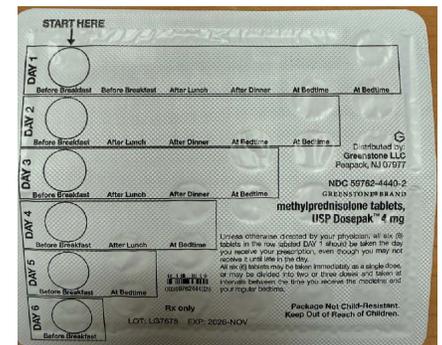

Figure 1. The instructions on the methyl**PREDNIS**olone dose pack from Greenstone are misaligned with the tablets.

If your organization purchases this product, review your inventory. If impacted product is found, sequester it and report it to the manufacturer, US Food and Drug Administration (FDA), and ISMP. When dispensing this product, the prescription label should include detailed instructions and not simply "Take as directed." Engage patients at the point of sale to review the dosing instructions. Remove the blister card from the carton and use the teach-back method to educate them about how they will use the product. This will also provide an opportunity to intercept any packaging issues and resolve potential points of confusion for the patient.

⚡ **Pharmacy software vendors should support safer drug name selection functionality.** Pharmacies and other healthcare organizations continue to report drug name selection errors due to the ability

Standardization and protocols involve the creation of clinically sound, uniform models of care or product designs to reduce variation and complexity. This increased predictability minimizes the potential for errors from inconsistent practices and product differences.

Redundancies create an extra layer of defense, ensuring that no single failure can cause harm. Redundancies ensure that if the primary pathway fails, a secondary pathway can detect the error and prevent adverse consequences. Similar to any workflow, this process needs to be reviewed and analyzed to ensure that the redundancy is effective and does not create undue burden on the system or have negative downstream effects.

Warnings and alerts serve as notifications that signal a potential problem or hazard requiring immediate attention, prompting swift corrective action. Reminders function as prompts designed to trigger a specific action or help to recall information at a designated time, proactively ensuring adherence to protocols and preventing oversights. Warnings, alerts, and reminders should be reviewed on a regular basis to ensure they do not become nuisance alerts and continue to achieve the intended outcome.

Checklists are structured tools used to ensure consistent and accurate completion of all required steps in a process, promoting thoroughness and minimizing the risk of omitted tasks.

Low-Leverage

Low-leverage strategies can serve as foundational elements in a comprehensive medication safety program. While these strategies primarily rely on human diligence and are most effective when used in conjunction with medium- or high-leverage strategies to create a robust safety net, they play a supportive role in fostering a culture of safety. It is important to understand that relying solely on low-leverage strategies will be insufficient for achieving significant and sustained reductions in medication errors, highlighting the need for a multifaceted approach.

Examples of these supportive strategies include rules and policies, formally established guidelines and directives designed to govern behavior and reduce variability, which are important but frequently violated and therefore unreliable; educational programs, which are structured learning initiatives intended to enhance the knowledge, skills, and competency of healthcare professionals; readily available information that includes accurate and up-to-date resources related to medications, patient information, and relevant guidelines; and informal suggestions or encouragement to staff to exercise increased vigilance and attention to detail, which can reinforce a sense of personal responsibility and commitment to safe practices.

Summary

Recognizing the inherent complexities of healthcare and the unavoidable presence of risk, ISMP's Hierarchy of Effectiveness of Risk-Reduction Strategies provides a practical roadmap for navigating the challenging landscape of medication safety. This model guides organizations to prioritize systemic changes and not rely solely on human diligence, fostering meaningful and lasting reductions in preventable errors, while acknowledging the ever-present challenge of achieving a risk-free environment. Implementing layered mitigation strategies based on this hierarchical model is crucial, demanding a balanced combination of high-, medium-, and low-leverage approaches. While the most effective strategies often require systemic changes that can be challenging to implement, they offer the greatest potential for creating a safer environment for patients and providers alike. By embracing this comprehensive approach and continually striving for improvement, healthcare organizations can move closer to the goal of zero preventable errors.

