

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Speaking up about patient safety requires an observant questioner and a high index of suspicion



Healthcare practitioners are expected to speak up about patient safety concerns to help intercept errors and avoid adverse patient outcomes. By ‘speaking up,’ we mean raising concerns for the benefit of patient safety and quality of care upon recognizing or becoming aware of a risk or a potential risk.¹ Such risks may include concerns about the safety of an order or treatment modality, a possible missed diagnosis, questionable clinical judgment, rule breaking, dangerous shortcuts, incompetence, and disrespect. Healthcare practitioners, especially frontline staff, are well positioned to observe unsafe conditions and bring them to the attention of those who can remediate them.

Speaking up is a behavioral choice under every healthcare practitioners’ control, but this is quite different than simply voicing a suggestion. A practitioner who bravely expresses a patient safety concern may cause the recipient to become defensive and set themselves up for negative repercussions. In deciding whether to speak up, the practitioner typically engages in a deliberate decision process whereby he or she considers both the positive and negative consequences, as well as the anticipated effectiveness and safety of voicing the concern.² It is a balancing act of trying to be proactive and constructive while at the same time considering the possible personal costs of speaking up. As a result, all too often, practitioners will hesitate to voice their concerns, choosing the “safe” response of silence.^{3,4} On the other hand, they may speak up and be ignored or easily convinced that their concerns are unfounded.⁵ Silence and dismissed concerns are especially dangerous types of communication breakdowns.

“Safe” Response of Silence

While there are numerous studies² and anecdotes that demonstrate the positive relationship between speaking up and patient safety, hesitancy to speak up is an important contributing factor in errors and adverse events.¹ Most practitioners, regardless of their position and specialty, have some experience with hesitating to voice a concern related to patient safety, even when they are aware of the risks and their moral obligation to report their concern.^{1,4,6} Silence can be caused by a variety of factors, including fear of reprisal, low perceived effectiveness, low motivation, clinical factors, individual factors, normative and social pressures, lack of confidence, fear of embarrassment if wrong, a disproportionate authority gradient, and many others (**Table 1**, page 2). In fact, raising patient safety concerns may be perceived as a high-risk, low-benefit proposition for many practitioners.^{1,7}

A study conducted with nurses several years ago found that more than half had been in situations where they felt it was unsafe to speak up.⁴ Almost 1 in 5 nurses said they were in this situation at least a few times a month. One in 3 nurses had shared concerns with their coworkers about dangerous shortcuts they had observed, and only 1 in 4 had confronted a previously disrespectful colleague to share their patient safety concerns. Although nurses in the study were more likely to take their safety concerns to their managers than to speak directly to the practitioner, fewer than half of these managers followed through and spoke up about the reported safety issue; thus, taking safety concerns to a manager may not produce reliable results.

continued on page 2 — [Speaking up](#) >

SAFETY briefs



“Insulin” should be easier to distinguish on Myxredlin labels.

We were pleased to learn earlier this year that Baxter would manufacture a new premixed insulin product, **MYXREDLIN** (insulin, human) 100 units per 100 mL (1 unit per mL). The product, which became available last month, has a shelf life of 30 days at room temperature or 24 months if refrigerated in the carton to protect it from light. Since preparing intravenous (IV) infusions can lead to potentially harmful compounding errors, the **ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations** call for the use of commercially prepared, premixed parenteral products to the maximum extent possible versus manually compounded sterile products. This is especially important for admixtures containing high-alert medications such as insulin. The availability of premixed insulin solutions can avoid potentially devastating errors.

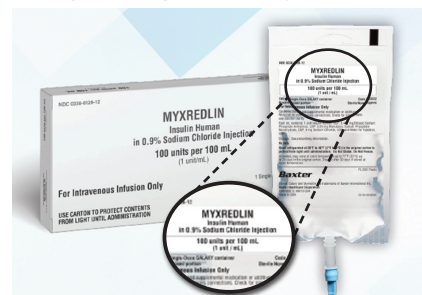


Figure 1. Commercially available premixed insulin (Myxredlin, 100 units per 100 mL) is now available from Baxter. To prevent confusion with other 100 mL minibags, the generic name, insulin, needs to be more prominent.

