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ISMP
An ECRI Affiliate

Community/Ambulatory Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Learning from errors with the new COVID-19 vaccines

PROBLEM: In mid-December, the US Food and Drug Administration (FDA) granted emergency use authorization (EUA) to both the Pfizer-BioNTech and Moderna coronavirus disease 2019 (COVID-19) vaccines. Since then, ISMP has received numerous voluntary reports of COVID-19 vaccine errors or hazards. (See the last recommendation on **page 5** regarding a mandatory requirement to report all COVID-19 vaccine errors and adverse reactions to the Vaccine Adverse Event Reporting System [https://vaers.hhs.gov].) The following highlights a few of the missteps happening across the nation and internationally, from vaccine dilution errors to look-alike product mix-ups. We conclude with safe practice recommendations to help prevent these types of errors.

Dilution Errors

A number of dilution errors have been reported with the Pfizer-BioNTech COVID-19 vaccine. After thawing, each Pfizer-BioNTech multiple-dose vaccine vial contains 0.45 mL, which must be diluted using 1.8 mL of preservative-free (not bacteriostatic) 0.9% sodium chloride injection. Once properly diluted, each vial contains 6, perhaps even 7, doses when using low dead-volume syringes/needles to extract each 0.3 mL (30 mcg) dose. The vaccine is administered intramuscularly (IM) as a series of 2 doses 3 weeks apart.

Dilution errors result in administering too much or too little vaccine. If you add too much diluent, doses may be ineffective; if you add too little diluent, doses may invoke stronger adverse effects (if one occurs). In one case, mixing the vaccine with too little diluent was suspected when only 0.25 mL remained in the vial when attempting to access the fifth dose. As instructed in the *Fact Sheet*, the remaining 0.25 mL of vaccine was discarded (rather than pooled with excess vaccine from other vials). The previous doses may have been overdoses.

According to a second report, an inadequate volume of 0.9% sodium chloride injection (approximately 1 mL) was added to the vaccine vial. Before the error was discovered, a 60-year-old patient received a nearly 2-fold overdose during his first vaccine dose. The patient had no initial reaction to the overdose and was discharged after an hour, with follow-up calls planned for the next 48 hours. Clinic staff called Pfizer to determine if the patient's second vaccine dose should be altered, but no immediate guidance was offered.

In a third case, which happened internationally, eight healthcare workers in a long-term care (LTC) facility received the entire vial contents (0.45 mL), without dilution, for their first dose of the Pfizer-BioNTech vaccine. Four of the eight workers were hospitalized as a precaution after experiencing flu-like symptoms from the overdose. According to BioNTech, doses up to 100 mcg (30 mcg is the recommended dose) were administered during a clinical trial of the vaccine, with only mild to moderate, transient local injection site reactions and flu-like symptoms being reported. No serious adverse effects were reported.

One of the latest reports, from a public health immunization clinic, describes a situation in which air, not the appropriate diluent, was added to the thawed concentrated vaccine liquid. A healthcare worker used a syringe whose plunger had already been pulled back to the 1.8 mL marking. Thinking it contained diluent, the worker injected the syringe contents into the Pfizer-BioNTech vaccine vial. The vaccine was "mixed," and the first dose of 0.3 mL was drawn into a syringe and given. However, when the second dose was withdrawn there was

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SAFETY briefs

Bamlanivimab confused with belimumab. Four residents at a long-term care (LTC) facility received 700 mg of belimumab (**BENLYSTA**) instead of the intended bamlanivimab intravenously (IV). Belimumab is indicated for patients with active systemic lupus erythematosus or active lupus nephritis who are also taking other lupus medications. Bamlanivimab was granted emergency use authorization (EUA) for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and children 12 years and older (weighing at least 40 kg) who are at high risk for progressing to severe COVID-19 and/or hospitalization. This event began when a nurse at the LTC facility called the offsite pharmacy with orders but either mispronounced or misread bamlanivimab. The pharmacist heard belimumab, which he prepared and dispensed. The preparations were infused over 60 minutes. No adverse reactions were reported.