Reference

1) Institute of Medicine (US) Committee on Quality of Health Care in America, Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Human: Building a Safer Health System. National Academies Press (US); 2000.

to search for a drug name using only one to three characters in the pharmacy software or electronic health record (EHR). Listing multiple drugs with names that begin with similar letters increases the risk of a selection error. In a recent case, a prescriber ordered am**LODIP**ine 10 mg. When entering the order into the pharmacy software system, a pharmacy technician typed only the first 2 letters of the drug name and 2 digits of the strength (i.e., 10). Instead of selecting am**LODIP**ine 10 mg from the search results, they selected amiodarone 100 mg which was the first medication on the list. The pharmacist did not catch the mistake and the wrong medication, amiodarone, was dispensed. Thankfully, the patient identified the error, contacted the prescriber and pharmacy, and did not take any of the incorrect medication.

Software system vendors should develop and implement a dynamic search function, an algorithm that allows users to enter the exact number of characters to get only one unique drug name to appear on the screen when searching for medication names. If a dynamic search function is not available, consider requiring entry of a minimum of the first five letters of the drug name. Organizations should build order sets that include the drug's indication and maximize dose range checking to alert wrong drug selection. Prescribers should include the purpose of the medication on the prescription. Pharmacists should clarify orders in which the prescribed drug does not match the indication or appropriate dose.

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

Table 1. Examples of high-, medium-, and low-leverage risk-reduction strategies.

Reliability	Leverage	Risk-Reduction Strategy	Description	Examples
System	High	Forcing Functions	■ Employs procedures or equipment design features that will prevent something from happening until certain conditions are met	■ Build a hard stop in pharmacy software systems to prevent a prescription from being processed without entry of the patient's allergy information ■ ENFit (enteral/oral) and NRFit (neuraxial) syringes that practitioners cannot connect to luer lock intravenous (IV) tubing ports
System	High	Barriers and Fail-Safes	■ Limits access/actions to prevent unintended harm (Barrier) ■ Automatically ensures a safe state in case of malfunction (Fail-Safe)	■ Limit access to controlled substances ■ Limit staff access level to making modifications to data in automated dispensing technology (e.g., robotics) until they have specific training and credentials ■ IV tubing automatically stops flow when removed from infusion pump to prevent free-flow if someone fails to manually close the gravity control clamp
System	High	Automation and Computerization	■ Decreases variability using technology (Automation) ■ Prevents errors and improves communication by linking technologies (Computerization)	■ Utilize barcode scanning to verify that medications are correct during the dispensing process ■ Automatically link the medication and dose prescribed to the appropriate size and type of dosing device
System	Medium	Standardization and Protocols	■ Creation of uniform care models to minimize variation	■ Build standard order sets and order sentences ■ Limit weight documentation to metric units (e.g., g or kg) only ■ Prescribe compounded medications in standard concentrations
System and Human	Medium	Redundancies	■ Provides alternative pathways to prevent harm from a single failure	■ Require the verification of two unique patient identifiers at multiple points during the care process, including at the point of sale ■ Check a patient's vaccine history in state and/or local immunization registries prior to vaccine preparation ■ Open the bag of filled prescriptions with the patient to verify that the medications are correct and for the right patient
System and Human	Medium	Warnings, Alerts, Reminders, Checklists	■ Signals hazards (Warnings and Alerts) ■ Prompts timely action (Reminders) ■ Ensures complete and accurate task execution (Checklist)	■ Build dose range checking to alert for doses outside of usual ranges ■ Build reminders into order sets or protocols if special monitoring is required ■ Use a chemotherapy order review checklist to ensure appropriateness of the chemotherapy regimen that was ordered
Human	Low	Rules and Policies	■ Formal directives governing medication-related activities	■ Organizational policy that outlines what and when patient identifiers are confirmed ■ Organizational policy that outlines who can and what steps are to be taken when refilling automated dispensing technology ■ Organizational policy that outlines who can and how to respond to patient concerns or reports of errors
Human	Low	Educational Programs	■ Structured learning to enhance medication safety competency	■ Initial and annual medication safety competency assessments ■ Use simulation to expose staff to common risks and to teach them to identify and manage the risks ■ Education (e.g., huddles) on new medications and processes
Human	Low	Available Information	■ Resources for informed medication-related decisions	■ Subscription to drug information websites and apps ■ Provide emergency drug dosing information to treat anaphylaxis after vaccination
Human	Low	Suggestions to "Be more careful"	■ Informal reminder to pay closer attention	■ Remind staff not to rush and to always read the medication label