

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

High-Alert Medication List...only effective when combined with risk-reduction strategies

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients. This is borne out repeatedly by reports submitted to the **ISMP National Medication Errors Reporting Program** (ISMP MERP).

Based on error reports submitted to the ISMP MERP, reports of harmful errors in the literature, and input from practitioners and safety experts, ISMP established lists of high-alert medications used in various healthcare settings, including community/ambulatory care. The original **ISMP List of High-Alert Medications in Community/Ambulatory Care Settings** was developed in 2008. To update the list, practitioners were surveyed. To assure its relevance and completeness, the clinical staff at ISMP, members of the **ISMP Medication Safety Alert! Community/Ambulatory Care Clinical Advisory Board**, and safety experts throughout the US were asked to review the list, including proposed additions to the list, and provide us with feedback and suggestions about any changes. The updated 2021 list can be found on **page 5** of this newsletter and on our website (www.ismp.org/node/129), and reflects the collective thinking of all who provided input.

ISMP is relying on community and ambulatory care settings to use this updated list as a resource to identify the high-alert medications prescribed, stored, dispensed, and/or administered in their organizations or the facilities they serve. However, this is just the first step in safeguarding the use of high-alert medications. Without highly effective processes for staff to follow to detect and prevent errors, a list will do little to increase medication safety. Similarly, a list of high-alert medications and related risk-reduction strategies that are not well known and understood by all staff will have little impact on safety.

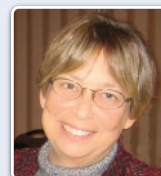
Implement Risk-Reduction Strategies

The purpose of identifying high-alert medications is to establish specific safeguards to reduce the risk of harm with these drugs in all phases of the medication-use process. Strategies should: 1) eliminate or prevent the errors, 2) make the errors visible, and/or 3) mitigate the harm from errors when they occur. To be effective, all of the following components need to be considered:

Understand the causes of errors. Effective strategies must address the underlying system-based causes of errors with each type of high-alert medication or class of medications. To learn about the causes of errors, review internal medication error-reporting data and the results of any applicable root cause analyses. Equally important, a search of the external literature, including this newsletter, should be completed to learn about errors with high-alert medications that have occurred elsewhere. Taking the step to understand the causes of errors in your facility should not be skipped. If you cannot describe the ways that errors have happened or could happen, your strategies may not be effective at targeting the risks within your organization.

continued on page 2 — [High-alert](#) >

*In loving memory of Hedy Cohen...
a mentor and dear friend who was
passionate about medication safety*



The ISMP family experienced a profound loss earlier this month when Hedy Cohen died on Sunday, September 19, 2021, after a long period of declining health. Hedy was the wife of Michael Cohen, President of ISMP, and the mother of Rachel Cohen (Brown) and Jennifer (Cohen) Gold, both of whom hold positions at ISMP. Hedy shared her husband's passion for medication safety and helped him found the nonprofit ISMP, tirelessly volunteering for several years before settling into a full-time position. A nurse by background, she quickly recognized the importance of an interdisciplinary approach to medication safety and promoted the important role that nurses need to play. During her tenure at ISMP, she was passionate about the need to train and mentor the next generation of medication safety leaders, often directly teaching and coaching students, residents, fellows, and novices in medication safety, and always supporting and cheering their rise in the medication safety world. She was a frequent speaker on current issues in medication safety, the author of many articles and book chapters on the subject, and an editor for the ISMP newsletters.

Words alone cannot express what Hedy has meant to the ISMP family and colleagues who knew her. We have lost a dear friend and an amazing person, but we were all blessed to have her touch our lives. We will always cherish the memories of her smile, laughter, unique sense of humor, and genuine desire to make medication use safer. Hedy's guiding hand will always sit on the shoulder of ISMP. Contributions in her memory can be made to ISMP (www.ismp.org/support/donate) or to a charity of the donor's choice.

