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ISMP
An ECRI Affiliate

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Implement strategies to prevent persistent medication errors and hazards: 2025

Reflecting on events that occurred in 2024, we have identified four concerns related to medication safety, which were included in ***ECRI's Top 10 Patient Safety Concerns for 2025*** or ***ECRI's Top 10 Health Technology Hazards for 2025***. Our selected top concerns are not solely based on the most frequently reported problems or those that have led to the most serious consequences, although these factors were considered. Rather, we focused on safety concerns and errors that continue to occur but can be avoided or minimized with system and/or practice changes. In a recent article, *Déjà Vu in Healthcare Tech Hazards: Why Are We Stuck on Repeat?*, ECRI president and chief executive officer Marcus Schabacker, MD, PhD, calls for embracing these issues using a total systems approach so that healthcare stakeholders and policymakers can move the needle on these persistent patient safety threats. If you have not already taken action to mitigate these risks, we hope increased awareness informs the priorities you set for your medication safety improvement plan!

Growing Threat of Substandard and Falsified Drugs

Problem: Substandard and falsified (SF) drugs (i.e., counterfeit or fake drugs made to resemble genuine pharmaceutical manufacturers' medications) are a threat to patient safety. In our May 16, 2024 article, *ISMP urges increased action at the practice level to halt the growing danger of counterfeit drugs*, we discussed how medications are increasingly being purchased from unregulated online marketplaces posing as legitimate pharmacies. Alarmingly, approximately 95% of so-called online pharmacies selling prescription drugs operate illegally.[1] Many illegal online pharmacies may be disguised as Canadian pharmacies providing low-cost medications. Some include the word "Canada" in their website address (URL) or display a maple leaf symbol on their page, making it difficult to discern between a legitimate and fake site.[2]

SF drugs are frequently adulterated with potentially lethal ingredients, including fenta**NYL**, fueling the epidemic of overdose deaths plaguing the United States.[2] Fenta**NYL** is the leading cause of death for Americans 18 to 45.[3] Ease of purchasing products through social media has increased fatal overdose risk.[4] In 2023, the US Drug Enforcement Administration (DEA) seized more than 80 million fenta**NYL**-laced SF tablets.[5] Although SF medications are often associated with illicit drug use, fake drugs represent a threat to all, from young people seeking help with attention-deficit/hyperactivity disorder (ADHD) to elderly patients looking for the lowest price for their prescriptions. Other harmful substances found in SF drugs include rat poison, cement, and heavy metals (e.g., arsenic, mercury).[6] Even when not contaminated with dangerous material, counterfeit drugs often lack the active ingredients to be effective.[2] Their use can impose a significant economic burden on patients and healthcare organizations due to costs associated with ineffective treatments and management of prolonged illnesses.

Safe Practice Recommendations: Educate staff about the potential for patients presenting to different healthcare settings with adverse reactions after knowingly or unknowingly taking SF drugs. Monitor patients for unexpected outcomes (e.g., increased side effects, medication not working as it previously had) and consider if counterfeit medications could be the culprit. When reviewing a patient's medication history, include a scripted open-ended question asking where they obtain their medications.

continued on page 2 — Medication errors and hazards >

SAFETY brief

Medication vial coring and fragmentation risks. The Anesthesia Patient Safety Foundation (APSF), along with ECRI and ISMP, have issued an alert after receiving several reports of medication vial coring incidents. Coring occurs when a small piece or pieces of the flexible stopper on a medication vial break off during needle insertion, which may lead to contamination of the medication and the risk of injecting stopper fragments into patients. The highest risk of coring seems to be associated with blunt needles.

APSF and ECRI/ISMP are actively working to develop evidence-based safe practice recommendations to minimize the risk of coring. For now, review the interim recommendations provided in the alert. Consult and follow the manufacturer's prescribing information for specific recommendations on accessing the vial. If instructions are not provided, avoid the use of blunt needles to remove medication

continued on page 2 — SAFETY brief >

Survey on Implementation of Targeted Best Practices

ISMP is conducting a short survey to get a sense of the current level of implementation of the ***Targeted Medication Safety Best Practices for Hospitals***. We would greatly appreciate your participation in this survey. Click here to start the survey.