For example, we received an error report in which an experienced nurse failed to notice that a graduate nurse had drawn 10 mL of insulin from a 10 mL vial of 100 units per mL (1,000 units) into a 10 mL syringe, instead of 1 mL (100 units) drawn into an insulin syringe. That amount was then added to a 100 mL bag of 0.9% sodium chloride to prepare an infusion (the preparation mistakenly had a concentration of 10 units per mL instead of 1 unit per mL). A similar report described a

continued on page 2 — [SAFETY briefs](#) >

> **Speaking up** — continued from page 1

Table 1. Influencing Factors that Reduce and Enable Speaking Up Behaviors^{1-4,6,7}

Influencing Factors	Factors that Reduce Speaking Up Behaviors	Factors that Enable Speaking Up Behaviors
Perceived effectiveness of speaking up	<ul style="list-style-type: none"> ■ Lack of response and impact □ Ignoring practitioner concerns □ Sweeping concerns under the rug □ No improvement in safety ■ Lack of managerial support ■ Lack of transparency and follow-up 	<ul style="list-style-type: none"> ■ Receptiveness and impact □ Listening to and valuing concerns □ Acting on practitioner concerns ■ Active managerial/leadership support/approachability ■ Providing feedback about reported concerns, safety data to units
Motivation to speak up	<ul style="list-style-type: none"> ■ Low index of suspicion ■ Low perceived patient harm ■ Feeling of helplessness, intimidation ■ Tolerance of risk ■ No social motivation to speak up ■ Belief that speaking up is an annoyance 	<ul style="list-style-type: none"> ■ High index of suspicion ■ High perceived patient harm ■ Empowered to voice concerns ■ Fierce intolerance of risk ■ Coworkers, leaders encourage and model speaking up behavior ■ Belief that speaking up is a moral obligation
Clinical factors	<ul style="list-style-type: none"> ■ Ambiguity of the clinical situation ■ Uncertainty about patient harm 	<ul style="list-style-type: none"> ■ Clarity of the clinical situation ■ Perceived risk of patient harm
Individual factors	<ul style="list-style-type: none"> ■ Distracted ■ Prior repercussions ■ Prior experiences with disrespect ■ Inadequate coping skills ■ Unassertive □ Diffident cultural background ■ Insufficient knowledge and skills ■ Low confidence, prior unfavorable experiences ■ Fear of damaging collegial relationships ■ Adaptive conformer (see Table 2) 	<ul style="list-style-type: none"> ■ Keen situational awareness ■ Joy in work, job satisfaction ■ Feels responsibility towards patients ■ Assertive ■ Knowledge of human factors ■ Understanding of best practices ■ Good interpersonal communication skills ■ High confidence, prior favorable experiences ■ Trusting collegial relationships ■ Observant questioner (see Table 2)
General contextual factors	<ul style="list-style-type: none"> ■ Feeling rushed ■ Cumbersome reporting process ■ Lack of teamwork ■ No input into policy making ■ No policy to speak up ■ No established procedure for resolving conflicts about safety 	<ul style="list-style-type: none"> ■ Adequate time to consider potential errors ■ Streamlined reporting process ■ Effective teamwork ■ Interdisciplinary policy making ■ Organizational edict to speak up ■ Clear procedure for resolving conflicts about safety not dependent on hierarchical structures (www.ismp.org/node/868) ■ Speaking up included in performance reviews
Perceived safety of speaking up	<ul style="list-style-type: none"> ■ Psychologically unsafe work environment □ Culture of blame, reprisal □ Fear of appearing incompetent □ Prior negative outcomes ■ Presence of an audience (e.g., patient) ■ Lack of manager/coworker coaching before, and support after, speaking up 	<ul style="list-style-type: none"> ■ Psychologically safe work environment □ Fair and just culture, culture of safety □ Leadership approachable and visible □ Certainty about the positive consequences of speaking up ■ Privacy when speaking up ■ Managers/coworkers offer coaching and advice before, and support after, speaking up
Tools and training	<ul style="list-style-type: none"> ■ No formal training on: <ul style="list-style-type: none"> □ Patient safety theory □ Effective communication strategies □ Working in teams ■ No tools provided to help gather and communicate critical concerns 	<ul style="list-style-type: none"> ■ Formal training provided in regular intervals (e.g., patient safety theory, crew resource management, TeamSTEPPS) ■ Having a speaking up rubric (e.g., SBAR) or structured communication technique (e.g., critical language) <ul style="list-style-type: none"> □ Established opportunities for speaking up (e.g., surgical time outs, SBAR handoffs)
Measurement	<ul style="list-style-type: none"> ■ No aggregation or analysis of voiced concerns 	<ul style="list-style-type: none"> ■ Measures the frequency of voiced safety concerns, responses, impact on the messenger and others, and outcomes ■ Uses these measures for improvement

continued on page 3 — **Speaking up** >

> **SAFETY** briefs cont'd from page 1

pharmacist mistakenly preparing an insulin infusion in a 10 units per mL concentration instead of the intended 1 unit per mL concentration (www.ismp.org/ext/310).

