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ISMP
An ECRI Affiliate

Community/Ambulatory Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Start the year off right by addressing these Top 5 Medication Safety Concerns from 2021

Last year began with such hope. Thanks to the availability of coronavirus disease 2019 (COVID-19) vaccines, society began to gradually return to life as we knew it prior to the pandemic. Sadly, our return to normalcy was delayed by the emergence and spread of the delta and omicron variants, overwhelming our healthcare providers once again. As we reflect on our newsletters in 2021 and the topics we wrote about last year, is it any wonder that three of our **Top 5 Medication Safety Concerns** from 2021 are errors with the lifesaving COVID-19 vaccines? We believe these medication safety concerns warrant continued attention and priority in 2022, especially if you have not already taken steps to mitigate them.

1 Mix-ups between the pediatric and adult formulations of the Pfizer-BioNTech COVID-19 vaccines

Late in 2021, after the US Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine for children ages 5 through 11 years, we began to receive reports of mix-ups between the formulation for ages 5 through 11 years (orange cap and label border) and the formulations for individuals 12 (or 16) years or older (purple cap and label border or gray cap and label border; brand name of the FDA-approved vaccine is **COMIRNATY**). The labels are not well differentiated, and once the caps are removed, the color difference is less apparent. Even the dose in mcg is not listed on the vaccine labels, which would likely help to differentiate the pediatric and adult formulations. Some of the vaccine mix-ups occurred due to look-alike vial or syringe mix-ups. In other cases, healthcare providers mistakenly believed it was acceptable to administer a smaller or diluted dose of the vaccine formulation intended for individuals 12 years or older to children ages 5 through 11 years. These mix-ups may have scared people, increased vaccine hesitancy, and weakened public health efforts to increase the number of vaccinated children.

To prevent mix-ups, separate the different formulations and label the storage bins. Never use vaccine vials formulated for individuals ages 12 (or 16) years or older (purple or gray cap) to prepare doses for children ages 5 through 11 years. Use barcode scanning during vaccine preparation and apply labels to vaccine syringes that differentiate between adult and pediatric doses. Only bring the intended vaccine(s) for one patient at a time into the vaccination area and include the parent/patient when verifying the prepared vaccine. Ideally, barcode scanning should be employed prior to administration. Document the lot number and expiration date prior to vaccine administration, and document administration afterwards. Report any vaccination errors to the FDA Vaccine Adverse Event Reporting System (VAERS; https://VAERS.hhs.gov/), which is mandatory for COVID-19 vaccines under an EUA, and to the ***ISMP National Vaccine Errors Reporting Program*** (ISMP VERP; www.ismp.org/VERP).

2 Preparation errors with the Pfizer-BioNTech purple cap or gray cap COVID-19 vaccines

Early in 2021, we published reports of dilution errors with the Pfizer-BioNTech COVID-19 vaccine (purple cap), which resulted in administering too much or too little vaccine.

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Worth repeating...

Caution when restarting cloZAPine

An October 2019 *Safety Brief* warned about the potential for severe cardiovascular effects when restarting clo**ZAP**ine (**CLOZARIL**). When restarting clo**ZAP**ine in patients who have not been taking it for 2 days or more, the manufacturer recommends administering 12.5 mg once daily or twice daily. This is necessary to minimize the risk of hypotension, bradycardia, and syncope. If the initial dose is well-tolerated, the dose may be titrated to the previous therapeutic dose more quickly than recommended for initial treatment.

We recently received another report of this harmful error. A 40-year-old woman with schizoaffective disorder had been taking a total daily dose of clo**ZAP**ine 500 mg for at least 10 years. However, recently she had not taken the drug for nearly 2 weeks due

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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 6 for details.

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In many cases, practitioners used too little diluent (often 1 mL instead of 1.8 mL), too much diluent, or diluted the vaccine vial twice. In other cases, the vaccine was administered without dilution, the wrong diluent was used (often sterile water instead of 0.9% sodium chloride), or 1.8 mL of air in a syringe was used to "dilute" the vaccine.