Please complete this online survey by **June 5, 2025**. For a detailed description and exact wording of the *Best Practices*, click here to download a copy. ISMP plans to present the results of this survey during the American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting and Exhibition in December 2025. The findings will also be described when introducing the new ***Targeted Medication Safety Best Practices for Hospitals*** early in 2026.

> Medication errors and hazards — continued from page 1

Leaders should stay informed about medication-related incidents shared by safety organizations and develop mitigation strategies for known problem drugs. Share warning signs with patients that may indicate an online pharmacy could be selling SF drugs. Refer them to resources such as the US Food and Drug Administration's (FDA) BeSafeRx campaign. Educate patients about the National Association of Boards of Pharmacy's (NABP) searchable list of accredited digital pharmacies that comply with quality assurance criteria. Encourage patients to check for a licensed pharmacist's availability at any online pharmacy they are considering, which can help determine the pharmacy's legitimacy. Inform patients that when a pharmacy does not require a provider's prescription to dispense a prescription medication, or when a provider issues a prescription without an online or in-person visit, the facility is likely illegal and unsafe.

Ask patients to review medication packages and labeling for spelling errors, which is one of the most noticeable mistakes on counterfeit products. Inform patients that, although manufacturers may change products or pharmacies may provide different generic products, any concerns about differences in a medication's size, color, or shape should be addressed. Ensure the drug description on the pharmacy label matches that of the drug inside the container. Explain to patients that legitimate medications will have a factory-made appearance. Patients should be suspicious if tablets are cracked, have a bubbled-up coating, are crumbly or moldy, or come in jars containing excess powders or crystals. If the original manufacturer's packaging has been opened, has a broken seal, appears to have been tampered with, comes in different packaging, has no packaging, is missing the label, or just does not look right, patients should check with a healthcare provider before taking the medication.[7]

Practitioners should also be aware of and share resources from government agencies that offer information to combat counterfeit drugs, such as:

- Centers for Disease Control and Prevention
- FDA
- National Intellectual Property Rights Coordination Center
- Fight the Fakes Alliance

Deteriorating Community Pharmacy Working Conditions

Problem: Community pharmacists have long endured unsatisfactory work conditions. The coronavirus disease 2019 (COVID-19) pandemic uncovered system weaknesses as work conditions further deteriorated, leading to conditions becoming dangerously overwhelming and threatening to both patient safety and staff well-being.[8-13] Community pharmacists have seen an increase in requests for vaccinations and point-of-care testing.[12,14] However, staffing has not always been able to accommodate this increase, leaving pharmacists rushing to administer vaccines, and verify and dispense prescriptions. Pharmacy phone calls with providers, patients, and insurers are numerous. Community pharmacists often feel forced to verify prescriptions while engaged on the phone, which has contributed to errors. Similarly, pharmacists have increasingly assumed pharmacy technician tasks after employers cut technician hours, and technicians resigned due to burnout and being underpaid.[12,14]

In a tragic example, a pharmacist suffered a heart attack and died while working as the lone pharmacist at a busy pharmacy.[15] Feeling pressure to meet performance metrics, she did not close the pharmacy when she began to experience symptoms. Unfortunately, production metrics aimed at increasing revenue must often be achieved at the cost of patient and staff safety.[11,14,16,17] Tasks are measured against corporate goals for staff evaluations,[7] and pharmacists must choose between meeting metrics for their job performance and providing safe, quality care.

continued on page 3 — Medication errors and hazards >

>SAFETY brief

cont'd from page 1

from the vial. Use sharp, smaller gauge needles (e.g., using 21-gauge rather than 18-gauge needles) with a safety guard when possible. Evaluate staff technique, including the angle at which the vial is entered, and ensure the vial stopper is only punctured once. Educate staff to inspect medication vials and prepared syringes for coring before adding the medication in the syringe into an infusion bag. Also, inspect the infusion bag for cores after final preparation. If coring is present, do not administer the medication, sequester the impacted vial and/or prepared medication, and notify the medication manufacturer. Report issues to ISMP.

