

Acute Care ISMPMedication Safety Alert Educating the Healthcare Community About Safe Medication Practices

2022 ushers in the beginning of a new era at ISMP



In January 2022, an era of unwavering leadership for the Institute for Safe Medication Practices (ISMP) comes to an end, as Michael R. Cohen, a persistent advocate for medication safety, has stepped down as President of ISMP. Mike will continue to support ISMP's critical lifesaving work as President Emeritus, and Rita K. Jew, a respected and worthy successor, has been appointed as the new ISMP President (to learn more about Rita, visit: www.ismp.org/node/22763). Mike will continue to be actively involved

with ISMP part-time, working on newsletters and special projects close to his heart, continuing his quest for excellence in medication safety. He is an inspiration to us all, and we are delighted that he will continue to be available to ISMP. Rita will lead ISMP into a new era, as ISMP continues to provide sage guidance to influence companies, organizations, practitioners, and consumers who make, regulate, prescribe, dispense, administer, and receive medications, always focusing on the patient.

(Looking Back

ISMP roots. As many know, the origin of ISMP is rooted in a monthly column entitled Medication Errors, that began in March 1975 in *Hospital Pharmacy*. The column grew from a conversation Mike had in 1974 with Neil Davis, both of whom were working at Temple University Hospital in Philadelphia. They were discussing a serious medication error that happened at a local hospital in which a prescriber had used an abbreviation, U for "units," and a nurse had misread the handwritten U as a zero and administered 40 units of regular insulin to a patient instead of 4 units. The patient developed signs of severe hypoglycemia that required immediate treatment.

Dr. Davis, who was an editor of *Hospital Pharmacy*, suggested that the incident served as an opportunity for educating other healthcare professionals about this error-prone abbreviation. During the discussion, it became clear that much could be gained by publishing other medication errors that readers may be inclined to report in confidence to prevent patient harm and save lives. Thus, an idea was born and realized to create a national medication error reporting program that practitioners could use to confidentially report medication errors, which could then be shared anonymously with others for learning purposes.

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Management of drug shortages with 0.9% sodium chloride, sterile water for injection, and EPINEPHrine

PROBLEM: Ongoing drug shortages in healthcare have become commonplace, with only the severity and urgency of the issue changing with the specific drugs in short supply. According to numerous inquiries to ISMP and frequent communications with Erin Fox, PharmD, BCPS, FASHP, a recognized expert in drug shortages at the University of Utah Health, current shortages of 0.9% sodium chloride for injection vials, prefilled saline flushes, sterile water for injection vials, and **EPINEPH**rine injection emergency syringes and autoinjectors, are all creating serious safety concerns and requiring even more effort from healthcare facilities to circumnavigate. (The University of Utah provides information for the American Society of Health-System Pharmacists [ASHP] Drug Shortages Resource Center [www.ashp.org/shortages].)

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SAFETY briefs



Potential for severe cardiovascular effects when restarting cloZAPine. A

40-year-old woman with schizoaffective disorder had been taking a total daily dose of cloZAPine 500 mg as an outpatient for at least 10 years. However, recently she had not received the drug for nearly 2 weeks, due to problems her psychiatrist was having with registering for the updated Risk Evaluation and Mitigation Strategies (REMS) certification. In July 2021, a new REMS platform (www.newclozapinerems.com) had been initiated by the US Food and Drug Administration (FDA) to merge different registries into one, and recertification of healthcare practitioners was supposed to be completed by November 15, 2021. However, practitioners ran into problems, including high call volumes and long wait times.

The patient was admitted to the hospital psychiatric unit and restarted on clo**ZAP**ine. Her physician did not want to restart her at the full dose since she had not been taking

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Become an ISMP Fellow

ISMP is now accepting applications until March 13, 2022, for three unique Fellowship programs that will begin in the summer—the ISMP Safe Medication Management Fellowship, the ISMP International Medication Safety Management Fellowship, and the FDA (US Food and Drug Administration)/ISMP Safe Medication Management Fellowship. An ISMP Fellowship can help you grow in your career and make major contributions to medication safety worldwide. For brief descriptions of the various Fellowships, candidate qualifications, brochures, program outlines, and directions for applying, visit: www.ismp.org/node/871. Also see page 8 for details.

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In 1977, Mike began a similar column for nurses in *Nursing '77*, and both the *Hospital Pharmacy* and *Nursing '77* columns became leading features in the respective monthly journals. The columns prompted reports of errors from across the US, and Mike would often follow up with the practitioner to learn more about what had happened. Then Mike would share the deidentified error stories and provide error-prevention recommendations in the journal columns so others could proactively take action. Mike and Dr. Davis also began to interact with the US Food and Drug Administration (FDA), USP, The Joint Commission (TJC), and product manufacturers when important issues arose.