In August 2021, a Pfizer-BioNTech COVID-19 vaccine, Comirnaty, was approved by FDA for the prevention of COVID-19 in individuals 16 years of age and older. Today, FDA-approved Comirnaty is available with either a purple cap or a gray cap. Similarly, the Pfizer-BioNTech vaccines still available under an EUA for individuals 12 through 15 years of age and for the administration of a booster dose (or a third dose for immunocompromised individuals) have either a purple or gray cap. The purple-capped Comirnaty and Pfizer-BioNTech EUA vaccines require dilution prior to use. However, Comirnaty and Pfizer-BioNTech EUA vaccines with gray caps MUST NOT be diluted prior to use. Although we have not received any error reports yet, we worry that these vaccines will be mixed up during preparation, resulting in erroneously diluting the gray-capped vaccine, or failing to dilute the purple-capped vaccine.

To avoid mix-ups between the purple- and gray-capped vaccine vials, do not store them together in the refrigerator during or after thawing (e.g., use separate storage bins on different shelves). To prevent dilution errors, have the pharmacy prepare and dispense predrawn, labeled syringes of the vaccine if feasible within the time-frame for stability at room temperature. If preparing either the purple- or gray-capped vaccine outside of the pharmacy, require an independent double check of the preparation process. When preparing the vaccine syringes, remove syringes from their packaging one at a time, immediately before drawing up diluents or doses; do not open syringe packages ahead of time and/or fill the syringes with air in preparation for later dose or diluent withdrawal. Educate pharmacy and vaccination staff regarding the common types of errors that may occur. Provide those who prepare the vaccines with an updated *Fact Sheet* for the EUA vaccines (www.ismp.org/ext/842, www.ismp.org/ext/813) or the package insert for Comirnaty (www.ismp.org/ext/843), and verify their competency regarding vaccine preparation.

3 Respond to Consumers' Error Concerns with Empathy, Transparency, and Honesty

ISMP frequently receives reports of medication errors directly from patients. Often these reports describe errors that occurred in community pharmacies. While the reporters are understandably concerned about the error, they are usually more upset about the response, or lack of response, from the pharmacist or pharmacy management team than with the actual error itself. Instead, responding to victims of errors with transparency and honesty puts the patient's safety and interests in focus. It encourages open communication about errors and supports system improvements. Most importantly, it's the right thing to do.

Practitioners should approach all patients reporting actual or potential medication errors with transparency and empathy. Every pharmacy should have written policies and procedures for responding to medication errors, including guidance on how to document and communicate the situation to all relevant parties. Policies on disclosure and apology to patients and caregivers (and others as necessary) are also a must. These policies and procedures need to be reviewed and discussed with the pharmacy team. Practice and role-play possible scenarios with all staff using your established procedures and guidelines. The attention and concern demonstrated to the patient and family through the admission and apology for an error as well as follow-up discussion of what will be done to prevent future occurrences can help achieve an amicable and fair resolution for all involved.

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to problems her psychiatrist was having registering with the updated Risk Evaluation and Mitigation Strategies (REMS) certification (www.newclozapinerems.com).

The patient was admitted to the hospital psychiatric unit and restarted on cloZAPine. Her physician did not want to restart her at the full dose since she had not been taking 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 practitioners are aware of the issue of cloZAPine-associated neutropenia and infection risk because the REMS program is designed to manage these risks. However, many practitioners are not aware of the potential severe adverse cardiovascular effects, including cardiac arrest, when the drug is abruptly discontinued and then restarted after 2 days or more. Ensure that all practitioners handling cloZAPine are aware of the potential for these adverse cardiovascular effects. Alert practitioners of 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. Investigate options to develop clinical decision support to help ensure practitioners check the date and time of the patient's last dose and to restart therapy according to manufacturer guidelines. 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. When dispensing cloZAPine and counseling patients, inquire about the date and amount of the last dose taken. The US Food and Drug Administration should work with manufacturers to incorporate into the boxed warnings a recommendation to slowly restart cloZAPine after an interruption in therapy for 2 days or longer.