Your Reports at Work

Label changes help differentiate Amneal infusion bags

A pharmacy technician was evaluating a new product, tranexamic acid 1,000 mg/100 mL, which had recently been purchased due to a shortage of supply from their typical manufacturer. They noted that the tranexamic acid injection bags looked very similar to esmolol hydrochloride 2,500 mg/250 mL injection bags and escalated this concern to pharmacy leadership. Both products, made by Amneal, are the same concentration (10 mg/mL) and had nearly identical outer wrappers with similar colors, fonts, and designs (**Figure 1**). The pharmacy reviewed the storage locations to ensure the

Figure 1. Tranexamic acid 1,000 mg/100 mL (left) and esmolol hydrochloride 2,500 mg/250 mL (right) injection bags by Amneal look nearly identical.

continued on page 3 — Reports >

> **Medication errors and hazards** — continued from page 2

Disrespectful behavior in the workplace can also jeopardize patient safety. In a 2022 survey, almost 25% of respondents indicated they were aware of a medication error in the past year in which disrespectful behavior played a role.[18] While disrespectful behavior occurs between healthcare practitioners and leaders, it may also come from patients or caregivers. Pharmacy staff report regular verbal abuse and/or threats from customers who are unhappy with wait times and frequent medication inventory shortages.[18]

One respondent to the 2022 survey noted that high pressure, inadequate staffing, and abuse from customers has led to the administration of the incorrect vaccine and dispensing prescriptions to the wrong patient.[18] The increased workload and poor working conditions contribute to pharmacy staff distress. Almost 33% of pharmacy staff in 2021 were at substantial risk for distress, which carries an eightfold higher risk of burnout and a twofold higher risk of medication error.[14,19]

Safe Practice Recommendations: Survey staff anonymously and confidentially every two to three years to assess their perceptions of workplace culture using a tool such as the Agency for Healthcare Research and Quality's (AHRQ) SOPS Community Pharmacy Survey. Use the findings to create an action plan and drive improvement.

Organizations that have outpatient pharmacies should utilize a call center and/or remote pharmacists to triage phone calls and conduct medication therapy management (MTM). Use a centralized dispensing operation for prescription refills. Isolate areas for critical steps of the medication dispensing process (e.g., where prescriptions are transcribed, verified, filled, and checked). Do not require staff to meet productivity-focused metrics which may compromise staff and patient safety; instead, prioritize measures that monitor patient and worker safety. Remove unnecessary administrative burdens and nonessential workflow tasks. Reallocate administrative and nonpatient care tasks to support personnel. Charge organizational leaders with recognizing the effects of burnout and committing to supporting staff.

Communicate to patients that safety is a priority. Ask for their participation in supporting a safe pharmacy environment (e.g., reasonable expectations for prescription filling times, pharmacy closed for lunch). Collaborate with patients to identify and address issues that they find burdensome. Consider appointment-based models to efficiently manage other clinical services (e.g., vaccinations, MTM, patient care calls). Create a reporting pathway for patients and families to share safety concerns.

Examine prescription volume data periodically. Gather feedback from staff regarding workload and conditions in the pharmacy; ask whether current staffing and resources are sufficient to provide safe and effective care. Use this information to determine appropriate staffing levels and use of automated dispensing technology (e.g., dispensing robotics). Include a backup plan for a short-staffed pharmacy in policies and procedures. Provide employee assistance and wellness programs and resources. Recognize the interconnections among job-related burnout, stress, psychological capital, and social support. Allow time off to attend appointments related to mental well-being.

Implement a fair and Just Culture—ensuring respectful management of serious adverse events and good catches. Provide transparency and feedback so staff feel safe voicing workplace and patient safety issues without fear of reprisal. Have leaders set a tone of mutual respect, encourage learning and discovery, remain open to suggestions, and maintain ongoing communication.

Mishandled Temporary Holds on Medication Orders

Problem: The need to suspend (or hold) the administration of a drug based on clinical circumstances is a common—but sometimes problematic—requirement during the course of patient care. In our October 19, 2023 article, *Temporarily holding medication orders safely to prevent patient harm*, we discussed how errors can arise if organizations lack carefully vetted workflows for documenting

continued on page 4 — **Medication errors and hazards** >

Your *Reports* at *Work*

cont'd from page 2

products were separated in the pharmacy and automated dispensing cabinets (ADCs). This was a great example of completing a safety analysis to proactively consider product characteristics that might cause confusion and lead to medication errors between two high-alert medications. The pharmacy decided to purchase the products from different manufacturers to prevent mix-ups.