Myxredlin (pronounced myx RED lin) is an important new product, but it would benefit from improved container labeling (**Figure 1**, page 1). No incidents have been reported to ISMP, but concerns about confusion with other Baxter minibag products have been raised. For example, one reporter was concerned about confusing Myxredlin with an antibiotic, which could lead to infusing the insulin over 30 minutes, as IV piggyback antibiotics frequently are administered.

The nonproprietary name, insulin human, should be easier to distinguish on the label. Currently, it is not highly visible on the bag in comparison to the brand name, which may increase the risk of confusing it with other premixed drugs in minibags. The use of color on the label might also help differentiate it from other drugs in minibags.

We have contacted Baxter to suggest using a larger font size for the nonproprietary name than the brand name. Although federal regulations (CFR 201.10) specify that the established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name, the regulation doesn't appear to restrict a larger type size. For now, consider adding an auxiliary warning, such as "contains insulin," to help identify Myxredlin as insulin. Since storing the product in its carton is recommended to protect it from light, such storage will also help with correct product identification because the carton label is easier to read. If a labeled infusion bag is dispensed from the pharmacy after being removed from the carton, specify the beyond-use date. And, as we often mention, barcode scanning at the bedside can help prevent container mix-ups, but only if scanning consistently happens. Both the bag and carton are barcoded.



Hepatitis C vial contamination despite using sterile needles and syringes.

A study published last month in *Anesthesiology* suggested an interesting alternative theory on how healthcare-acquired hepatitis C infections may be transmitted

continued on page 3 — **SAFETY** briefs >

> **Speaking up** — continued from page 2

Several studies have identified the factors that influence and enable practitioners to voice their patient safety concerns (summarized in **Table 1**, page 2).^{1-4,6,7} For example, many studies emphasized the importance of:

- 1) The perceived effectiveness of speaking up, such as managerial/leadership support/approachability and feedback
- 2) Motivation to speak up, such as a high index of suspicion, a high perceived risk, and clarity of the situation
- 3) Individual factors, such as job satisfaction, situational awareness, confidence, and communication skills
- 4) Contextual factors, such as effective teamwork and a nonhierarchical process for resolving conflicts
- 5) Perceived safety of speaking up, such as a psychologically safe work environment and managerial/coworker support
- 6) Tools and training, including a standardized rubric for speaking up (e.g., SBAR [situation, background, assessment, recommendation])
- 7) Measurement of the frequency, responses, and outcomes of voiced safety concerns

Awareness of the factors that influence and enable speaking up behaviors can help leaders create a workforce who can candidly and effectively discuss their patient safety concerns without fear. The goal is to help practitioners feel comfortable and competent with being an **observant questioner** who speaks up about patient safety concerns, not an **adaptive conformer** who quietly remains silent (**Table 2**).⁸

continued on page 4 — **Speaking up** >

Table 2. Adaptive Conformer vs. Observant Questioner⁸

Worker Faces	Adaptive Conformer (undesired)	Observant Questioner (desired)
Obstacles	Adjusts, improvises without bothering managers or others; fixes it and forgets it (www.ismp.org/node/254)	Noisy complainer: Remedies immediate situation but also lets managers and others know when the system has failed
Others' risky behaviors (e.g., dangerous shortcuts)	Does not intervene; if it is clear the patient is at risk of serious harm, may report it to a manager	Eager coach: Coaches peers and others to see the risk associated with their behavioral choice, regardless of actual harm, and suggests a safer choice; reports the behavior for learning purposes only
Own risky behaviors	Rationalizes their behavioral choice to cut corners as required under the circumstances; does not report the behavior	Concerned drifter: Lets manager and others know that they have drifted away from the way processes are designed, and reports the underlying (often system-based) causes so they can be remedied
Potentially unsafe orders	Defers to experts and gives the prescriber the benefit of the doubt; does not clarify the order unless it is clear that a mistake has been made	Persistent clarifier: Makes no assumptions and clarifies all potentially unsafe orders with the prescriber
Others' errors	Seamlessly corrects errors of others, without confronting them	Curious interrupter: Asks what others are doing and lets others know they have made a mistake, for learning purposes only
Own errors	Creates an impression of never making errors	Self-aware error maker: Lets manager and others know they have made a mistake so everyone can learn; communicates openness to hearing about his or her own errors discovered by others
Subtle opportunities for improvement	Understands the "way things work around here"	Disruptive questioner: Asks: Why do we do things this way? Is there a better way of providing care?