There are several elements in common with belimumab and bamlanivimab. Each drug is added to a 250 mL intravenous (IV) bag of 0.9% sodium chloride injection. Other diluents may also be used with belimumab, but 0.9% sodium chloride injection is one of the recommended base solutions. Also, the dosages can overlap. The pharmacist did not question the dose of 700 mg for belimumab because it aligned with the patients' weights and fell within a safe dosing range. Both are infused IV over 60 minutes. Bamlanivimab is available in 700 mg vials, while belimumab comes in 120 mg and 400 mg vials for IV use, and a prefilled syringe or autoinjector for subcutaneous injection. In this case, the pharmacist processing the order was not familiar with either drug. Apparently, the preparations, labeled as belimumab, did not raise a red flag at the LTC facility. The incident occurred just as bamlanivimab

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not enough to prepare a 0.3 mL dose. It was determined that 1.8 mL of air was injected into the vial, but no actual diluent. The patient who received the first dose received undiluted vaccine. Investigation of the event uncovered that the syringes had been unpackaged and drawn up with air for use with the diluent vials. Injecting air into the vial in the same amount as the volume being removed from the vial equalizes the pressure and allows the desired amount of diluent to be withdrawn.

The Moderna COVID-19 vaccine does NOT require dilution. After thawing, each Moderna multiple-dose vaccine vial contains 10 (perhaps 11) doses of 0.5 mL each. To date, we have not received any reports of unnecessary dilution of the Moderna vaccine.

Vaccine and Monoclonal Antibody Mix-Up

Instead of receiving the first dose of the Moderna COVID-19 vaccine, 44 adults (77 years and older) at a West Virginia (WV) clinic received IM injections of casirivimab, one of two new Regeneron monoclonal antibodies recently granted EUA in the US to treat adults and children (12 years or older weighing at least 40 kg) with mild to moderate COVID-19 who are at risk for progressing to severe COVID-19 and/or hospitalization. The two monoclonal antibodies, casirivimab and imdevimab, are intended to be administered together as an intravenous (IV) infusion. They are supplied in individual, 2.5 mL or 11.1 mL single-dose vials. To prepare the infusion, 10 mL of casirivimab and 10 mL of imdevimab must be withdrawn into separate syringes and then diluted in the same 250 mL bag of 0.9% sodium chloride injection. Any product remaining in the vials must be discarded.

The mix-up between the Moderna vaccine and casirivimab started during the distribution process. The county health department dispatched two individuals from the National Guard to retrieve COVID-19 vaccine supplies from an area medical center for the WV clinic. When the individuals arrived at the medical center, they signed a chain-of-custody form stating that the product they were picking up was the "Moderna COVID-19 vaccine." The small white case they were given mentioned REGN10933 (**Figure 1**, above right), which the individuals did not recognize as a monoclonal antibody. According to media reports (www.ismp.org/ext/626), nothing on the white case led the individuals to believe it was not the vaccine listed on the chain-of-custody form. Instead, they thought it must be special labeling for the new vaccine. The case was then transported to the clinic. Inside the case, the vial cartons and vials were, again, only labeled with REGN10933, not the product name (**Figure 2**, middle right). Unfortunately, the error was not recognized, and casirivimab was administered IM to the patients instead of the vaccine. No serious adverse reactions were reported, and patients were offered the vaccine as soon as possible.

Although we do not have a detailed description of why the error happened, product packaging and labeling issues were likely involved. Both the Moderna vaccine and the Regeneron monoclonal antibody are available in 5 mL glass vials. The vaccine vial contains 5 mL (10 doses of 0.5 mL each) while the vials of the monoclonal antibodies contain 2.5 mL. The Regeneron antibodies (casirivimab and imdevimab) also are available in larger vials containing 11.1 mL, which may have been used at the time of the error. Vials of both the Regeneron antibodies and the Moderna vaccine have identical red caps (**Figure 3**, bottom right). If the clinic staff had previously administered the Moderna vaccine, they may have expected a vial with a red cap, similar to the monoclonal antibody, casirivimab.