In our July 25, 2024 article, *Proactive assessment uncovered look-alike calcium gluconate and tranexamic acid bags*, we discussed a similar risk with Amneal's calcium gluconate 1,000 mg/50 mL and tranexamic acid 1,000 mg/100 mL injection bags (**Figure 2**).

Figure 2. Calcium gluconate 1,000 mg/50 mL (left) and tranexamic acid 1,000 mg/100 mL (right) injection bags by Amneal look nearly identical.

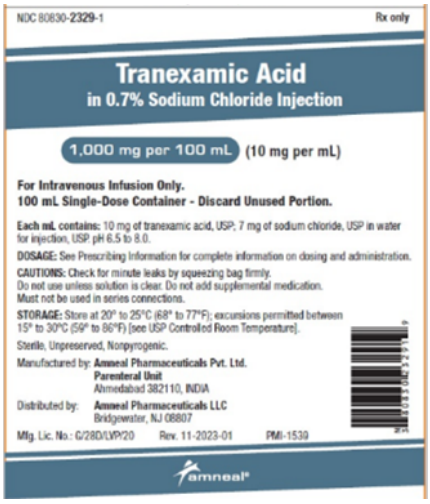

Figure 3. Amneal's tranexamic acid label is highlighted with a blue diagonal background around the drug name and a blue oval background around the concentration.

We contacted the US Food and Drug Administration and Amneal again and recommended differentiating the labels. We are pleased to share that Amneal updated the

continued on page 4 — ***Reports*** >

> **Medication errors and hazards** — continued from page 3

medication hold order parameters in the electronic health record (EHR). Medications may be held before or shortly after a patient undergoes a procedure, or when a patient's condition changes (such that the continued administration of a drug is inappropriate), or as dictated by clinical protocols. Failure to hold a medication when indicated, or neglecting to either restart or discontinue a held medication as circumstances require, can lead to patient harm.

Errors associated with hold orders often can be attributed to uncertainty about what a hold order means, how the order should be communicated, or what process should be followed. One key concern is that the EHR configuration may prevent easy access to details about a hold order. For example, the EHR may require practitioners to scroll, browse, or search for information about whether and when to hold (or resume) a medication. Or prescribers may document this information where it is not easily visible to other practitioners.

Safe Practice Recommendations: Organizations should create and vet hold order workflows that support safe practices. Understand the various ways that medications can be placed on hold in your EHR system and then restarted. Identify which medications should be held, and when, based on a specific parameter (e.g., heart rate, blood pressure), and build required fields in the EHR that the prescriber must enter prior to placing the order. Evaluate the clinical decision support alerts configured in the system, and ensure the appropriate practitioners are receiving applicable system warnings related to the held/resumed medication and that they are addressing those alerts at the appropriate time. Ensure held orders are visible to all practitioners on all medication lists and the medication administration record, and that those orders clearly indicate how long the medication is on hold (e.g., number of doses, number of days) if known.

Organizations and institutional leadership must have a formal process outlining the designated prescriber (e.g., hospitalist, surgeon) responsible for completing medication reconciliation during transitions of care. Avoid vague orders such as, "resume all pre-op medications" or "continue all prior medications." All new postoperative medication orders should be reconciled with previously prescribed medications; prescribers should not rely solely on summaries for patient medication orders. A review of medications held and discontinued is also essential, and this information needs to be communicated during handoffs.

Additionally, EHR vendors should implement effective hold order functionality that allows practitioners to view held medication orders and associated parameters at all points of care, from the pharmacy to the bedside. Organizations should provide feedback to vendors to push for improved processes that support safe workflow.

Incomplete Investigations of Infusion Pump Incidents

Problem: Organizations will want to conduct a thorough investigation in the aftermath of any technology-related adverse event. Investigations involving infusion pumps can be particularly challenging due to the variety of potential contributing factors. Organizations that lack the expertise or resources to conduct a thorough investigation of such incidents will be poorly positioned to prevent future, potentially fatal infusion-related medication errors or other incidents. Furthermore, it is not uncommon for staff to take steps after an event that inadvertently hinder a future investigation.