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4 Mix-ups between the COVID-19 vaccines or boosters and the 2021-2022 influenza (flu) vaccines

Once the 2021-2022 flu vaccine became available in September 2021, health authorities strongly encouraged people to receive both the flu vaccine and the COVID-19 vaccine during the same visit. Unfortunately, once the flu vaccine was available, mix-ups between the flu and COVID-19 vaccines started happening. Many of the reported errors occurred with patients who consented to a flu vaccine receiving a COVID-19 vaccine instead, or vice versa. Some of the mix-ups were associated with unlabeled syringes or labeled syringes that were next to each other in vaccination areas. Other mix-ups were linked to distractions or staffing shortages that led to managing both dispensing and vaccination responsibilities simultaneously.

To prevent mix-ups, schedule vaccinations for a dedicated block of time each day and ensure adequate staffing. Staff should not be expected to accomplish both vaccine administration and other responsibilities simultaneously. Provide a separate area for vaccine administration, away from distractions and interruptions. Use barcode scanning during vaccine preparation and label all prepared syringes. Only bring the intended vaccine(s) for one patient at a time into the vaccination area and include the parent/patient in verifying the prepared vaccine(s). Before vaccine administration, ask the patient which vaccine(s) they have requested, and verify the vaccine(s) with signed consent form(s). Ideally, barcode scanning should occur prior to administration. Document the lot number and expiration date prior to administration, and document administration afterwards. If a mix-up occurs, apologize to the patient and provide the intended vaccine before they leave the vaccination area (or ask the patient to return to the vaccination site). Report any vaccination errors to FDA VAERS (https://VAERS.hhs.gov/) and ISMP VERP (www.ismp.org/VERP).

5 Increasing error reporting

Error-reporting systems are an important tool for improving patient safety and often represent the primary means of learning about hazards and errors. But encouraging staff to submit reports is not easy given the potential disincentives to reporting, including embarrassment, the perception that reporting is not worth their time, or if reporting is time consuming, confusing, or complex. Furthermore, the workforce is understandably reluctant to report errors if they are worried that the information will get them in trouble, impact their job, or lead to the perception of being careless or incompetent.

Some highly functional error-reporting systems exist today from which best practices that promote error reporting can be identified. These best practices fall into nine categories that impact the quantity and quality of reports:

- **Trustworthiness:** Earning reporters' trust and proving the leaders' dependability
- **Open, fair, and learning culture:** Reporting without fear of being treated unfairly
- **Confidential:** Keeping the identity of reporters and involved staff confidential
- **Clear:** Defining the types of hazards and errors, including close calls, to be reported
- **Easy:** Making the reporting process exceedingly easy and readily accessible
- **Credible and useful:** Avoiding inaction and using the report to improve safety
- **Rewarding:** Recognizing reporters for playing a positive role in patient safety
- **No severity bias:** Not allowing the severity of the outcome to influence the response
- **Reinforced imperative:** Mentoring new and existing staff about reporting

SAFETY briefs

Error involving Paxlovid packaging.

A patient diagnosed with coronavirus disease 2019 (COVID-19) presented at a hospital emergency department (ED) with a package of **PAXLOVID** (nirmatrelvir and ritonavir tablets) that she had been using at home to prevent severe disease. The patient, who had moderate renal impairment, was admitted to the hospital. The admitting physician ordered to continue administering the Paxlovid blister packages from home. The medication was brought to the pharmacy for identification. The pharmacist identified the medication but realized that the missing tablets did not match the patient's instructions to take one ritonavir and one nirmatrelvir orally, twice a day, which is the correct dose for patients with moderate renal impairment. Although labels were affixed over missing nirmatrelvir tablets on each blister card, there were also missing ritonavir tablets and some remaining nirmatrelvir tablets that should have been removed from the blisters.