Adapted from Tucker & Edmondson⁸

> **SAFETY** briefs cont'd from page 2

between patients—not through the reuse of needles or syringes when accessing vials for multiple patients, but through inadvertent contamination of the vial diaphragm followed by access with a *sterile needle and syringe* (van Vlymen JM, Magnus J, Jaeger M, et al. Hepatitis C contamination of medication vials accessed with sterile needles and syringes. *Anesthesiology*. 2019;131(2):305-14).

The study examined this theory in anesthesia environments after the means of contamination with several patient-to-patient hepatitis C outbreaks could not be explained. In their investigation of a potential source for the transmission, all anesthesia staff and other practitioners claimed to have used *sterile needles and syringes* for each patient. In other studies, inadvertent contamination of anesthesia workspaces (e.g., anesthesia machine surfaces, anesthesia carts, the outer surfaces of syringes, injection ports) has been demonstrated, and the hepatitis C virus has been shown to remain infectious for up to 6 weeks at room temperature on inanimate surfaces. Thus, the authors tested if hepatitis C virus can be transferred via a *sterile needle and syringe* if a vial diaphragm is contaminated; if hepatitis C virus remains viable in medications; and if cleaning with 70% isopropyl alcohol eliminates the transmission risk.

The authors were able to demonstrate that, when caring for hepatitis C virus–infected patients, practitioners may inadvertently contaminate a medication vial diaphragm, and that subsequent access with *sterile needles and syringes* can transfer hepatitis C virus into the medication, where it remains stable for at least 72 hours in sufficient quantities to infect subsequent patients. The medications that were examined included: dexamethasone, lidocaine with methylparaben as a preservative, neostigmine, phenylephrine, propofol, rocuronium, and normal saline. The most unsettling observation may be that wiping the diaphragm with an alcohol swab was insufficient to eliminate hepatitis C virus infectivity. No differences were observed if the alcohol was allowed to dry before vial access.

While further research into this novel theory of patient-to-patient hepatitis C transmission is needed, this risk could be eliminated by

continued on page 4 — **SAFETY** briefs >

> **Speaking up** — continued from page 3

Dismissed Concerns

When a practitioner voices a concern, there may be an explanation from competent practitioners that dispels the initial concern too quickly, before it has been given sufficient consideration. A pharmacist reassures a technician that the compounding directions are correct when questioned about an unusual volume of ingredients; a pharmacist assures a nurse that the strength of an infusion is correct when questioned about the final volume; a nurse reassures a patient that the medication is correct when questioned about its appearance; a physician convinces a pharmacist that the prescribed dose is correct when questioned because it differs from what he found during investigation. These are real, all-too-frequent examples of backing away from an initial concern that subsequently led to fatal adverse drug events. Those who questioned the patients' care were easily convinced that others knew more than they did, particularly if the provider who was questioned had an otherwise stellar reputation.

Is this a form of intimidation? Perhaps, but it may be more akin to a logical deference to expertise, meaning it is natural and often reasonable for people to defer final judgment to those they perceive to be more "qualified." The person questioning the patient's care has been easily convinced that their concern is unfounded, and the person being questioned has not perceived the voiced concern as a possible, credible patient threat. Neither the questioner nor the person being questioned possess a required element to safeguard patients: an appropriately high index of suspicion for errors. A low index of suspicion is particularly problematic in a healthcare system that is often reluctant to acknowledge human error or value the contributions from every person, regardless of rank, who interacts with the patient.

An *index of suspicion* is defined as "awareness and concern for potentially serious underlying and unseen injuries or illness."⁹ *Suspicion* is defined as "the act or an instance of suspecting something wrong without proof or on slight evidence, or a state of mental uneasiness and uncertainty."¹⁰ A high index of suspicion requires consideration of a large differential so that a serious possibility is not accidentally discounted; a potential medical error should always be considered one of the possibilities. An appropriately high index of suspicion should lead a person with a concern to pursue it until it's *proven* to not be a credible patient threat, even when met with opposition from experts. It should also prompt the provider to be responsive to voiced concerns and to initiate a suitable investigation to determine if there is a credible threat to the patient.