Labeling problems with Regeneron's casirivimab and imdevimab also played a role in the mix-up. Two versions of vial and carton labels for each monoclonal antibody exist, which were used during investigational trials. Neither version includes the name of the specific antibody contained within and instead lists a product code number for casirivimab

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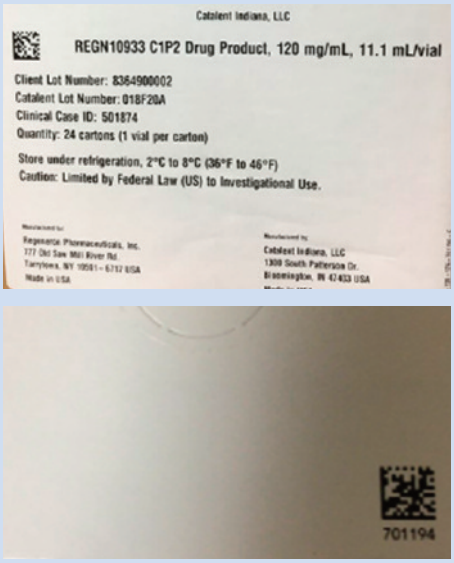

Figure 1. Front (top) and back (bottom) of a case of a Regeneron monoclonal antibody, which is labeled with a product code name (REGN10933), not the established name, casirivimab.

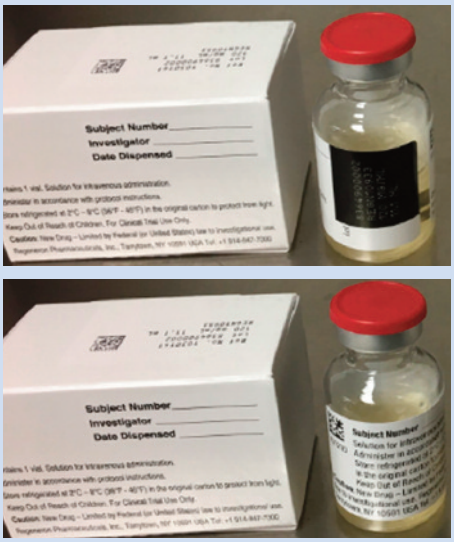

Figure 2. Vial carton and front (top photo)/back (bottom photo) of a vial of Regeneron's casirivimab is labeled with a product code name, not the established name.

Figure 3. The Moderna COVID-19 vaccine vial has a red cap, similar to the red cap on vials of Regeneron's monoclonal antibodies (see **Figure 2**).

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(REGN10933) and imdevimab (REGN10987). Although a barcode is on the vial label, it is not functional or tied to a National Drug Code (NDC) number. Initially, supplies of these monoclonal antibodies affixed with investigational new drug (IND) labels were used to meet the immediate demands for this COVID-19 treatment option. Regeneron confirms that a third version of the carton and vial label (www.ismp.org/ext/601) meant for EUA use is now being applied to the product and hopefully will be in the field in a few weeks. These EUA-specific labels are color differentiated and include a functioning barcode.

Waste of Vaccine Doses

ISMP received one report of vaccine contamination and several emails about concerns associated with unnecessary waste of the COVID-19 vaccines. In the reported event, a vaccinator found that one of the pharmacy-prepared syringes of the Pfizer-BioNTech COVID-19 vaccine dispensed that morning did not have a cap over the needle, and that the safety shield was locked over the needle. The vaccine dose was appropriately discarded.

We also learned that Operation Warp Speed, the federal COVID-19 vaccine response, has been shipping out a variety of syringe types since vaccinations began, some of which are not low dead-volume syringes and, thus, not efficient enough to extract more than 5 doses from the Pfizer-BioNTech vaccine or more than 10 doses from the Moderna vaccine vials (www.ismp.org/ext/627). While the number of doses withdrawn from a vial is influenced by the healthcare worker's technique, using a syringe designed to limit the dead space between the syringe hub and needle reduces the amount of wasted vaccine and increases the ability to extract an extra dose(s) from COVID-19 vaccine vials.

Finally, we learned about concerns regarding the waste of leftover vaccine doses. Some of the wasted vaccines were due to cancellations of scheduled vaccine appointments or "no-shows" exacerbated by leadership miscommunications regarding vaccine scheduling. The rest of the wasted vaccines were due to leftovers at the end of the day. Since both the Pfizer-BioNTech and Moderna vaccines must be used within 6 hours after dilution (Pfizer-BioNTech vaccine) or vial puncture (Moderna) and cannot be refrozen or refrigerated again, facilities with leftover doses in vials or prefilled syringes at the end of the day are sometimes scrambling to find unvaccinated people or are wasting the unused doses.