By 1990, Mike realized that his advocacy work for safe medication practices and products was a full-time calling that should be supported by a nonprofit organization. Shortly thereafter, ISMP was founded, and by 1994, the organization became the nation's only 501c (3) nonprofit organization devoted entirely to preventing medication errors. Since then, ISMP has served as a vital force for progress in medication safety through its unyielding advocacy and the development of resources and learning opportunities for healthcare practitioners and consumers.

ISMP's impact. ISMP has had a tremendously positive impact on patient safety, medication safety, and the practices of caregivers striving to provide quality and safe patient care, both across the US as well as internationally, including through ISMP sister organizations located in Brazil, Canada, and Spain, and as a founding member of the International Medication Safety Network (IMSN). Along the way, ISMP has cultivated excellent relationships with other patient safety and professional organizations, accreditors, regulators, standards-setting organizations, and the medical products industry that allow us to share our recommendations with organizations so necessary changes can be made to prevent both product- and practice-related medication errors. For example, over the years, ISMP's frequent interactions with FDA, USP, and the medical products industry have improved the safety of thousands of products, and have had a significant impact on labeling, packaging, and nomenclature guidances and standards. Additionally, ISMP's collaboration with TJC, the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), professional organizations, and patient safety organizations has resulted in collaborative projects to advance our mutual goal of medication safety, as well as substantial changes in medication safety standards. Likewise, our recommendations to practitioners, healthcare providers, and organizations have also resulted in system- and practice-level changes. In fact, ISMP was among the first, if not the first, organization to recommend the following concepts to improve medication safety, many of which are widely implemented by healthcare providers and industry:

- Free flow protection for infusion pumps
- Removal of potassium chloride injection concentrate from patient care units
- Vin**CRIS**tine administration via a minibag instead of a syringe
- Establishing a list of high-alert medications with layered error-reduction strategies
- Use of failure mode and effects analysis (FMEA) in healthcare
- Spotlighting Targeted Medication Safety Best Practices for Hospitals
- Employing a medication safety officer
- Maintaining a look-alike/sound-alike drug name list
- Maintaining a list of error-prone abbreviations that should never be used
- Use of tall man letters
- Calling infusion pumps with a dose error-reduction system (DERS) "smart pumps"

Throughout the years, there have been numerous times when ISMP has also brought together key stakeholders, sometimes for the first time, to discuss complex medication safety issues and create consensus-based best practices and/or action plans for organizations to implement. In some cases, ISMP has been a prickly thorn in the side, provoking important questions, challenging preexisting assumptions, exposing harmful medical products, and chipping away at the resistance to much needed system changes.

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it for nearly 2 weeks. He thought a reduced dose of 400 mg was appropriate since the patient had been stable on 500 mg daily for an extended time. Unfortunately, a little over 1 hour after receiving her first dose, the patient was found pulseless, face down in her room. Cardiopulmonary resuscitation was initiated with return of spontaneous circulation but she suffered cerebral hypoxia and ongoing shock. CloZAPine re-initiation as a cause of the cardiac arrest is a diagnosis of exclusion, and no other etiology of the cardiac arrest was found in this case.

Many healthcare practitioners are aware of the issue of cloZAPine-associated neutropenia and infection risk because the REMS program is designed to manage these risks. However, it is clear that many practitioners are not aware of the potential for severe adverse cardiovascular effects, including cardiac arrest, especially when the drug is abruptly discontinued and then restarted after 2 days or more. Clo**ZAP**ine has a boxed warning stating the following: "Orthostatic hypotension, bradycardia, syncope, and cardiac arrest have occurred with cloZAPine treatment. The risk is highest during the initial titration period, particularly with rapid dose escalation. These reactions can occur with the first dose, with doses as low as 12.5 mg per day. Initiate treatment at 12.5 mg once or twice daily; titrate slowly; and use divided dosages." Product labeling (not within the boxed warning) further states: "When restarting cloZAPine tablets in patients who have discontinued cloZAPine tablets (i.e., 2 days or more since the last dose), re-initiate with 12.5 mg once daily or twice daily. This is necessary to minimize the risk of hypotension, bradycardia, and syncope. If that dose is well-tolerated, the dose may be increased to the previous therapeutic dose more quickly than recommended for initial treatment." Similar wording is also included in the warnings and precautions section of the package insert. Unfortunately, these warning statements are not being effectively communicated and/or taught to many healthcare practitioners.

Please ensure that prescribers and others handling cloZAPine are aware of the potential for adverse cardiovascular effects, especially considering the potential for breaks in therapy with the ongoing

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At other times, ISMP has been a nurturing, healing shoulder to cry on when well-meaning and competent providers have inadvertently harmed a patient-because we are fallible human beings deeply troubled by our inability to "do no harm."