> **High-alert** — continued from page 1

Layer comprehensive strategies. A single risk-reduction strategy for each high-alert medication is rarely enough to prevent harmful errors. The keys to success include many of the following components:

- A variety of risk-reduction strategies should be used simultaneously to reduce the risks associated with a particular high-alert drug. David Marx, a culture and system reliability expert, likens the relative safety of a system to a dice game—with each dice representing a risk-reduction strategy in the layer of the safety net.¹ Rolling a snake eye (one) represents failure; rolling anything else represents success. The more dice you roll, the less the risk of getting all snake eyes, and the safer the system will be due to the simple power of math. As noted by Marx, “in no place is the single dice more deadly than that of healthcare...”¹ Roll a single die, and harm is only a single failure away. Design the safety system to be 3, 4, or 5 dice away from harm, and it will vastly improve safety.
- Risk-reduction strategies should impact as many steps of the medication-use process (e.g., prescribing, transcribing, storing, dispensing, administering, and monitoring) as feasible given the underlying causes.
- Choose strategies that provide reliable protection each time (e.g., using automation, technology alerts), and limit reliance on strategies that require staff to follow rules/policies or rely on memory to avoid error. Please reference **Table 1** (on **pages 4 and 5**) when risk-reduction plans are being developed.
- The best strategies will be sustainable over time.

Communicate the List and Strategies

A list of high-alert medications and associated risk-reduction strategies that is not well known to all who touch the medication-use process will have little impact on patient safety. Be sure to discuss with all staff why the list and strategies are important, whom they will impact, and why they were created in the first place. This will help them understand their value, the medication errors and patient harm they will prevent, and why it is critical to implement each of the risk-reduction strategies. Also, there is no point in having the high-alert medication list and associated risk-reduction strategies buried in a policy and procedure manual. Make the document electronic and mobile-friendly so that staff can easily access it and quickly search it whenever needed. Print it out and place it in areas visible to staff.

Assess the Effectiveness of Strategies

Regularly ask your staff for ideas and feedback about the high-alert medication list and associated risk-reduction strategies. Find out any concerns they may have at staff meetings, via anonymous surveys, during leadership rounds, via suggestion boxes, or using any other means of communication. This is essential not only to keep all staff engaged, but also to hear if there are any barriers to implementation of the planned risk-reduction strategies. Use this information to make any necessary adjustments to the list and strategies.

Also, routinely audit practice to determine the effectiveness of risk-reduction strategies for the identified high-alert medications. The results should be shared regularly with leadership or at other appropriate meetings or huddles. Reviewing the effectiveness of the established safeguards is vital to the ongoing success in lowering the risk of medication errors with high-alert medications.

Reference

- 1) Marx D. Play with three dice, when you can. *What We Believe*. Outcome Engenuity. 2017;1(3):1-2. www.ismp.org/ext/709

Table 1 — pages 3 and 4; **Updated list** — page 5 >

SAFETY briefs



Manufacture of legacy feeding tubes ended. The Global Enteral Device Supplier Association (GEDSA) announced that its member manufacturers ended production of legacy feeding tubes and cross-application connectors on July 1, 2021, as scheduled, to support the transition to ENFit enteral feeding devices (www.ismp.org/ext/733). On January 1, 2022, GEDSA members will end production of transition sets and adaptors sold separately from other devices. Individual GEDSA members will continue to provide legacy devices until their supplies run out. **GEDSA recommends that all US healthcare facilities convert to ENFit by the end of the year.**



Use “mcg,” not µg. A report from the Netherlands mentioned hepatitis B vaccine label strengths listed as 10 µg/mL and 20 µg/mL. When translating the Dutch text using Google translate, this became 10 g/mL and 20 g/mL. It is unlikely one would mistake the strength of a hepatitis B vaccine, but what other products have strengths or doses expressed in mcg that may be confused as grams and not be as easily recognized as an error? Despite advances in software capabilities and information technology, translation from one system to another may result in unusual or missed characters. We suggest using mcg to abbreviate micrograms instead of µg.

Special Announcement

ISMP webinar for community pharmacy
Join us on **October 26, 2021**, from **2:00-3:00 p.m. ET** for a **FREE** webinar on **Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors**. Using the newly revised *ISMP List of High-Alert Medications in Community/Ambulatory Care Settings*, faculty will highlight common high-alert medications, error-prone processes, and often overlooked strategies. Faculty will also provide fresh insight into the proactive steps community/ambulatory pharmacies can take to prevent medication and vaccination errors. For more information and to register, visit: www.ismp.org/node/27619.