Administration to the Wrong Age Group

A 17-year-old at one clinic received the Moderna vaccine instead of the Pfizer-BioNTech vaccine, and a 15-year-old at another clinic inappropriately received the Moderna vaccine. According to the EUAs, the Pfizer-BioNTech vaccine is intended for individuals 16 years and older, and the Moderna vaccine is intended for individuals 18 years and older.

Error with Scheduling the Second Dose

An elderly patient who had received his initial Moderna COVID-19 vaccination reported that he had misspelled his email address on a registration form, which was needed for registration and confirmation of his appointment for his second dose one month later. The patient had been told he would receive an email providing instructions to register for his second vaccination and then to confirm his next appointment. Because of the misspelled email address, the patient never received directions for registering for his second vaccination. Although he contacted the facility where he received his first dose, as well as the state health department, he was unable to register for his second vaccination.

Administration of the Wrong Vaccine for the Second Dose

A patient who had received her first dose of the Pfizer-BioNTech vaccine was inadvertently administered the Moderna vaccine for her second dose. When the patient arrived at the

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use was increasing for patients with early COVID-19 symptoms and a positive COVID-19 test, so personnel were not as familiar with the product.

With increasing numbers of monoclonal antibodies reaching clinical practice, confusion between these products is growing given generic name similarities. For this reason, it is critically important to adhere to the basics. Limit verbal orders to true emergencies or circumstances in which the prescriber is physically unable to electronically transmit, write, or fax orders. When verbal orders cannot be avoided, enunciate orders clearly. The receiver should then read back the order, including spelling out drug names, as transcribed in the patient's record or onto a prescription pad. Prescribers should also communicate the purpose of the medication during the ordering process. Finally, it is important for organizations to ensure staff become familiar with new medications.

Discard rufinamide oral suspension within 90 days of opening. Rufinamide (40 mg/mL) oral suspension, a generic anticonvulsant from Hikma, should be discarded within 90 days after opening the bottle. This is noted in the product's package insert but not on the bottle or outer carton. The carton and bottle label for the reference rufinamide product, **BANZEL** (40 mg/mL) oral suspension from Eisai, mentions this important warning. We spoke with Hikma and they told us it has initiated a revision of the carton and bottle labeling to include this statement. The new labeling will be implemented in the next production cycle. For now, the facility that reported the problem is attaching auxiliary labels to the bottle to draw the patient's attention to the 90-day limit.

USP COVID-19 vaccine toolkit. USP has published a free ***COVID-19 Vaccine Handling Toolkit*** (www.ismp.org/ext/634). The organization recently convened national experts, stakeholders, members of various USP expert committees, and representatives of the US Food and Drug Administration (FDA) and the Centers for Disease

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clinic, she checked in and told the staff person that she was there for her second dose of the Pfizer-BioNTech. She also presented her COVID-19 vaccination card indicating she previously received the Pfizer-BioNTech vaccine. The patient also had a conversation with the administering nurse that she was there for her second dose of the Pfizer-BioNTech vaccine, but a dose of the Moderna vaccine was administered instead. The Centers for Disease Control and Prevention (CDC) currently recommends that no additional doses of either product be given if two doses of different mRNA COVID-19 vaccines are administered inadvertently.

Allergic Reactions

ISMP received a few reports of serious but not life-threatening allergic responses to the Pfizer-BioNTech vaccine that required immediate treatment and overnight hospitalization. According to the CDC, anaphylaxis occurs at a rate of 11.1 case per million doses of the Pfizer-BioNTech vaccine (www.ismp.org/ext/631) and 2.5 cases per million doses of the Moderna vaccine (www.ismp.org/ext/637), making it a rare outcome. Most individuals who have had a severe allergic reaction had a documented history of allergies and experienced the response within minutes of receiving the vaccine.