But perhaps ISMP's greatest contribution to healthcare has been giving a voice to health professionals who, in confidence, report errors to ISMP for altruistic reasons and/or share their ideas, observations, or questions with ISMP, without fear of even a disparaging thought. ISMP empowers others to give voice to their experiences because they trust ISMP and know their information will be used productively. Every idea, observation, question, or error report ISMP receives is carefully reviewed. Then ISMP healthcare professionals interact internally to apply their collective expertise to arrive at safety recommendations and then share compelling stories about medication errors and impactful change strategies. ISMP aims to draw national attention to medication safety problems, offers healthcare providers new ways of looking at problems, and inspires change.

(Looking Forward

As we reflect on our many years of existence and the remarkable achievements that have been made in medication safety, we recognize that we have certainly not done it alone. Many of you have been on this journey with us, reporting hazards and errors, listening to the stories we share, implementing our recommendations, completing our surveys and self assessments, supporting our initiatives, and helping us learn more about how medications are used or misused. Although ISMP is a small organization, with your passionate support, we have had an enormous impact in the world of patient safety. Your participation in surveys and your detailed error reports are powerful drivers of change and will continue to serve as a major force in the patient safety movement and the foundation of our work at ISMP. We are humbled by the trust you place in ISMP and are truly indebted to you.

It has been an amazing journey thus far; however, there is still much more work to do. The role of ISMP moving forward is clear. For our entire staff, medication safety is not just a mission, it is a passion and a life's work. We feel incredibly grateful to have been working with you to advance medication safety for more than a quarter century, and we are so proud of the shared narrative around medication safety and the accomplishments we have achieved together. Improvement is only possible within a culture that ensures all changes are well understood, embraced, and sustained-nothing sums up our mission more than this. Please continue reporting medication hazards and errors (www.ismp.org/MERP), sharing your ideas, questioning complex medication safety issues that are not well understood, and responding to our efforts to improve medication safety. You can contact ISMP at any time via email at: ismpinfo@ismp.org.

> Drug shortages — continued from page 1

0.9% Sodium Chloride Shortage

The most impactful shortage involves 0.9% sodium chloride in 10 mL, 20 mL, and 50 mL preservative-free, single-dose vials, prefilled flush syringes, and certain small volume (25 mL, 50 mL, 100 mL) bags. Shortages of the 0.9% sodium chloride vials have increased the demands for prefilled flush syringes, small volume bags, and vials of 23.4% sodium chloride, which have resulted in the current shortages of these products. Sodium chloride 0.9% is often needed to dilute or reconstitute certain medications. Also, nurses regularly use prefilled saline flush syringes, which are essential for vascular access device (VAD) maintenance and to reduce the risk of bloodstream infections.

Due to the shortage of 0.9% sodium chloride vials, we worry that the few remaining saline flushes are being used inappropriately and unsafely to dilute and reconstitute medications in patient care units, further depleting the supply and resulting in a serious safety issue. First, the mislabeling that occurs when medications are added to a prefilled saline flush

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> **SAFETY** briefs cont'd from page 2 problems with obtaining REMS certification. Importantly, practitioners may not be aware that there is currently a temporary FDA waiver for the dispense authorization requirement. FDA has stated that pharmacists may dispense cloZAPine without a REMS authorization and wholesalers may continue to ship it during the temporary suspension of REMS (www.ismp.org/ext/841). Also, alert practitioners to the need to restart cloZAPine treatment at 12.5 mg once or twice daily when there has been a break in therapy for 2 days or longer. The hospital where this event occurred is considering an electronic requirement for the prescriber to input the patient's previous dose and when the last dose was administered when entering a new order. Or, the pharmacy could be required to gather this information for all new orders for cloZAPine. The hospital is also considering an electronic inquiry to learn if the order is a new start or restart, along with providing dose titration parameters. FDA and product manufacturers should work together to incorporate into the boxed warnings a recommendation

All about the slashed zero glyphs. Hos-

in therapy for 2 days or longer.

to slowly re-initiate clo**ZAP**ine after a break

HIGH-ALERT pital pharmacy staff noticed a discrepancy with the lot numbers they were entering when repackaging enoxaparin injection by Amphastar Pharmaceuticals. The lot number imprinted on one label appeared to read "E0073G1," with two zeros after the letter "E." At the same time, another enoxaparin injection label from the same manufacturer clearly read, "E0Ø73G1," revealing that what was thought to be the number zero was actually the letter 0, while to the right of that was actually the number zero (Figure 1). This

> E0073G1 06-2023



GTIN: 00305485601002 SERIAL: 20000000520724 EXP: 2023-06

NDC: 0548-5601-00

Figure 1. Lot number in the top label appears to be E0073G1. The bottom label clarifies the lot number, listing the letter O followed by the number zero with a slash mark through it.

