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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

Written by Kara Jensen, PharmD, BCPS; 2025-2026 ISMP Safe Medication Management Fellow, supported by the US Army

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.

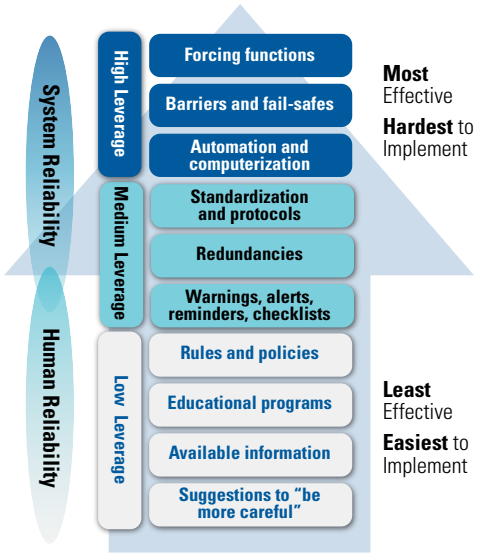

Figure 1. ISMP's Hierarchy of Effectiveness of Risk-Reduction Strategies.

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.

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Your Reports at Work

Shingrix prefilled syringe is coming

By Kara Jensen, PharmD, BCPS

In July 2025, the US Food and Drug Administration (FDA) approved a new formulation of **SHINGRIX** (zoster vaccine recombinant, adjuvanted) in a prefilled syringe by GSK. Unlike the two-vial system that requires reconstitution before use, the prefilled syringe is ready-to-administer. ISMP had been in contact with GSK in the past to lobby for such a product. We have previously written about preparation and administration errors with two-component vaccines that require reconstitution. In these cases, the practitioner used the wrong diluent to reconstitute the lyophilized powder component, or the liquid component alone was administered to the patient. In fact, from August 2024 to August 2025, there were six events reported to the ISMP National Vaccine Errors Reporting Program (ISMP VERP) in which practitioners only administered the adjuvant suspension (liquid component) from the two-component Shingrix formulation. The new Shingrix prefilled syringe formulation aims to mitigate this risk. GSK anticipates discontinuing production of the two-vial system once the prefilled syringe formulation is available.

According to the prescribing information, the prefilled syringe formulation has the same indications as the two-component Shingrix formulation. It is used for the prevention of herpes zoster (shingles) in adults aged 50 years and older, and in adults aged 18 years and older who are at increased risk of shingles due to immunodeficiency or immunosuppression caused by known disease or therapy. The dosing schedule also remains unchanged. Two intramuscular doses are required. After the first dose, a second dose is administered 2 to 6 months

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Urgent Hazard Alert! Broselow Tape Error: Click here to read the full alert issued by ISMP, in collaboration with ASHP and PPA.

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In our June 4, 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.

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Your *Reports* at *Work*

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later. The prefilled syringes must be stored in the refrigerator and protected from light. Once removed from the refrigerator, the prefilled syringe should be used as soon as possible but may be kept for up to 72 hours at room temperature.

We highly recommend switching to this product as soon as it becomes available. Hopefully, vaccine manufacturers are looking at ways to do the same with other two-component vaccines. We sincerely appreciate organizations continuing to report medication and vaccine errors to us so that we can work together to prevent patient harm.

SAFETY brief

Confirm the expiration date on the Abrysvo vial. The Pfizer **ABRYSVO** (respiratory syncytial virus [RSV] vaccine) vial and syringe presentation is supplied in a carton that contains kits. Each kit includes a vial of lyophilized antigen component (powder), a prefilled syringe containing sterile water diluent, and a vial adapter. A pharmacist reported concerns that the expiration date most visible on the kit (**Figure 1**) is NOT the expiration date of the actual vaccine (vial); it is the expiration date printed on the vial adapter. The vaccine vial may expire much sooner (**Figure 2**, page 3). If a pharmacy technician removes the kits from the carton to refill the product in an automated dispensing cabinet (ADC) and enters the expiration date that is printed on the outer label of the kit rather than the expiration date printed on the vial, the ADC will not generate a warning

Figure 1. The expiration date most visible on the Abrysvo kit (9/1/2028) is for the vial adapter and NOT the actual vaccine expiration date.