Safe Practice Recommendations: Please expect that mistakes will be made and, importantly, that lessons can be learned from them so steps can be taken to prevent their recurrence. While this is not a comprehensive list of all that can be done to prevent COVID-19 vaccination errors, consider the following targeted recommendations:

Safely select vaccination sites. Be sure vaccination sites have enough space to assess patients before vaccination, observe them after vaccination, and treat patients who experience a reaction, while maintaining social distancing and other pandemic precautions.

Verify the competency of vaccinators. Educate vaccination staff regarding the storage, preparation, and administration of the COVID-19 vaccines, as well as the common types of errors that may occur. Provide vaccinators with an up-to-date *Fact Sheet for Healthcare Providers* for the vaccine(s) being used, and verify their competency regarding:

- Proper vaccine storage and temperature monitoring
- Patient assessment prior to vaccination
- Age indications for each vaccine
- Providing patients with a *Fact Sheet for Recipients and Caregivers* before vaccination
- Proper dilution of only the Pfizer-BioNTech vaccine (e.g., prepare one vial at a time, do not pre-open syringe packages and draw up air in advance)
- Withdrawal of the correct dose for each vaccine from multiple-dose vials using strict aseptic technique and low dead-volume syringes/needles
- Administration of IM vaccines, including identification of the correct injection site
- Post-vaccination observation and recognition of the signs and symptoms of an allergic reaction
- Emergency treatment of anaphylaxis (e.g., immediate IM injection of **EPINEPH**rine, transport for further medical care)
- Timing and scheduling of a second vaccine dose

Implement an independent double check. When preparing the Pfizer-BioNTech vaccine, require an independent double check of the dilution process (if staffing permits).

Maximize doses withdrawn from vials. Whenever possible, use low dead-volume syringes/needles to withdraw as many doses as possible of the COVID-19 vaccine from each vial (6 or 7 from the Pfizer-BioNTech vaccine and 10 or 11 from the Moderna vaccine).

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Control and Prevention (CDC), to identify and help address operational efficiency gaps to help increase COVID-19 vaccinations. ISMP was a participating organization. The toolkit will be updated as new information and vaccines become available. The toolkit includes operational strategies for: preparation and labeling; storage, handling and transport; and waste and disposal.

Meet our 2020-2021 Fellows

Merissa Andersen, PharmD, MPH

Merissa is the **2020-2021 International Medication Safety Management Fellow**, supported by Baxter International, Inc. She completed her Doctor of Pharmacy and Master of Public Health degrees at the Massachusetts College of Pharmacy and Health Sciences University, Boston, MA. Merissa completed a PGY-1 pharmacy practice residency at Mount Auburn Hospital, Cambridge, MA.

Damon Birkemeier, PharmD

Damon is the **2020-2021 FDA/ISMP Safe Medication Management Fellow**. He completed his Doctor of Pharmacy degree at the University of Toledo, Toledo, OH, and a PGY-1 pharmacy practice residency at Mercy Health St. Rita's Medical Center, Lima, OH.

Bennet Ninan, PharmD

Bennet is the **2020-2021 Safe Medication Management Fellow**, supported by Baxter International, Inc. He received his Doctor of Pharmacy degree from Temple University, Philadelphia, PA, and most recently was as a clinical pharmacist at Rothman Orthopaedic Specialty Hospital in Philadelphia, PA.

Jill Paslier, PharmD, CSP

Jill is the **2020-2021 International Medication Safety Management Fellow**, supported by Novartis, Name Creation & Regulatory Strategy. She completed her Doctor of Pharmacy degree at the University of Minnesota College of Pharmacy, Minneapolis, MN. Prior to the Fellowship, Jill spent several years developing clinical services for a new specialty pharmacy with Banner Health near Phoenix, AZ.

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Identify/differentiate monoclonal antibodies. If Regeneron monoclonal antibodies are received in investigational drug packaging without the product name on the case, vial carton, or vial (**Figures 1** and **2**), immediately upon receipt identify and differentiate each antibody from other medications, including the Moderna COVID-19 vaccine. For example, the pharmacy at Beaumont Hospital in Royal Oak, Michigan, affixes brightly colored labels (pink for casirivimab, green for imdevimab) that include the product name, strength, and a scannable barcode. NDCs available in the *Fact Sheets* can be used to prepare the barcodes.