ISMP has previously discussed the need to maintain a high index of suspicion for errors in our newsletters, including an article about *mindfulness*, a defining characteristic of organizations with highly reliable outcomes.¹¹ *Mindfulness* refers to the deep and chronic sense of unease and preoccupation with failure that arises from admitting the possibility of error, even with well-designed, stable processes. People in organizations with highly reliable outcomes worry about system failures and human errors. They ask, "What will happen when an error occurs?" not "What will happen if an error occurs?" They are wary of complacency and naturally suspicious, so they expect people to speak up

Table 3. Examples of "Red Flag" Responses to Voiced Concerns

That will never happen here
That doesn't apply to me (us)
The patient says that's how he takes it at home
It's just a nuisance alert; it alarms all the time
That's the way we always do it
This is how we get the work done here
Everyone else is doing the same thing
No one ever says anything, so it can't be too wrong
Just do it
You must be new here; I've been doing this for years
It's not your job to question that

continued on page 5 — **Speaking up** >

> **SAFETY** briefs cont'd from page 3

never using a medication vial, including a multidose vial, for more than one patient. According to the Centers for Disease Control and Prevention (CDC), providers should "dedicate multidose vials to a single patient whenever possible. If multidose vials are used for more than one patient, withdraw patient specific doses in a centralized medication area and do not bring the multidose vial into the immediate patient treatment area (e.g., operating room)." The authors note that, while a remote medication preparation area may be possible in most areas, it does not always exist in the operating room (OR). Thus, they call for the use of pharmacy-prepared, single-dose syringes and elimination of multidose vials. They also call on the pharmaceutical industry to package medications in single-patient doses. Frequent hand hygiene, better environmental cleaning between cases, and removal of all used syringes and vials from the OR at the end of a case are additional strategies.



Oral or ENFit syringe availability in clinical areas.

A 55-year-old hospitalized woman was prescribed oral oxyCODONE liquid, 2.5 mg per 2.5 mL for pain. This strength was available in the nursing unit's automated dispensing cabinet (ADC) in a unit dose cup containing 5 mg in 5 mL. The patient's nurse drew up the 2.5 mg dose from the cup using a parenteral syringe because no oral or ENFit syringe was available for dose preparation. The parenteral syringe was brought to the bedside for administration, but the nurse became distracted and attached the syringe to an intravenous (IV) access port and injected it. Fortunately, no harm was reported, but similar errors involving inadvertent IV administration of oral suspensions and other liquids have resulted in serious patient harm and even death.

We mention this incident because we want you to ensure that oral syringes or ENFit devices exist wherever oral liquids might be prepared and administered in clinical areas. Providing medications to patient units in the most ready-to-use form minimizes the need for nurses to prepare patient doses. Still, even though unit dose liquids are dispensed to nurses for patient use or stored in ADCs, there will still be occasional situations where exact doses aren't available and thus require dose preparation in clinical areas. The case above is a good illustration.

> **Speaking up** — continued from page 4

about any concerns they may have. Their high index of suspicion is a predominant factor in achieving laudable safety records. Furthermore, position and experience do not necessarily dictate who is an important contributor or decision maker.

To diminish unconvincing threats, healthcare needs to raise the index of suspicion for errors, always anticipating and investigating the possibility when any person, regardless of experience or position, voices concern, or when patients are not responding to treatment as anticipated. Staff need to be trained and mentored to resolve potential concerns and to trust in their own experiences to augment the expertise of others. All healthcare practitioners need to encourage, and be receptive to, practitioners who ask questions, even if they just have a sense that “something” is wrong or can’t articulate the concern well. When concerns are met with quick responses that initially appear to be “evidence” of safety (**Table 3**, page 4), caution is recommended. These quick responses should be viewed as “red flags” that require more reliable answers and actual proof.

Conclusion

ISMP is not discounting the fact that many complex factors influence whether healthcare practitioners speak up about patient safety concerns. We also do not discount the extraordinary courage it may take for many to step up to these conversations. However, tolerance of risk that goes unchallenged is a serious patient safety concern, and to combat that, all who interact with patients must become an observant questioner and raise their index of suspicion of errors. Healthcare practitioners need to ensure that patient safety concerns are not only raised but also properly investigated and addressed. You can be sure that those involved in serious and fatal errors wish that they had taken the opportunity to do just that.