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> **Drug shortages** — continued from page 3

syringe without applying a secondary label increases the risk for significant errors. In many cases, the manufacturer's label is permanently affixed to the syringe barrel and contains product codes and a barcode specific to the prefilled saline syringe. When a medication is added to this syringe, the syringe frequently remains labeled only as 0.9% sodium chloride, and also lacks an appropriate barcode to scan because it now contains the diluted or reconstituted medication. Furthermore, most commercially available prefilled syringes of saline (and heparin) flushes are regulated by the US Food and Drug Administration (FDA) as devices, not as medications, since these products keep lines open as a result of a physical effect and have no therapeutic effect when used as directed. While these devices have received approval for the flushing of VADs, they have not been tested and approved for the reconstitution, dilution, or subsequent administration of medications.

Sterile Water for Injection Shortage

Most sterile water for injection vials (i.e., 5 mL, 10 mL, 20 mL, 50 mL, 100 mL) are in short supply. These vials are primarily used to reconstitute medications available as lyophilized powders. While the prescribing information for some medications suggests that an alternative sterile liquid can be used for reconstitution, many specify that sterile water for injection must be used. The consequences of using a different sterile liquid to reconstitute medications may be unknown but could include poor dissolution of the powder, precipitation, or deactivation of the active pharmaceutical ingredient before administration.

A pharmacist recently reported a dangerous workaround caused by the sterile water for injection shortage. Understanding the infection control risk, a nurse called a pharmacist's attention to a sterile water for irrigation bottle (500 mL) that had been spiked with a port and was being used as a common-source bottle to prepare syringes of sterile water to reconstitute intravenous (IV) push antibiotics. However, the pharmacy had been preparing unit doses of sterile water for injection from larger bags in batches using a primary engineering control, and stocking the pharmacy-prepared unit doses of sterile water for injection in an automated dispensing cabinet (ADC) refrigerator for nurses to use when reconstituting lyophilized antibiotics. Not all staff knew the pharmacy had provided a supply of sterile water for injection in unit doses in the ADC.

It is an unsafe practice to prepare syringes used for flushing, dilution, or reconstitution for more than one patient from a common-source bottle or bag outside the pharmacy. In the pharmacy, the practice might be safe if primary engineering controls are used and strict sterile compounding regulations are followed. But outside of the pharmacy, there is a risk of contamination and disease transmission to a large group of patients, even if the solution is discarded after 24 hours. In addition, sterile water for *irrigation* is not labeled for use as an *injection* in patients. Sterile water for *injection* must pass a USP particulate-matter test that sterile water for *irrigation* does not have to pass, so they are not considered equivalent.

(EPINEPHrine Shortage

Currently, there are shortages of **EPINEPH**rine injection 1 mg/10 mL syringes (0.1 mg/mL) as well as certain **EPINEPH**rine autoinjectors (0.3 mg/0.3 mL, 0.15 mg/0.15 mL, 0.15 mg/0.3 mL). Autoinjectors are used for the emergency treatment of anaphylaxis. Emergency syringes are commonly found in code carts and used for the treatment of ventricular fibrillation or pulseless ventricular tachycardia unresponsive to initial defibrillation, pulseless electrical activity, and asystole. If prefilled syringes cannot be provided, ISMP has previously recommended providing an emergency kit containing vials of **EPINEPH**rine (1 mg/mL) and 0.9% sodium chloride (10 mL) for dilution, along with directions for preparing a 0.1 mg/mL concentration for IV push administration. Primarily, 0.9% sodium chloride is needed to facilitate the dilution of **EPINEPH**rine in vials and the administration of this critical emergency drug; however, 0.9% sodium chloride is also in short supply.

SAFE PRACTICE RECOMMENDATIONS: Sometimes drug shortages can lure practitioners and organizations to employ unsafe practices in order to provide immediate care. However, continued on page 5 — **Drug shortages** >

> **SAFETY** briefs cont'd from page 3 could be a safety issue if there are any medication recalls that have this font for lot numbers that include the letter "0" or the number zero. A zero with a slash through it (Ø)—called a glyph—helps distinguish

"zero" ("0") from the Latin script letter "0."

It would be helpful if drug companies would

Look-alike tablets with nearly identical imprints. A pharmacist verifying a patient's medication from home discovered two brown, round tablets that had nearly identical imprints, "I 2" and "I-2," mixed in the same container. The pharmacist searched to learn whether these look-alike tablets were the same medication, but he found that they were different medications—amitriptyline

and ibuprofen (Figure 1).

follow through with this strategy.



Figure 1. Similar tablet imprints appear on amitriptyline ("I 2") supplied by Accord Healthcare (left) and ibuprofen ("I-2") supplied by various companies (right).