Table 1. Key Safety Strategies for Safeguarding High-Alert Medications

Key Strategy	Description	Examples
Failure Mode & Effects Analysis (FMEA) & Self Assessments	Proactively identify the ways that processes or medication-related equipment can fail, why they might fail, how they might affect patients, and how they can be made safer; assess current systems and practices against best practices	<ul style="list-style-type: none"> ■ Consider elements of the antithrombotic self assessment found at: www.ismp.org/node/56 ■ Consider elements of the community/ambulatory pharmacy self assessment found at: www.ismp.org/node/534 ■ Perform an FMEA on a new high-alert medication before initial use ■ Perform an FMEA on a high-risk process associated with medication use
Forcing Functions & Fail Safes	Employ procedures or equipment design features that will: <ul style="list-style-type: none"> ■ Prevent something from happening until certain conditions are met (forcing function) ■ Prevent malfunctioning or unintentional operation by reverting back to a predetermined safe state if a failure occurs (fail safe) 	<ul style="list-style-type: none"> ■ Use features that stop (e.g., hard stop in computer order entry) a process from moving forward or require the entry of key information (e.g., allergies) before proceeding
Limit Access or Use	Use constraints to restrict access to certain medications or error-prone processes; require special education or conditions for prescribing, dispensing, or administering a particular drug; require special authorization for participation in certain tasks	<ul style="list-style-type: none"> ■ Sequester U-500 insulin vials in a separate container or area to hinder mix-ups with other insulin products ■ Limit the ability to make modifications to automated dispensing machines to staff with specific training and credentials
Constraints & Barriers	Use of special equipment or environmental conditions to prevent a hazard from reaching a target	<ul style="list-style-type: none"> ■ Use of personal protective equipment to reduce employee exposure to hazards ■ Eliminate tincture of opium from community pharmacy inventory if possible.
Standardize	Create clinically sound, uniform models of care or products to reduce variation and complexity	<ul style="list-style-type: none"> ■ Employ evidence-based, standard order sets (one for each care process)
Simplify	Reduce the number of steps, handoffs, and options without eliminating crucial redundancies	<ul style="list-style-type: none"> ■ Use commercially available products instead of compounding products ■ Optimize pharmacy computer systems to better accept electronic prescriptions to eliminate transcription errors
Redundancies	Implement multiple pathways so if the first pathway fails, a second pathway may detect the error and be successful	<ul style="list-style-type: none"> ■ Require the verification of two unique patient identifiers to verify patient identity before dispensing medications ■ Mandate patient counseling for high-alert medications
Externalize or Centralize Error-Prone Processes	Transfer error-prone tasks to an external site or centralized area to help ensure they are completed in a distraction-free environment by those with expertise, with appropriate quality control checks in place	<ul style="list-style-type: none"> ■ Establish a centralized call center to triage all incoming calls thus reducing call burden and interruptions in the pharmacy
Differentiate Items	Modify the packages and labels of medications to help distinguish them from other medications with look-alike packaging or look- and sound-alike names	<ul style="list-style-type: none"> ■ Purchase look-alike medications from different manufacturers to maximize label differences in appearance ■ Use tall man lettering with drug names on computer screen drug listings to call out differences in look-alike drug names ■ Use color or a pen/marker to draw out or circle important information (e.g., strength) on labels ■ Affix auxiliary labels to call attention to important information