References

- 1) Okuyama A, Wagner C, Bijnen B. Speaking up for patient safety by hospital-based health care professionals: a literature review. *BMC Health Serv Res*. 2014;14:61.
- 2) Nacioglu A. As a critical behavior to improve quality and patient safety in health care: speaking up! *Safety in Health*. 2016;2(10):1-25. www.ismp.org/ext/314
- 3) Morrison EW, Milliken FJ. Speaking up, remaining silent: the dynamics of voice and silence in organizations. *J Manage Stud*. 2003;40(6):1353-8.
- 4) Maxfield D, Grenny J, Lavandero R, Groah L. The silent treatment: why safety tools and checklists aren’t enough to save lives. Report: VitalSmarts, AORN, AACN. www.ismp.org/ext/312
- 5) Institute for Safe Medication Practices (ISMP). Raising the index of suspicion: red flags that represent credible threats to patient safety. *ISMP Medication Safety Alert!* 2012;17(15):1-3.
- 6) Lyndon A, Sexton JB, Simpson KR, Rosenstein A, Lee KA, Wachter RM. Predictors of likelihood of speaking up about safety concerns in labour and delivery. *BMJ Qual Saf*. 2012;21(9):791-9.
- 7) Attree M. Factors influencing nurses’ decisions to raise concerns about care quality. *J Nurs Manag*. 2007;15(4):392-402.
- 8) Tucker AL, Edmondson AC. Why hospitals don’t learn from failures: organizational and psychological dynamics that inhibit system change. *Calif Manage Rev*. 2003;45(2):55-72.
- 9) Pollak, AN, ed. *Emergency Care and Transportation of the Sick and Injured*, 10th ed. Sudbury, MA: Jones and Bartlett Publishers; 2011.
- 10) Merriam-Webster. Online dictionary. www.merriam-webster.com/dictionary/suspicion
- 11) ISMP. Safety requires a state of mindfulness (part I). *ISMP Medication Safety Alert!* 2006;11(5):1-2.

If you would like to subscribe to this newsletter, visit: www.ismp.org/node/10



ISMP Medication Safety Alert! Acute Care (ISSN 1550-6312) © 2019 Institute for Safe Medication Practices (ISMP). Subscribers are granted permission to redistribute the newsletter or reproduce its contents within their practice site or facility only. Other reproduction, including posting on a public-access website, is prohibited without written permission from ISMP. This is a peer reviewed publication.

Report medication and vaccine errors to ISMP: Please call 1-800-FAILSAFE, or visit our website at www.ismp.org/MERP or www.ismp.org/VERP. ISMP guarantees the confidentiality of information received and respects the reporters’ wishes regarding the level of detail included in publications.

Editors: Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Ann Shastay, MSN, RN, AOCN; Russell Jenkins, MD; Ronald S. Litman, DO, ML. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.

Special Announcements

Get intensive about medication safety

Don’t miss our last *Medication Safety Intensive* (MSI) workshop of the year being held in Las Vegas, NV, on **December 6-7!** You won’t want to miss this unique opportunity to maximize your error prevention efforts and learn to look at your organization through the eyes of leading safety experts. For information and to register, visit: www.ismp.org/node/127.

Attend ISMP program at CSHP meeting

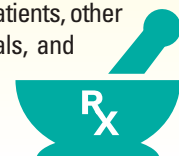
If you are going to the *California Society of Health-System Pharmacists* conference in Anaheim, it’s not too late to register for a **FREE** ISMP breakfast seminar on **October 18** on *Improving Intravenous Drug Delivery Safety*, which is supported by Fresenius Kabi. Program speakers will discuss the primary safety issues, at-risk behaviors, and ISMP guidelines and best practices associated with intravenous (IV) drug therapy. For more information and to register, visit: www.ismp.org/node/1482.

FREE FDA webinar series


The US Food and Drug Administration’s (FDA) Division of Drug Information is presenting a **FREE** webinar, *FDA Drug Topics: FDA Oncology Center of Excellence’s Project Facilitate: An Overview of the Oncology Expanded Access Program*, on **October 29**. Continuing education credit is available. For details, visit: www.ismp.org/ext/30, and to register, visit: www.ismp.org/ext/31.

Join ISMP in celebrating **National Pharmacy Week** from **October 20-26, 2019!**


National Pharmacy Week is a time to recognize the significant contributions pharmacists and pharmacy technicians make to patient care in hospitals, clinics, and other settings, along with their leadership in ensuring that patients receive optimal outcomes from their medications. Use the tools at www.ismp.org/ext/313 to highlight your organization’s pharmacy team and share their work with patients, other healthcare professionals, and the community.





ISMP Medication Safety Alert!® ActionAgenda



 One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, the following selected items from the **July – September 2019** issues of the *ISMP Medication Safety Alert!* have been prepared for leadership to use with an interdisciplinary committee or with frontline staff to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue number to locate additional information. Look for our high-alert medication icon under the issue number if the agenda item involves one or more medications on the *ISMP List of High-Alert Medications* (www.ismp.org/node/103). The Action Agenda is also available for download in a Microsoft Word and Excel format (www.ismp.org/node/12694) that allows expansion of the columns in the table designated for organizational documentation of an assessment, actions required, and assignments for each agenda item. Continuing education credit is available for nurses at: www.ismp.org/nursing-ce.