The tablet with the "I 2" imprint was amitriptyline hydrochloride 25 mg, a tricyclic antidepressant, while the tablet marked "I-2" was ibuprofen 200 mg. It is not difficult to imagine the danger of product misidentification. For example, an emergency department patient with a tricyclic antidepressant overdose, which is associated with severe cardiovascular, anticholinergic, and central nervous system adverse effects, could be mistaken as overdosing on a nonsteroidal anti-inflammatory drug.

ISMP has reached out to the US Food and Drug Administration (FDA) to report this lookalike tablet and imprint concern, as we have previously done in other situations where oral dosage forms are practically impossible to properly identify given their similar appearance. For example, in our August 12, 2021 issue, we discussed an incident involving tablet misidentification between topiramate 50 mg and tra**ZOD**one 50 mg tablets, and in the March 12, 2020 issue, we discussed potential harm from tablet mixups due to similar-looking indapamide 2.5 mg

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when drug shortages do occur, organize the response to seek safe alternatives and to comply as much as possible with medication safety best practices that embrace conservation and inventory management of the drug in short supply, as well as clinical management and error-mitigation strategies. The tiered strategies listed below should be based on your current inventory and will allow you to relax some of the conservation and inventory management strategies as your supply improves, while reserving some clinical management strategies **ONLY** after all resources have been exhausted.

General

- Contact your wholesaler or the manufacturer's representative to keep abreast of their inventory of products in short supply (purchase depends on hospital contracts and existing customer relationships).
- Examine your current usage, inventory, distribution, and waste of a product in short supply and alternatives to develop conservation strategies for managing the inventory and prioritizing its use.
- Work with your materials management department to transfer and centralize solutions in short supply and alternatives (e.g., small volume bags) to the pharmacy.
- Use multiple pathways to communicate conservation strategies, practice changes, safe use of alternatives, and error-mitigation strategies to impacted practitioners.
- **Do NOT** use IV solutions in containers (e.g., infusion bags, bottles, minibags) as common-source containers to prepare IV flush syringes or to dilute or reconstitute medications outside the pharmacy, even if labeled and only used for 24 hours.
- **Do NOT** reuse a syringe or reuse any remaining solution or medication in the syringe (single use only).
- **Do NOT** use multiple-dose vials for multiple patients in clinical areas; dedicate multiple-dose vials to a single patient.

0.9% Sodium Chloride Shortage

- Once all inventory of saline flush syringes is in the pharmacy, employ the following <u>pharmacy</u> conservation strategies:
 - ☐ Reduce floor stock quantities to reserve inventory
 - ☐ Procure and dispense 10 mL (diameter) flush syringes that hold smaller volumes of saline (e.g., 3 mL or 5 mL fill volume) for use with central lines
 - ☐ Maximize the use of bag and vial systems for drug reconstitution or dilution and premixed medications (as available)
 - ☐ Consider alternative methods for reconstitution or dilution, such as pharmacyprepared infusions
 - ☐ Reserve small volume bags of 0.9% sodium chloride for medication preparation
- Employ the following nursing conservation strategies for saline flushes:
 - ☐ Eliminate unnecessary medication dilution (<u>www.ismp.org/node/582</u>)
 - ☐ Reserve 10 mL (diameter) saline flushes for central lines as much as possible
 - ☐ Use large volume 0.9% sodium chloride bags for starting IV lines and administering blood products
- Reserve 10 mL vials of 0.9% sodium chloride for use in emergency code cart kits dispensed (with **EPINEPH**rine) from the pharmacy.
- **Do NOT** dilute or reconstitute medications by drawing up the contents into a commercially available, prefilled flush syringe of 0.9% sodium chloride and then administering the resultant product.
- **Do NOT** reuse the same saline syringe to flush VADs before and after medication administration.
- **Do NOT** use sterile water for injection for flushing VADs.
- Remove IVs, central lines, and saline locks if not used for 24 hours or more.
- Use central VADs with the least number of lumens needed.
- Purchase saline flush syringes from a pharmacy outsourcer.
- In a complete outage: Have pharmacy prepare saline flushes (e.g., repackaged from bags and labeled appropriately) in compliance with sterile compounding regulations. Assign a beyond-use date based on USP <797>.

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> **SAFETY** briefs cont'd from page 4 and spironolactone 25 mg tablets. While the Code of Federal Regulations (CFR § 206.10) requires code imprints that, in conjunction with the product's size, shape, and color, permit the unique identification of the product, it does not mention specific instructions to ensure solid oral dosage forms are not too similar in appearance. We have asked the FDA to determine whether the CFR requires modification. At one point, USP explored the development and promotion of standardized imprint coding for solid oral dosage forms. USP members agreed that the current system for identifying oral dosage forms needed improvement. However, this effort was abandoned due to cost considerations and uncertainty regarding the most optimal solution. ISMP will also be reaching out to Accord Healthcare and various suppliers of ibuprofen to address these look-alike safety concerns.