> **Table 1** — continued from page 3

Key Strategy	Description	Examples
Maximize Access to Information	Use active, not passive, means of providing staff and patients with necessary information at the appropriate time while performing critical tasks	<ul style="list-style-type: none"> ■ Use of computer systems with clinical decision support, thus providing immediate warnings (e.g., soft stop) if unsafe orders are entered
Checklists & Reminders	Provide a list of items for comparison, verification, or to assist with remembering important steps or information; provide additional alerts or warnings to make important information highly visible (overuse of reminders can lead to desensitization and alert fatigue)	<ul style="list-style-type: none"> ■ Use checklists for complex tasks ■ Build reminders into order sets or protocols if special monitoring is required
Situational Awareness & Critical Thinking	To enhance an accurate understanding of the environment in order to understand how information, events, and one's own actions will impact patient safety and other goals, both immediately and in the near future; a strategy used to reduce drifting into unsafe practice habits	<ul style="list-style-type: none"> ■ Use simulations to expose staff to common risks and to teach them to identify and manage the risks ■ Coach staff to recognize the specific risks associated with their behavioral choices that were not seen or were misread as being insignificant or justified ■ Teach and encourage self-briefings before critical tasks to reinforce memory cues and knowledge, and to seek answers to questions ■ Implement team huddles with a specific focus to communicate and share information concurrently with a team
Positive Performance Shaping Factors	An aspect of the human's individual characteristics, environment, task, or organization that specifically improves human performance, thus decreasing the likelihood of human error	<ul style="list-style-type: none"> ■ Limit distractions in the environment and multi-tasking when staff are carrying out critical and/or complex tasks ■ Provide hands-on experiences and/or simulation training to rehearse and reinforce new skills and knowledge ■ Establish realistic workloads ■ Establish staffing patterns and workflow that guard against fatigue ■ Promote a Just Culture to foster reporting and learning
Education & Competency Validation	A baseline strategy intended to impart upon staff and patients, specific knowledge (what they know) and skills (the ability to apply the knowledge) about medications and their safe use, and to verify their knowledge and skills	<ul style="list-style-type: none"> ■ Provide patients receiving a high-alert medication with written information regarding the types of errors that have happened with the drug and how to avoid them ■ Educate staff about each high-alert medication/class of medications on the organization's high-alert medication list, how errors happen, the steps the organization is taking to avoid errors, and the staffs' role in error-reduction
Recovery	Recognize that, despite efforts, an error might occur, so enhance the ability to detect the initiating event and correct it before significant patient harm can occur	<ul style="list-style-type: none"> ■ Implement a post-fill audit program to compare the actual prescription received from the prescriber to the computer-generated label within 24 hours of dispensing the medication ■ Monitor drug levels and drug-related lab values (e.g., INR) regularly

If you would like to subscribe to this newsletter, visit: www.ismp.org/node/126



ISMP Medication Safety Alert! Community/Ambulatory Care (ISSN 1550-6290) © 2021 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: Call 1-800-FAIL-SAF(E), or visit www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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

ISMP List of High-Alert Medications in Community/Ambulatory Care Settings

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as standardizing the prescribing, storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to certain high-alert medications; using auxiliary labels; employing clinical decision support and automated alerts; and using redundancies such as automated or independent double checks when necessary. (Note: manual independent double checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list.)

Ambulatory care sites such as long-term care facilities, long-term acute care facilities, dialysis facilities, ambulatory surgery centers, and the pharmacies that provide services to them should also reference the **ISMP List of High-Alert Medications in Long-Term Care (LTC) Settings** (www.ismp.org/node/130) and/or the **ISMP List of High-Alert Medications in Acute Care Settings** (www.ismp.org/node/103).



Specific Medications

Car BAM azepine
EPINEPH rine, IM, subcutaneous
Insulin U-500 (special emphasis)*
Lamo TR igine
Methotrexate, oral and parenteral, nononcologic use (special emphasis)*
Phenytoin
Valproic acid

**All oral and parenteral chemotherapy, and all insulins are considered high-alert medications. These specific medications have been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with these medications.*

Classes/Categories of Medications

Antithrombotic agents, oral and parenteral, including:

- Anticoagulants (e.g., warfarin, low molecular weight heparin, unfractionated heparin)
- Direct oral anticoagulants and factor Xa inhibitors (e.g., dabigatran, rivaroxaban, apixaban, edoxaban)
- Direct thrombin inhibitors (e.g., dabigatran)

Chemotherapeutic agents

- Oral and parenteral chemotherapy (e.g., capecitabine, cyclophosphamide)
- Oral targeted therapy and immunotherapy (e.g., palbociclib [**IBRANCE**], imatinib [**GLEEVEC**], bosutinib [**BOSULIF**])
- Excludes hormonal therapy

Immunosuppressant agents, oral and parenteral (e.g., aza**THIO**prine, cyclo**SPORINE**, tacrolimus)

Insulins, all formulations and strengths (e.g., U-100, U-200, U-300, U-500)

Medications contraindicated during pregnancy (e.g., bosentan, **ISO**tretinoin)

Moderate and minimal sedation agents, oral, for children (e.g., chloral hydrate, midazolam, ketamine [using the parenteral form])

Opioids, all routes of administration (e.g., oral, sublingual, parenteral, transdermal), including liquid concentrates, immediate- and sustained-release formulations, and combination products with another drug

Pediatric liquid medications that require measurement

Sulfonylurea hypoglycemics, oral (e.g., chlorpro**PAMIDE**, glimepiride, gly**BURIDE**, glipi**ZIDE**, **TOLBUT**amide)



Background

Based on error reports submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP), reports of harmful errors in the literature, studies that identify the drugs most often involved in harmful errors, and input from practitioners and safety experts, ISMP created and has periodically updated a list of high-alert medications in community and ambulatory care settings. The original list was developed in 2008, which included input from community pharmacy practitioners who participated in focus groups or responded to an ISMP survey on the topic. To update the list, practitioners were once again surveyed. To assure relevance and completeness, the clinical staff at ISMP, members of ISMP's community/ambulatory care advisory board, and other safety and clinical experts in the US were asked to review the list and potential changes. This current list reflects the collective thinking of all who provided input.