From January 2023 to August 2024, a total of 204,163 infusion pump events were submitted to FDA's MAUDE (Manufacturer and User Facility Device Experience) database. The reporters of those events categorized the outcomes as 204 deaths, 1,901 injuries, and 202,025 malfunctions. Pump-related incidents are also commonly reported to ISMP and ECRI. In our May 18, 2023 article, *Smart infusion pump investigations after an unexplained over-infusion*, we shared a series of unexplained over-infusion events. Any unexplained infusion pump incident can be a logistical nightmare for practitioners and can erode end-users' trust in infusion pump technology. When programming errors are ruled out

continued on page 5 — **Medication errors and hazards** >

Your *Reports* at *Work*

cont'd from page 3

labels for some of their products, including esmolol and calcium gluconate, to better differentiate them from tranexamic acid. See **Figures 3** (page 3), **4**, and **5**. These changes make the products appear less similar.

We want to thank you for reporting these issues to us. Without you, we believe these changes would not have been made. We cannot emphasize how important it is to report errors to ISMP and encourage you to continue to do so.

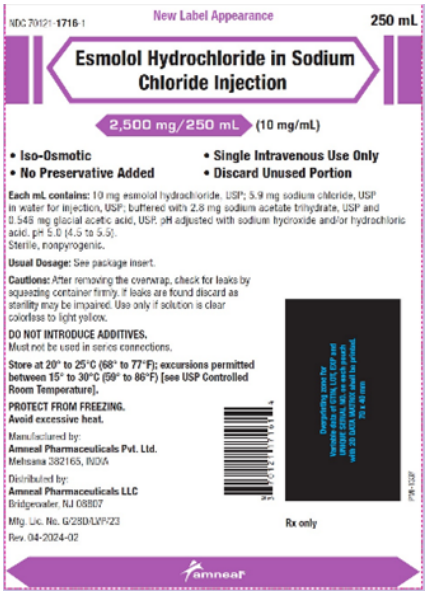

Figure 4. Amneal's updated esmolol label is highlighted with a purple diamond accent around the drug name and concentration.

Figure 5. Amneal's updated calcium gluconate label is highlighted with a lime green background behind the drug name and concentration.

> **Medication errors and hazards** — continued from page 4

and an error cannot be replicated during laboratory testing, practitioners are left uncertain about what led to the incident and what actions to take to prevent a recurrence. Numerous factors—alone or in combination—must be examined, including issues related to the pump hardware and software, the intravenous (IV) administration set and other accessories, and the actions of the user.

Safe Practice Recommendations: Immediately following an infusion incident, review error alerts on the infusion pump screen and the corresponding actions taken. Be sure that the pump, the involved module, all other modules attached at the time of the incident, and any consumables (e.g., IV bag and infusion set), are preserved and sequestered. To the extent possible, preserve how the pump was set up when the incident occurred. Do not detach the modules. Educate staff about the importance of saving any consumables associated with a suspected infusion pump incident, when clinically acceptable. Ensure that the pump is removed from clinical use and appropriately labeled or tagged so it is clear that the pump should not be used. Extract and review the usage logs for all pump modules taking note of the timeline of events including any issues (e.g., removal of the administration set from the pump, error alerts and the corresponding actions taken). Report the incident to the appropriate personnel.

If a practitioner suspects a significant discrepancy between the expected rate and how fast or slow an IV infusion was administered, review the medication order and confirm the infusion was programmed correctly (e.g., correct medication, concentration, dose-rate, and volume to be infused). If there are concerns that an infusion could have been prepared with a different volume than what was prescribed, pharmacy should investigate the possibility of a dispensing error. Reconcile event logs and physical evidence with the event description, if possible. It is helpful to have a form that can be used to gather and document detailed information about the issue.

When investigating the event, examine the pump and all its components, for missing parts, damage, wear, corrosion, and broken warranty seals. If approved by risk management, notify biomedical engineering to help test the device's operation including flow rate accuracy and verification of detection and alarm for air in line and occlusion conditions.

Seek assistance from the pump vendor or a third-party consultant to support the investigation. ECRI provides this service along with ISMP support as needed. To learn more about the safe use of infusion systems refer to the ISMP ***Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps***. To learn more about how to conduct a thorough incident investigation, consider taking ECRI's *Healthcare Incident Management and Investigation (HIMI) Training* course.

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