Separate vaccine storage. To avoid mix-ups, do not store the Pfizer-BioNTech and Moderna vaccines together in the refrigerator while or after thawing (e.g., use separate shelves). Do not place the vaccines close to the Regeneron monoclonal antibodies.

Plan for leftover vaccine and avoid waste. Ensure the vaccine scheduling process is efficient, accurate, and includes a reliable communication system to remind patients and confirm their appointments. Establish a standard process (e.g., daily list of readily available alternative recipients) for dealing with any leftover doses at the end of a vaccination clinic (but within 6 hours of storage at room temperature). Consider preparing vaccines in small batches for confirmed appointments only to minimize leftover doses at the end of the day.

Prepare for allergic reactions. At all vaccination sites, be prepared to immediately treat an allergic reaction. Make sure emergency equipment and medications (e.g., **EPINEPH**rine prefilled syringe or autoinjector, H_1 antihistamine such as diphenhydr**AMINE**) are readily available. Monitor patients for at least 15 minutes after vaccination for signs of an adverse reaction, or at least 30 minutes if patients have a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy, or a history of anaphylaxis due to any cause. Avoid administration of the vaccine to patients with a known severe allergic reaction to ingredients in the two COVID-19 vaccines, including polyethylene glycol, or a reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity to polyethylene glycol). Patients with general allergies should consult a healthcare provider prior to vaccination. Patients with anaphylaxis after the first vaccine dose should not receive the second dose.

Establish scheduling workflow. Establish a vaccination scheduling system that does not allow patients younger than 16 years to obtain an appointment, and schedules appointments for patients who are 16 and 17 years old only for receipt of the Pfizer-BioNTech vaccine. Establish a communication system for confirming all vaccine appointments. If relying on email, respond to all unconfirmed deliveries with phone calls or other means of rapid communication. Consider establishing a "hotline" for vaccine scheduling questions.

Confirm the vaccine to be administered. Update policies and procedures to require staff to verify the patient's current immunization status, and the manufacturer of the patient's first dose when receiving a second dose of the COVID-19 vaccine, prior to vaccination by checking the patient's health/vaccination record and/or vaccine registry. Ask the patient which vaccine they are to receive and check the vaccine documented on their COVID-19 vaccination card. Compare the manufacturer name of the prepared vaccine to the one listed on the card.

Report errors and adverse reactions. Report all COVID-19 vaccine errors and adverse reactions to the Vaccine Adverse Event Reporting System (https://vaers.hhs.gov), which is mandatory for healthcare providers. We also ask providers to report vaccine errors to ISMP (www.ismp.org/VERP). Vaccinated patients should receive a "v-safe" information sheet and be encouraged to enroll in the program (www.cdc.gov/vsafe). V-safe is a smartphone-based monitoring tool from CDC that provides a personalized "check in" after vaccination so patients can easily report any adverse vaccine reactions.

Special Announcements

Virtual MSI workshops – dates for 2021

Do not miss a unique opportunity to learn how to establish a comprehensive medication safety program. Register for one of the virtual ***ISMP Medication Safety Intensive (MSI)*** workshops in 2021. The 2-day workshops will be offered on: **February 25 & 26**, **April 22 & 23**, **June 24 & 25**, and **August 5 & 6**. For details, visit: www.ismp.org/node/127.

Healthcare Safety Challenge

The **Healthcare Safety Challenge**, sponsored by the Jewish Healthcare Foundation, is looking for innovative ideas to improve outcomes and save time, money, and lives. The project is awarding over $60,000 in cash prizes to the most exciting patient/healthcare safety solutions! Apply before **March 7, 2021**. Learn more at: www.ismp.org/ext/632.

FREE ISMP webinar with ACPE CE

Join us on **February 24, 2021**, for a webinar, ***Call to Action: Experience in Adopting the ENFit System to Guard Against Accidental Tubing Misconnections***, supported by Avanos. Our presenters will discuss wrong route errors that brought about the design standard and development of ENFit devices, the patient safety benefits of transitioning to ENFit, and the lessons learned after successful transition to ENFit. For details and to register, visit: www.ismp.org/node/22062.