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 agenda items have been prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors. These agenda topics appeared in the *ISMP Medication Safety Alert! Community/Ambulatory Care* between May 2021 and August 2021. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue to locate additional information. The *Action Agenda* is also available for download in Excel and Word formats at: www.ismp.org/node/27720.


Key:  — ISMP high-alert medication

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Review persistent safety hazards and implement strategies to reduce the risk for errors					
05/21 	Over the past few years, a number of safety issues continue to be reported to ISMP. These are persistent errors or safety hazards that have the capacity to cause devastating harm to patients. Three of these safety issues are: 1) prescribing, dispensing, and administering extended release (ER) opioids to opioid-naïve patients; 2) daily instead of weekly administration of oral methotrexate for non-oncologic conditions; and 3) use of error-prone abbreviations, symbols, or dose designations.	Establish definitions for opioid-naïve and opioid-tolerant patients, document each patient’s opioid status and type of pain (acute vs. chronic), and distinguish between allergies and drug intolerances. Enhance computer systems to default to a weekly dosage regimen for oral methotrexate, require an appropriate oncologic indication for daily methotrexate orders, and provide patient education. When communicating medical information, never use the abbreviations listed in the ISMP List of Error-Prone Abbreviations, Symbols and Dose Designations (www.ismp.org/node/8).			
Shoulder injury related to vaccine administration (SIRVA) persists with coronavirus disease 2019 (COVID-19) vaccine administration					
05/21	We continue to receive reports of COVID-19 vaccine-related SIRVA, which presents as persistent shoulder pain and weakness after intramuscular (IM) injection into the shoulder capsule instead of the deltoid muscle. For one patient, an x-ray revealed a ligament tear and capsule involvement which might require surgical repair.	Vaccinators must understand the proper technique for IM injection into the deltoid muscle: expose the upper arm/shoulder area, measure 2 to 3 finger widths from the acromion process (bony prominence above the deltoid), and locate the armpit as the lower border. Outline the deltoid muscle and inject the needle at a 90-degree angle.			
Patients received EPINEPHrine instead of the Moderna coronavirus disease 2019 (COVID-19) vaccine					
05/21 	A nurse mistakenly administered pharmacy-prepared syringes containing EPINEPH rine to two patients instead of pharmacy-prepared syringes of the COVID-19 vaccine. The pharmacy had prepared batches of syringes containing EPINEPH rine and COVID-19 vaccines and dispensed them in separate plastic bags, but the pharmacy-prepared syringes looked very similar.	COVID-19 vaccination sites should stock EPINEPH rine autoinjectors rather than pharmacy-prepared syringes so the vaccine and EPINEPH rine syringes look different. Store the EPINEPH rine autoinjectors in a different location than the vaccine syringes but close enough to be quickly retrieved. Consider storing the EPINEPH rine autoinjectors in an anaphylaxis kit.			