On January 4, 2022, ISMP published an alert highlighting important renal dosing modifications outlined in the Paxlovid *Fact Sheet* (www.ismp.org/node/29046). The *Fact Sheet* instructs pharmacists to remove one of the two nirmatrelvir tablets for both the morning and evening doses from each of the blister cards before dispensing the drug to patients with moderate renal impairment. Ideally, there should be separately available packaging for patients with moderate renal impairment, along with a specific set of clear instructions for patient use. Alternatively, the reporter suggested that the manufacturer could conduct a risk assessment to determine whether it would be safe to supply one blister card with 10 ritonavir tablets and two separate blister cards with 10 nirmatrelvir tablets each, so pharmacists could dispense the correct amount of each drug without manipulating individual blisters. Either way, more user-friendly packaging would reduce the risk for dosing errors, which we have communicated to Pfizer, the manufacturer.

It is extremely important for pharmacists to counsel patients, even if this must be done via the telephone, to take both the nirmatrelvir and ritonavir tablets together in the morning and evening. For patients

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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.

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

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with moderate renal impairment, pharmacists should also explain that the packaging has been altered to provide the proper dose. If you learn of serious adverse events or medication errors potentially related to Paxlovid, report them to the US Food and Drug Administration MedWatch program (www.ismp.org/ext/609), which is mandatory for medications available under an Emergency Use Authorization. Please also fax a copy of the MedWatch form to Pfizer (866-635-8337). ISMP also asks providers to report errors to the ***ISMP National Medication Errors Reporting Program*** (www.ismp.org/MERP).

Errors with injectable specialty medications. ISMP has received numerous reports of risks and errors related to the quantity and package size of specialty medications. In one example, an outpatient pharmacy dispensed two syringes of **STELARA** (ustekinumab) 45 mg/0.5 mL because the data entry technician mistakenly entered a quantity of "1" for one syringe, not realizing that Stelara is billed (and dispensed) per mL. This resulted in 1 mL, or two syringes, being dispensed.

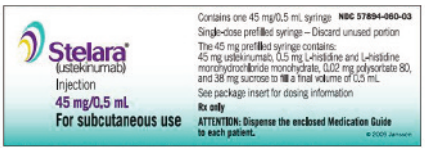

Figure 1. Stelara carton contains one syringe (0.5 mL), with a "milliliter" billing unit of 0.5 mL.

The National Council for Prescription Drug Programs' (NCPDP) Billing Unit Standard defines the standard "billing units" (www.ismp.org/ext/817) for medications, including injectables. The "milliliter" (mL) billing unit is used when a product is measured by its liquid volume, as seen with Stelara (**Figure 1**). However, other injectable products, such as **CIMZIA** (certolizumab pegol), are billed as "each" as they are considered kits containing a combination of a syringe, pen, or a tray of multiple syringes/pens and an alcohol swab(s). One challenge with selecting the correct billing unit is that pharmacy staff may not be aware of the exact contents inside the carton since these are usually not opened.

To learn more about specialty medication quantity and package size errors, ISMP sent a targeted 5-question survey to 36

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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, 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 the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), accreditors, professional organizations, and patient safety organizations has resulted in collaborative projects to advance medication safety and medication safety standards. Likewise, our recommendations to practitioners, healthcare providers, and organizations have also resulted in system- and practice-level changes.

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 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.

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specialty pharmacies. Sixty-four percent (N=23) of pharmacies responded to the survey. Ninety-six percent of the respondents indicated that they were aware of errors or close calls related to specialty injectable medication quantities or package sizes. The most common concerns were associated with confusion whether the billing unit was based on "milliliters" or "each" (e.g., kits), actual starter pack quantities, and when multiple syringes were needed for one dose. The medications most frequently cited by respondents as being involved in events were **DUPIXENT** (dupilumab), **HUMIRA** (adalimumab), Cimzia, and **SKYRIZI** (risankizumab-rzaa).