Unfortunately, the National Library of Medicine's (NLM) Pillbox program was retired on January 29, 2021 (www.ismp.org/ext/806), so this program cannot be used for pill identification anymore. Resources like Medline-Plus Drugs, Herbs and Supplements (www.ismp.org/ext/811) serve as trustworthy sources of consumer information, and DailyMed (www.ismp.org/ext/812) provides container labels and package inserts for all marketed drugs; however, these resources do not provide pill identification. Hopefully FDA will improve data sources for the public to accurately identify drug products.

Prasugrel unavailable in unit dose packaging. In our December 16, 2021 newsletter, we mentioned that we had confirmed availability of the antiplatelet drug prasugrel in unit dose packaging from Aurobindo. In 2020, Eli Lilly discontinued production of unit dose packaging of its prasugrel product, **EFFIENT**. That brand is now marketed in the US by Daiichi Sankyo, and unit dose Effient remains unavailable. Although Aurobindo initially confirmed to us that unit dose packaging was available, several hospitals reported that they have been unable to obtain this packaging of prasugrel from Aurobindo. We contacted the company again and learned that we were given incorrect information due to internal confusion within the company. Aurobindo now confirms that unit dose packaging is not available. ISMP regrets any inconvenience this misinformation may have caused.

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Sterile Water for Injection Shortage

- Employ the following <u>pharmacy</u> conservation strategies:
 - Switch to premixed products, bag and vial systems, or dual-chamber flexible containers whenever possible
 - ☐ Reserve vials of sterile water for injection for the reconstitution of medications
 - □ Batch the preparation of medications that require reconstitution in compliance with USP <797> to minimize waste
 - ☐ Switch to a large-volume bag of sterile water for injection for reconstitution of medications using a closed system dispensing device (e.g., www.ismp.org/ext/838)
- **Do NOT** use bacteriostatic water for injection in place of sterile water for injection (unless directed in the prescribing information), especially for intrathecal or epidural injections or for neonates.
- **Do NOT** use 0.9% sodium chloride in place of sterile water for injection (unless directed in the prescribing information) to reconstitute medications, which can result in hyperosmotic solutions at or near the saturation point and cause crystallization or infusion site reactions.
- **Do NOT** use sterile water for *irrigation* in place of sterile water for *injection*.
- In a complete outage: Have pharmacy repackage large bags (1,000 mL or less, not pharmacy bulk packages) of sterile water for injection into empty sterile vials in compliance with sterile compounding regulations. Assign a beyond-use date based on USP <797>. **ONLY** repackage the sterile water for injection into syringes as a last resort if empty sterile vials are not available, as sterile water for injection prepared in syringes risks mix-ups with saline flush syringes.

(EPINEPHrine Shortage

- Conserve **EPINEPH**rine emergency syringes for code carts and code situations.
- Limit the number of emergency EPINEPHrine syringes stocked in code carts.
- If using 1 mg/1 mL vials in lieu of emergency syringes, package the vial, diluent (10 mL of 0.9% sodium chloride), and syringe label in a kit prominently labeled with the drug name and strength, and include instructions for preparing a dilution equivalent to a prefilled 1 mg/10 mL emergency syringe (i.e., EPINEPHrine 1 mg/mL: Dilute 1 mg [1 mL] in 9 mL of 0.9% sodium chloride for a final concentration of 0.1 mg/mL).
- Quarantine expired EPINEPHrine products and check with FDA (www.ismp.org/ ext/833) about extended dating before discarding (FDA has extended the expiration date for certain lots of EPINEPHrine syringes).
- **Do NOT** stock the 30 mL multiple-dose **EPINEPH**rine vials in code carts, emergency boxes, or floor stock.
- Purchase syringes of EPINEPHrine (0.1 mg/mL, 1 mg/10 mL) from a pharmacy outsourcer.
- In a complete outage of EPINEPHrine syringes and 0.9% sodium chloride vials: ONLY if all resources are exhausted and prefilled saline flush syringes are needed for dilution of EPINEPHrine during code situations, withdraw the EPINEPHrine into an empty syringe and use a Luer-lock-to-Luer-lock transfer device (e.g., www.ismp.org/ext/837; www.ismp.org/ext/840), which must be provided with **EPINEPH**rine kits on code carts, to withdraw the 0.9% sodium chloride from the prefilled saline flush syringe into the syringe with the pre-drawn **EPINEPH**rine. **Avoid** diluting or reconstituting medications by drawing up the contents into a commercially available, prefilled flush syringe of 0.9% sodium chloride and then administering the resultant product. If you must do this as a last resort during code situations, the saline flush syringe **MUST** be relabeled, covering the original contents and barcode and replacing it with a new label showing that EPINEPH rine is in the syringe (provide the new label in a kit). Another last-resort option is to provide a 250 mL bag of 0.9% sodium chloride labeled as a flush solution that can be used to dilute EPINEPHrine-but only during a single code. The bag should be immediately disposed of after the code. These last-resort options should **NOT** be utilized outside of emergency code situations.