©2021 ISMP

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
MUSE (alprostadil) urethral inserts require counseling to prevent patient administration errors					
07/21	The Muse urethral insert, prescribed for erectile dysfunction, is available in a preloaded applicator system. One carton of Muse contains six individual applicator systems but only a single copy of the professional package insert which includes patient information at the end. Patients have reported not receiving counseling or written instructions for use leading to confusion regarding how to properly use the product. Improper administration has led to ineffectiveness and sometimes urethral hemorrhage.	Prescribers and dispensing pharmacists must familiarize themselves with the administration process for Muse. They must teach patients how to administer the drug safely and verify the patient's understanding. They also must make sure to provide the patient with the manufacturer's professional package insert with the included patient information, if one is available. There are several useful videos about Muse on YouTube, including this one: www.ismp.org/ext/723 .			
Confirm correct mg and mL dose based on product concentration supplied					
08/21	A prescription for testosterone cypionate 100 mg/mL in oil for intramuscular (IM) injection included directions to administer 0.5 mL (50 mg) every week. The pharmacy dispensed a 200 mg/mL strength product as that is what they had in stock. However, the original instructions to inject 0.5 mL each week were used. The directions should have been changed to inject 0.25 mL for a 50 mg dose.	Pharmacists should contact the prescriber if the ordered strength is not available. Technicians at this pharmacy now communicate both the mL and mg amounts to the pharmacist to confirm the dose in mg and mL during verification. For the patient instructions printed on the pharmacy label, include the dose only in the unit of measure used for administration. Discuss changes in strength with the patient.			
Confusion with INPEN Bluetooth-connected "smart" insulin pen systems					
06/21 	InPen, an insulin pen system for mealtime insulins, uses either insulin aspart (NOVOLOG or FIASP) or insulin lispro (HUMALOG) U-100 cartridges. A near miss occurred when a prescription for "InPen (for Novolog or Fiasp) subcutaneous" was mistakenly filled with an InPen to be used with Huma LOG (insulin lispro). While there are six different InPen devices there are only two different models, and each model is available in three colors. When ordering the InPen device, the pharmacy technician incorrectly assumed the pens just differed by color but worked for the different types of insulin.	Educate pharmacy staff on the details of these products and the packaging differences between Novo LOG /Fiasp cartridges and Huma LOG cartridges. Add warnings in the computer system to alert pharmacy staff to verify that the InPen device selected is compatible with the patient's insulin cartridges and clearly name each InPen in the computer system with the name of the insulin with which it is compatible. Show the patient the InPen and insulin cartridges. Have both the patient and pharmacy staff independently verify that the device and cartridge are compatible.			

©2021 ISMP

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Careful identification of US Food and Drug Administration (FDA)-approved color additives is required for patients with allergies					
06/21 	<p>Ibuprofen oral suspension was prescribed for a child with a red dye allergy. The principal display panel on the ibuprofen bottle (Perrigo, prescription-only size) listed a yellow #6 additive. The pharmacist and technician believed this to be the only color additive but later found that red #33 was listed in the package insert (PI). According to federal regulations, oral prescription drugs are not required to list all inactive ingredients on the container label, outside wrapper, or in the PI (although most list these voluntarily in the PI).</p>	<p>If patients have a known food dye intolerance or allergy, list it in a standardized, visible location on all drug-related pages as well as pharmacy system and electronic health record screens. Read the PI or <i>Drug Facts</i> label, and if you are not sure whether a medication contains a color additive, call the manufacturer. If a patient cannot take a medication critical to their recovery or health due to the color additive in the medication, compounding pharmacies might be able to provide the medication without the allergen.</p>			
Ensuring the safe use of automated dispensing technology					
08/21	<p>One bottle of topiramate 50 mg tablets and one bottle of traZODone 50 mg tablets were used to refill a dispensing robot cassette containing traZODone 50 mg tablets. The topiramate and traZODone tablets, both manufactured by Zydus Pharmaceuticals, look similar and are packaged in 500 count bottles that look nearly identical. The bottle containing topiramate had been stored next to the traZODone bottle. Only the traZODone bottle was scanned at the robot. A pharmacist verifying a prescription for traZODone caught the error when they noticed two different tablets in the prescription vial.</p>	<p>Engage staff and establish standard work practices to barcode scan each stock bottle. Use only unopened stock bottles. Complete the entire process of filling one cell before moving to the next cell and corresponding drug bottle(s). Privileges to make modifications, adjustments, or changes in the bin contents of automated dispensing systems should be restricted to properly trained staff members. Pharmacy managers and/or regional personnel for chain pharmacies should periodically perform quality control checks by observing the processes involving robotics and automation to ensure adherence to the standardized work practices.</p>			
Look-alike ophthalmic containers a long-standing problem					
06/21	<p>Look-alike ophthalmic products have been a long-standing problem. The ophthalmic product color-coding system from the American Academy of Ophthalmology (www.ismp.org/ext/674) contributes to similarities in packaging and labeling. Recently, we have received reports of look-alike Bausch + Lomb ophthalmic ointment tubes as well as look-alike ophthalmic solutions from Akorn Pharmaceuticals.</p>	<p>Purchase products from different manufacturers to reduce the number of look-alike containers. Storing ophthalmic products intermingled with the rest of the pharmacy inventory, rather than segregating them in their own section, might be of benefit. When dispensing these products, careful visual product verification and barcode scanning are critical.</p>			

©2021 ISMP