The survey respondents shared strategies they have implemented to prevent quantity and package size errors. One in three pharmacies use dispensing software notes to alert the team to the correct package size for specific products (e.g., quantity 1 = 2 syringes). Nearly one in five pharmacies requires two pharmacists to double check/verify the entry of all orders for specialty drugs. Two pharmacies suggested the use of a proactive risk assessment to evaluate the package size prior to dispensing a new medication. Two pharmacies also reported that they employed barcode scanning to detect package size discrepancies. Other strategies include clarifying the billing unit as "mL" vs. "each" (i.e., kit) in the dispensing system, adding a default package size to the dispensing software, configuring the computer system to print the number of labels based on the number of packages needed, and taping packages together.

Prescribers should include the units (mL vs. syringe vs. kit) with the quantity to minimize pharmacy staff confusion. If you dispense specialty medications, consider the above strategies. Please share with us (email ismpinfo@ismp.org) the strategies you have implemented to help prevent these types of errors.

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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.

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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.

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 September 2021 and December 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/29540.

Key: ⚠ **— ISMP high-alert medication**

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Mix-ups between adult and pediatric Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccines					
11/21 12/21	Mix-ups between the Pfizer-BioNTech COVID-19 pediatric vaccine formulation (orange cap) for ages 5 to 11 years and the adult formulations for individuals 12 (or 16) years or older (purple or gray caps) have been reported, impacting thousands of individuals. The labels are not distinct and fail to prominently show the intended age ranges. Also, once the caps are removed, the color difference is less apparent. Some mix-ups involve mistakenly believing it is appropriate to administer a smaller or diluted dose of the adult vaccine formulation to children.	Separate the formulations and clearly label the storage bins. Do not use vaccine vials formulated for individuals 12 (or 16) years or older (purple or gray caps) to prepare doses for children ages 5 to 11 years. Use barcode scanning during preparation and administration. Label syringes to differentiate adult and pediatric doses. Only bring the intended vaccine(s) for one patient at a time into the vaccination area. Include the patient/parent in verifying the vaccine. Report vaccination errors to the US Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS) and to ISMP.			
Mix-ups between influenza (flu) vaccines and coronavirus disease 2019 (COVID-19) vaccines					
10/21	Reports of mix-ups between the flu and COVID-19 vaccines have been reported ever since the 2021-2022 flu vaccine became available. Most of the reported mix-ups occurred in patients who consented to a flu vaccine but received a COVID-19 vaccine instead. Causative factors include vaccine syringes stored near each other, unlabeled syringes, distractions, and staffing shortages.	Ensure adequate and dedicated staff are present to assist in the vaccination process. Provide dedicated space for vaccination administration, away from distractions and interruptions. Bring only the prepared and labeled vaccine syringe(s) for one patient at a time to the vaccination area. Involve the patient/parent to confirm the correct vaccine(s), and scan the vaccine barcode(s) prior to administration when possible			
US Food and Drug Administration (FDA) warns about possible overdose with ENFit low dose tip (LDT) syringes					
11/21	FDA issued a warning (www.ismp.org/ext/798) about the potential for overdoses when using ENFit LDT syringes (0.5 to 0.6 mL). Liquid medications can collect in the moat area when the syringe is dipped into liquid medication without using an ENFit cap or medication straw.	Use a syringe filling adapter (straw, ENFit cap) when preparing ENFit LDT syringes. If fluid or air bubbles enter the moat area, tap or flick the syringe tip to remove them. ISMP and FDA recommend the use of enteral devices and syringes, including ENFit LDT syringes, to reduce the risk of misconnections.			