Sources of recommendations appear at the top of the right column >

Sources of recommendations

- 1) Drug Shortages Resource Center (www.ashp.org/ shortages)
- 2) ASHP Connect posting from Kevin Hansen (www.ismp.org/ext/835)
- 3) ASHP and the University of Utah Drug Information Service Sterile Water for Injection Shortage Frequently Asked Questions (<u>www.ismp.org/ext/829</u>)
- 4) FDA Drug Shortages (<u>www.ismp.org/ext/830</u>)
- 5) Infusion Nurses Society and National Coalition for IV Push Safety Saline Flush and Vial Shortage (www.ismp.org/ext/834)
- 6) ISMP Safe Practice Guidelines for Adult IV Push Medications (www.ismp.org/node/97)

Special Announcements

Virtual MSI workshops

Don't miss the opportunity to register for our first 2-day virtual ISMP Medication Safety Intensive (MSI) workshop of the year, offered on January 27-28, 2022. For details and more dates in 2022, visit: www.ismp.org/node/127.

Virtual ISMP mentorship

Take advantage of ISMP's online Practitioner in Residence (PIR) mentorship program, which will consist of five weekly sessions on Tuesdays, from **February 1** through March 8, 2022 (no session on February 22). For details, visit: www.ismp.org/node/28657.

FREE FDA webinar series

The US Food and Drug Administration's (FDA) Division of Drug Information is presenting a FREE webinar, FDA Drug Topics: Biosimilar and Interchangeable Biosimilars: Review of Scientific Concepts, Case Studies, and Resources, on January 25, 2022. For details, visit: www.ismp.org/ext/30, and to register, visit: www.ismp.org/ext/31.

To subscribe: www.ismp.org/node/10

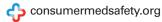


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Report medication and vaccine errors to ISMP: Call 1-800-FAIL-SAF(E) or visit our website at: www.ismp.org/ report-medication-error

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Special thanks to our **2021 MSOS Member Briefings Presenters**

The Medication Safety Officers Society (MSOS) holds Member Briefings every other month on various medication safety topics. The MSOS Member Briefings are webinars that feature three 10-minute presentations from volunteer MSOS members who highlight a project, initiative, or relevant medication safety topic. The goal is for participants to take the information presented and use it to implement similar medication safety initiatives within their own organization. At each Member Briefing, ISMP President Emeritus Michael Cohen also provides an update on ISMP activities. Please let us know (ismpinfo@ismp.org) if there is a medication safety topic you would like to present (or see presented) during a 2022 MSOS Member Briefing. We hope others can join us as presenters in 2022! To join the MSOS and attend the Member Briefings, visit: www.medsafetyofficer.org/user/register. MSOS membership and the 2022 Member Briefings are **FREE**.

Production of the MSOS Member Briefings would not be possible without the assistance of voluntary MSOS member presenters. ISMP sincerely thanks all of the 2021 presenters who helped make the Member Briefings a valuable medication safety resource for MSOS members.

Thank You!