Key:  — ISMP high-alert medication

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Unintentional 1,000-fold zinc overdose when transposing mcg and mg dosing units					
(13)	When prescribing parenteral nutrition (PN) for a child, a physician ordered 700 <u>mg</u> instead of 700 <u>mcg</u> of zinc. The PN template defaulted to <u>mg</u> dosing units, which could not be changed to <u>mcg</u> had the physician noticed the error. Two pharmacists verified the order but failed to notice the error. A dose warning was not issued until transmitting the order to an outsourcer, but it was overlooked. A pharmacist noticed the error while compounding the PN.	Ensure that a warning with a hard stop for critical zinc overdoses (e.g., above 250 mcg/kg) appears in order entry systems. Default to <u>mcg</u> dosing units for zinc in pediatric PN templates and ensure that this corresponds to the way orders are entered in automated compounders. Conduct effective order verification processes in the pharmacy. Validate the competencies of staff who order, transcribe, verify, and compound PN.			
Mix-ups continue between PROLIA (denosumab; Amgen) and UDENYCA (pegfilgrastim-cbqv; Coherus BioSciences)					
(10, 14, 17)	Mix-ups continue between subcutaneous Prolia and Udenyca. Both syringes are packaged in similar green and white cartons, with the concentration listed in a green circle, and may be stored near each other in the refrigerator. The most recent errors, administration of Udenyca instead of Prolia, resulted in patient harm.	Store these products away from one another and verify the medications via barcode scanning prior to dispensing and administration. Apply prominent auxiliary labels to the outer cartons that warn against confusion. Staff may also circle the product names on the cartons using a permanent marker to draw attention to them.			
Mix-up between methotrexate and metOLazone					
(18) 	A patient died after receiving daily methotrexate for a month instead of metOLazone. A common cause of drug name mix-ups is searching by just the first few letter characters, which presents multiple look-alike drug names on the screen. In this case, the first three letters are the same (M-E-T), and both are available in 2.5 and 5 mg tablet strengths.	Use at least 5 letters (see ISMP Guidelines for Safe Electronic Communication of Medication Information , www.ismp.org/node/1322) to reduce the number of different drugs that appear on a screen during a search. Use tall man letters for met OL azone. Employ a hard stop in order entry systems to avoid daily methotrexate orders without an appropriate cancer indication.			

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
IV push Gap Analysis Tool (GAT) helps uncover national priorities for safe injection practices					
(17)	Results from ISMP's IV push GAT (www.ismp.org/node/1188) reveal low scores for many of the best practices in the ISMP Safe Practice Guidelines for Adult IV Push Medications (www.ismp.org/node/97), including: dispensing IV push medications in a ready-to-administer form; NOT diluting or reconstituting IV push medications in a saline flush syringe; permitting emergency administration of rescue agents per protocols/orders; administering IV push medications and flushes at the recommended rate; and barcode scanning of flush syringes.	Review the results of the IV push GAT, particularly the 10 national priorities for safe injection practices related to the lowest scoring best practices (www.ismp.org/node/11496). Assess your organization's compliance with these practices and determine an actionable plan to address any gaps in the safe use of IV push medications in your organization.			
Confusion between FIASP and NOVOLOG (both formulations of insulin aspart by Novo Nordisk), which have different onsets of action					
(15) 	NovoLOG and Fiasp are both formulations of insulin aspart but they are not substitutable. Fiasp contains niacinamide to increase the speed of absorption and is given at the start of a meal or within 20 minutes afterwards. NovoLOG is given 5-10 minutes before a meal. Confusion has led to dispensing errors if the brand name is not on the prescription. In one case, a physician selected Fiasp but the system sent an insulin aspart prescription to the pharmacy; NovoLOG was dispensed.	If Fiasp is intended, prescribers should include the brand name on the prescription. Electronic order systems should communicate the brand name if selected by the prescriber instead of only including the generic name. Practitioners (particularly pharmacists) should confirm the brand name if it isn't specified on the prescription. Also, patients should be made aware of the intended product and check the drug they receive from a retail pharmacy.			
Fatal error due to PAXIL (PARoxetine) and TREXALL (methotrexate) sound-alike names					
(14) 	A prescription for Paxil 10 mg daily was called into a pharmacy. Pharmacy staff likely misheard the drug name and dispensed Trexall 10 mg tablets with directions to take 1 tablet daily. The patient thought Trexall (on the pharmacy label) was the new antidepressant she was expecting. Seven days later, she was hospitalized and died.	Order entry systems should default to a <u>weekly</u> oral methotrexate dose; any daily orders should cause a hard stop. All patients filling methotrexate prescriptions should be counseled. A consumer learning guide for oral methotrexate from ISMP is freely available (www.ismp.org/ext/290).			