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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.

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>SAFETY brief

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that the vaccine has expired. If a practitioner does not look at the expiration date on the vaccine vial prior to administration, there is a risk that a patient may receive an expired vaccine.

We have reached out to Pfizer to notify them of this concern. Organizations should develop a plan to ensure that practitioners know where to find the correct vaccine expiration date. The hospital that reported this issue is adding a sticker with the vial's expiration date to the outside of each kit, which is a manual process and not ideal.

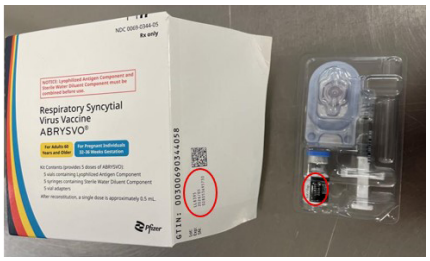

Figure 2. The expiration date of the vaccine found on the Abrysvo outer carton and vial may be much sooner (5/2026) than the expiration date on the kit label (see Figure 1).

Survey on IV workflow management systems - extended deadline

Med Safety Board, an ISMP company, is conducting a survey on the use of intravenous workflow management systems (IVWMS) regarding the adoption, features, and medication safety concerns. We are interested in hearing from you whether IVWMS has been implemented yet or not. Please take 5 to 10 minutes to complete the survey by **January 25, 2026**. Thank you!

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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	▪ ENFit (enteral/oral) and NRFit (neuraxial) syringes that practitioners cannot connect to luer lock intravenous (IV) tubing ports ▪ Build a hard stop in the EHR for vinca alkaloids (e.g., vin**CRIS**tine, vin**BLAS**tine) that does not allow practitioners to modify the IV route
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)	▪ Restrict distribution and storage of certain high-alert medications ▪ IV tubing automatically stops flow when removed from infusion pump to prevent free-flow if someone fails to manually close gravity control clamp ▪ Controlled access using automated dispensing cabinet (ADC) profiles and locked-lidded pockets
System	High	Automation and Computerization	▪ Decreases variability using technology (Automation) ▪ Prevents errors and improves communication by linking technologies (Computerization)	▪ Implement barcode medication administration (BCMA) ▪ Use an intravenous workflow management system (IVWMS) within the pharmacy ▪ Automated data transfer between infusion pump and EHR (interoperability)
System	Medium	Standardization and Protocols	▪ Creation of uniform care models to minimize variation	▪ Establish standard order sets and order sentences ▪ Require weight documented in metric units (e.g., g or kg) only ▪ Dispense compounded medications in standard concentrations
System and Human	Medium	Redundancies	▪ Provides alternative pathways to prevent harm from a single failure	▪ Require an independent double-check before administering a specific high-alert medication ▪ Require the verification of two unique patient identifiers at multiple points during the care process
System and Human	Medium	Warnings, Alerts, Reminders, Checklists	▪ Signals hazards (Warnings and Alerts) ▪ Prompts timely action (Reminders) ▪ Ensures complete and accurate task execution (Checklist)	▪ Soft-stop warnings when exceeding normal medication limits in the smart pump library ▪ Configure interactive ADC alerts that require users to enter or select clinically relevant information (e.g., the purpose for removing a neuromuscular blocking agent [a code situation], and whether the patient is ventilated) prior to removal ▪ Use a chemotherapy order review checklist
Human	Low	Rules and Policies	▪ Formal directives governing medication-related activities	▪ Organizational policy that outlines what and when patient identifiers are confirmed ▪ For institutions where pediatric medication preparations occur infrequently, create a rule requiring all pediatric medication preparations to be independently double-checked by two pharmacy personnel
Human	Low	Educational Programs	▪ Structured learning to enhance medication safety competency	▪ Medication safety orientation for staff during onboarding ▪ Initial and annual competency assessments (e.g., medication administration) ▪ Education (e.g., huddles, newsletter) to review new medication added to formulary
Human	Low	Available information	▪ Resources for informed medication-related decisions	▪ Subscription to drug information websites and apps ▪ Provide emergency drug dosing information on adult and pediatric code carts specific to weight ranges based on the organization's standard concentration(s)
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