- Scott D. Alcott, MSN, RN, NEA-BC; Director of Nursing Education & Professional Development Safety Officer, Einstein Medical Center Montgomery, East Norriton, PA
- Lisa Asmar-Abdien, BS Pharm, MBA; Clinical Research Content, City of Hope Hospital & Healthcare, Duarte, CA
- Jessica Anderson, PharmD, BCPPS; PICU Clinical Pharmacy Specialist, Monroe Carell Jr. Children's Hospital at Vanderbilt, Nashville, TN
- Phil Ayers, BS, PharmD, BCNSP, FMSHP, FASHP; Chief, Clinical Pharmacy Services, Mississippi Baptist Medical Center, Jackson, MS
- Callee Brooks, PharmD candidate; The University of Tennessee Health Science Center, Methodist Le Bonheur Healthcare, Memphis, TN
- Joseph Boullata, PharmD, RPh, CNS-S, FASPEN, FACN; Clinical Nutrition Pharmacy Specialist, Hospital of the University of Pennsylvania, Philadelphia, PA
- Samantha Burton, PharmD, FISMP; Medication Safety Pharmacist Smart Pumps, Cleveland Clinic Foundation, Cleveland, OH
- Joel Daniel, PharmD, MS, CPPS; System Medication Safety Pharmacist, CoxHealth, Springfield, MO
- Morgan Greutman, PharmD, BCPS; Medication Safety Officer, Choctaw Nation Health Services Authority, Talihina, OK
- Cassandra Hickman, PharmD; EHR Pharmacy Analyst, University of Kentucky HealthCare, Lexington, KY
- G. Morgan Jones, PharmD, BCCCP, FCCM; Clinical Pharmacy Specialist Neurocritical Care, Methodist Le Bonheur Healthcare, Memphis, TN
- Sarah Kim, PharmD, BCOP; Senior Protocol Content Administrator, City of Hope Hospital & Healthcare, Duarte, CA
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- Magdalene (Maggie) Mastalerz, PharmD; PGY2 HSPAL Resident, University of Kentucky HealthCare, Lexington, KY
- Andrew Mays, PharmD, BCNSP, CNSC; Clinical Pharmacy Specialist, University of Mississippi Medical Center, Jackson, MS
- Casey Moore, PharmD; Medication Safety Pharmacist Enterprise Pediatrics, Cleveland Clinic, Cleveland, OH
- Jill Paslier, PharmD, CSP, FISMP; Paslier Consulting, LLC, Philadelphia, PA
- 🖊 Amy Potts, PharmD, MMHC, BCPPS, FPPA; Program Director, Quality, Safety & Education, Monroe Carell Jr. Children's Hospital at Vanderbilt, Nashville, TN
- Kathryn Ruf, PharmD, MBA; Associate Director, Pharmacy Value and Analytics, University of Kentucky HealthCare, Lexington, KY
- **Donald Singh**, PharmD, MBA, BCPS; PGY2 Resident, Johns Hopkins Hospital & Healthcare, Baltimore, MD
- Joseph Vu, PharmD; PGY2 Resident, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
- Nicola Wake, BPharm, MRPharmS; Specialist Pharmacist: Lead Medication Safety, NHS Specialist Pharmacy Service, Medication Safety Officer, Northumbria Healthcare NHS Foundation Trust, Newcastle Upon Tyne, UK
- Mark Wolf Jr., PharmD; PGY2 Medication-Use Safety & Policy Pharmacy Resident, Univerity of Kentucky HealthCare, Lexington, KY



ISMP Safe Medication Management Fellowships

ISMP is now accepting applications for three unique **Fellowship** programs commencing in **2022**

ISMP Safe Medication Management Fellowship

Location and Term: This Fellowship commences in July 2022. The Fellow will spend 12 months with ISMP, which is located in the suburbs of Philadelphia (Montgomery County), Pennsylvania. Relocation to the Philadelphia area will depend on the state of the COVID-19 pandemic.

Description: Now in its 30th year, this Fellowship offers a **healthcare professional with at least 1 year of postgraduate experience in a healthcare setting** an unparalleled opportunity to work collaboratively with the nation's experts in medication safety to assess and develop interdisciplinary medication error-prevention strategies.

FDA/ISMP Safe Medication Management Fellowship

Location and Term: This Fellowship commences in the summer of 2022. The Fellow will spend 6 months with ISMP, which is located in the suburbs of Philadelphia (Montgomery County), Pennsylvania, and 6 months with the US Food and Drug Administration (FDA), which is located in Silver Spring (near Washington, DC), Maryland. Relocation to these areas will depend on the state of the COVID-19 pandemic.

Description: This Fellowship, open to a **healthcare professional with at least 1 year of postgraduate experience in a healthcare setting**, is a joint effort between ISMP and FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Divisions of Medication Error Prevention and Analysis I and II. The Fellowship allows the candidate to benefit from ISMP's years of medication safety experience along with FDA's valuable regulatory experience focused on medication error prevention.

ISMP International Medication Safety Management Fellowship

Location and Term: This Fellowship commences in July 2022. The Fellow will spend 12 months with ISMP, which is located in the suburbs of Philadelphia (Montgomery County), Pennsylvania. Relocation to the Philadelphia area will depend on the state of the COVID-19 pandemic.

Description: This Fellowship, open to a **healthcare professional with at least 1 year of postgraduate experience in a healthcare setting**, will help train a medication safety leader interested in seeking a long-term career at an international level. The Fellow will be involved in both US and international medication safety initiatives, helping to address medication safety issues on a national and global level.

Applicants for all three Fellowship programs must be legally eligible to work in the US and have excellent written and verbal communication skills. A competitive stipend is provided with all Fellowship programs.

How to Apply

For a complete description of candidate qualifications and how to apply online, visit: www.ismp.org/profdevelopment/.

For questions regarding the Fellowships or the application process, please contact ISMP at: fellowship@ismp.org or 215-947-7797.

The application deadline for all three Fellowship programs is March 13, 2022.