© 2019 ISMP

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Ring that remains after removing tamper-evident cap may fall off					
(18)	Some pharmacies use tamper-evident caps for medication syringes. When the caps are removed, a plastic ring remains on the end of the syringe. The ring can fall off or be a choking hazard if left at the bedside. During an abdominal procedure, the plastic ring from a ceFAZolin syringe fell off into an irrigation solution but was noticed before intra-abdominal irrigation.	The cap manufacturer, International Medical Industries, recommends discarding the ring after removing the cap and before administering the medication. Remind nurses and other providers who use these products about the hazards of a fallen ring and to remove and properly dispose of the ring prior to using/administering the syringe contents.			
Dangerous Alvogen look-alike products					
(15) 	Complaints continue to be reported about look-alike labeling of Alvogen vials, including rocuronium, metoprolol, tranexamic acid, deferoxamine mesylate, dexrazoxane, midazolam, labetalol, vancomycin, and ketorolac. All have carton and vial labels with the same distinct yellow background. Mix-ups could lead to patient harm.	Purchase these medications from different manufacturers when possible. Affixing auxiliary labels may also help prevent mix-ups. ISMP has repeatedly alerted the company to these complaints, but no information has been provided about addressing the issue. ISMP has also contacted the US Food and Drug Administration (FDA) about the situation.			
Mix-up between insulin and tranexamic acid					
(16) 	Two reports of mix-ups between 100 mL look-alike bags of insulin and tranexamic acid were reported in the operating room (OR), where barcode scanning was not used. The bags had similar white pharmacy labels with very small text. The wrong product was administered to both patients, who recovered after receiving IV dextrose.	Barcode scanning in the pharmacy prior to dispensing and in the OR prior to administration could prevent these errors. Also consider applying auxiliary labels to pharmacy-prepared IV bags that look similar to help identify their contents.			
Mix-ups between concentrations of Dr. Reddy's levETIRAcetam premixed bags					
(17)	Dr. Reddy's premixed bags of levETIRAcetam 1,000 mg per 100 mL (10 mg/mL) and 500 mg per 100 mL (5 mg/mL) were erroneously mixed together in the pharmacy storage bins. The different strength bags look nearly identical, and concentrations appear in very small print.	Purchase premixed bags of levETIRAcetam from different manufacturers with better labeling. If you use Dr. Reddy's products, store the bags apart from each other, place prominent warning labels in the storage areas, affix auxiliary labels, and use barcode scanning before dispensing and administration.			

© 2019 ISMP

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Mix-up between look-alike bottles (from Medisca) of phenol and flexible collodion leads to phenol-related burn					
(17)	A surgeon was accidentally handed a bottle of liquified phenol (89%) that was stored near the requested bottle of flexible collodion skin adhesive needed to close a surgical wound. Both 100 mL bottles are dark amber with white caps and have almost identical-looking green and white labels. The surgeon applied phenol to the wound, which resulted in burns that required extensive irrigation.	If phenol is stored in your facility, determine why it is being used and whether alternatives are plausible (e.g., prepackaged phenol applicators, which contain a small amount of phenol for procedures). If bulk bottles of liquid phenol must be used, store them in the pharmacy and repackage in small applicator bottles with auxiliary label warnings to dispense to areas outside of the pharmacy.			
New recommendations to improve drug allergy capture and clinical decision support (CDS)					
(14)	Timely access to accurate drug allergy information is critical to avoid harmful adverse reactions. But how allergy information is gathered, documented, communicated, and used remains a challenge. The process is increasingly influenced by CDS tools such as alerts. However, excessive alerting has led to high override rates, and appropriate alerts are not being triggered because allergy information has not been documented properly. Thus, drug allergy events continue to occur.	Standardize documentation of drug allergy information to aid in triggering alerts based on criticality and necessity. To reduce unnecessary alerts and increase attention to high-severity alerts, develop alert tiering based on severity and clinical relevance. Employ technology to track allergy alerts and override rates, and make improvements as necessary. Develop and use patient-facing technologies (e.g., patient portals) so patients can communicate their allergy information. For details, visit: www.ismp.org/ext/282 .			
Mix-ups with rifAMPin and rifAXIMin					
(13)	During a telephone consultation, a physician misheard rifAXIMin and prescribed rifAMPin 550 mg IV. Due to the unusual dose, a pharmacist questioned the order, but the physician confirmed it. The next day, the pharmacist learned the patient had hepatic encephalopathy and that the intended drug was rifAXIMin. Brand and generic name mix-ups are possible with all the rifamycin antibiotics.	Practitioners should familiarize themselves with various dosing parameters and indications for all rifamycin antibiotics. Pharmacists should persist in clarifying unusual orders that do not match the usual indications or doses.			

© 2019 ISMP