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
TRULICITY (dulaglutide) pen should never be primed					
10/21	Some nurses have been priming Trulicity pens, as they do for **VICTOZA** (liraglutide), **OZEMPIC** (semaglutide), and **BYETTA** (exenatide), which require the attachment of a disposable needle and priming. But Trulicity pens are more like autoinjectors and have an attached needle. Attempting to prime the pen empties its contents and wastes the drug.	Consider copying and including the manufacturer's information leaflet when dispensing Trulicity since nurses may not be familiar with this pen. Color copying is preferred since the instructions use color to make them easier to understand. Alerts in the medication administration record (MAR) that state, "Do NOT Prime the Trulicity Pen," are also recommended. When the pens are prescribed and dispensed directly to patients, educate the patient on how to use these devices.			
Ensure TRULICITY (dulaglutide) pens are stored properly					
10/21	An ambulatory care clinic provider recently increased a patient's weekly dose of Trulicity because they were not responding to therapy. It was later discovered that the patient was not storing their Trulicity pens in the refrigerator, and therefore, at least two single-dose pens each month were likely expired when used by the patient. Trulicity pens should be stored in the refrigerator. If needed, a pen can be kept at room temperature for a total of 14 days.	Teach patients how to properly store and use Trulicity pens. Consider marking Trulicity prescriptions mandatory for patient education. Establish a process to ensure pharmacy staff affix an auxiliary label to the medication carton to alert the patient to store the medication in the refrigerator. Leverage technology such that the pharmacy computer system automatically includes the appropriate auxiliary warning message(s) as part of the pharmacy label.			
Updated list of high-alert medications in community/ambulatory care settings released					
09/21 ⚠	The ***ISMP List of High-Alert Medications in Community/Ambulatory Care Settings*** was first developed in 2008. To update the list, practitioners were surveyed. To ensure 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.	The ***ISMP List of High-Alert Medications in Community/Ambulatory Care Settings*** was updated (e.g., narrowed oral hypoglycemics to sulfonylureas; removed met**FORMIN**, propylthiouracil, antiretroviral agents; moved warfarin and heparins into the new Antithrombotic agents category). Review the updated list (www.ismp.org/node/129) to determine if changes are indicated on your list. Layer a variety of effective risk-reduction strategies to prevent errors, make errors visible, and mitigate patient harm.			

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Tips for increasing error reporting					
12/21	Error reporting is a fundamental safety component, but staff may be reluctant to report hazards and errors due to the following barriers: 1) fear of reprisal and low psychological safety; 2) candid confessions of mistakes are uncomfortable; 3) staff may perceive no benefit from reporting; 4) a time consuming, confusing, and complex reporting process; and 5) reporting may not be a priority, especially for close calls.	Evaluate your reporting program: 1) Is the process clear, easy to use, and detailed enough to get causative information? 2) Is your culture fair and based on trust? 3) How do you acknowledge and address reports, communicate with reporters, and document error reports? 4) Do you avoid allowing the severity of the outcome to influence decisions? Also, review how you measure reporting success; it is not the quantity of reporting but the learning and prevention of harm that results.			
Labeling change of transdermal scopolamine can cause confusion about the product strength					
12/21	A pharmacist noticed that the strength of transdermal scopolamine was expressed in terms of how much medication was released over 3 days (1 mg/3 days) as opposed to the amount of scopolamine contained in the patch (1.5 mg). A US Food and Drug Administration (FDA) draft guidance (www.ismp.org/ext/774) calls for the strength of transdermal products to be expressed as a rate instead of the total drug content. FDA has worked with manufacturers to update all transdermal scopolamine product labeling. Until older stock has been exhausted, the potential for confusion will continue.	Alert staff to the change in dose expression for transdermal scopolamine. Consider editing pharmacy computer systems, order entry systems, and medication administration records (MARs) to indicate the drug delivery rate of 1 mg/3 days. During the availability of mixed labeling of these products, include a note on the order that states, "1.5 mg = 1 mg/3 days."			
Teach patients how toxic fluorouracil is to pets					
11/21 ⚠	When cats or dogs ingest fluorouracil, the urea cycle is disrupted, resulting in toxic hyperammonemia which is often fatal. Exposure happens when a pet licks the owner's skin where the medication was applied or chews the fluorouracil container. In a recent case, a patient was receiving intravenous fluorouracil via an elastomeric pump at home. His puppy chewed through the chemotherapy line and ingested the medication. Sadly, the puppy died.	Counsel patients about the toxicity of fluorouracil in pets, including how to ensure pets do not accidentally ingest the medication. This can be done by keeping pets away from chemotherapy lines, keeping the medications out of reach, and ensuring that pets do not lick the medication on a patient's skin if the medication is applied topically. Consider creating and adding an auxiliary label to warn patients of this toxicity to pets.			