To subscribe: www.ismp.org/node/126

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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. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

ISMP Safe Medication Management Fellowships

ISMP is now accepting applications for three unique **Fellowship** programs commencing in **2021**

ISMP Safe Medication Management Fellowship

Location and Term: This Fellowship commences July 2021. 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 29th 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 late summer/fall 2021. 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, Division of Medication Error Prevention and Analysis. 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 July 2021. 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 the online application, 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 31, 2021.

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 2020 and December 2020. 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/22448.

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

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Prevent *shoulder injury related to vaccine administration* (SIRVA) when administering the coronavirus disease 2019 (COVID-19) vaccines					
12/20	SIRVA presents as persistent shoulder pain, weakness, and limited range of motion within hours to days after administration of an intramuscular (IM) vaccine into the shoulder capsule instead of the deltoid muscle. This condition is preventable, given healthcare providers follow proper IM vaccine administration technique.	When administering IM vaccinations in the deltoid muscle, expose the upper arm/shoulder area, measure 2 to 3 finger widths from the acromion process (bony prominence above the deltoid), and locate the armpit as the lower border. Use the thumb and forefinger to make a V outlining the deltoid muscle before injecting the needle at a 90-degree angle.			
Mandatory error reporting for drugs granted Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA)					
12/20	Drugs and biologics used under an EUA (including COVID-19 vaccines) are not officially approved for use in the US by FDA but instead are temporarily authorized for use during a crisis. Thus, FDA requires mandatory reporting of adverse events, including errors, within a specified time period for all EUA drugs and biologics (FDA MedWatch; www.ismp.org/ext/609) as well as vaccines (Vaccine Adverse Event Reporting System; https://vaers.hhs.gov).	Refer to the product-specific *Fact Sheet* to determine the process and timeline for reporting adverse events and/or errors, as requirements may differ depending on the drug or biologic. Also, continue to report errors with these drugs or biologics, including vaccines, to ISMP (www.ismp.org/report-medication-error); however, this does not replace the need for mandatory reporting to FDA.			
Learn from influenza (flu) vaccine errors to prepare for coronavirus disease 2019 (COVID-19) vaccine campaigns					
11/20	Analysis of recent flu vaccine errors can be used to prepare for COVID-19 vaccine campaigns. Risk factors include look-alike vaccine names, labels, and packaging; unsegregated refrigerator/freezer storage; mixing/dilution errors; communication barriers; not checking/documenting administration in the immunization information system (IIS); inability to use technologies during mass immunizations; and temperature excursions.	When planning vaccine campaigns, consider infection control measures, optimal staffing patterns, anticipated language barriers, and storage for cold chain requirements. Before vaccination, screen patients for contraindications and precautions, verify prior vaccinations, and provide patients with a *Fact Sheet*. Establish best practices for vaccine preparation, administration, and documentation, and treatment of adverse reactions.			

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Differences between human error, at-risk behavior, and reckless behavior					
10/20	Organizations often struggle with differentiating and responding justly to human error, at-risk behavior, and reckless behavior. Human error is inadvertent. With at-risk behaviors, often staff knowingly violate policies and procedures because they have lost the perception of risk associated with the violation or mistakenly believed it to be insignificant or justified. Reckless behavior is the conscious disregard of what is known to be a substantial and unjustifiable **RISK** (not just the conscious disregard of a policy).	In a Just Culture, human error is managed by consoling the individual and redesigning the system to make it more human error proof. At-risk behavior is managed by coaching the individual to see the risk, system redesign, and a reward system that encourages safe behavioral choices. Reckless behavior is managed through disciplinary actions. The focus of safety programs should be the just and proactive management of at-risk behaviors, not just the management of inescapable human error and the rare reckless behavior.			
Insulin HUMALOG (insulin lispro) and TRESIBA (insulin degludec) pen mix-ups at home					
10/20 ⚠	Two patients mixed up their rapid-acting (Huma**LOG**) and long-acting (Tresiba) insulin pens, leading to loss of glycemic control. Although the pens are produced by different manufacturers and have different label colors, both are similarly shaped blue pens.	Since insulin pens do not need to be refrigerated once opened, teach patients to store their pens (up and away from children) where they will be administered (e.g., bedroom for long-acting Tresiba, kitchen for rapid-acting Huma**LOG**). Pharmacists can flag the pens with "rapid-acting" or "long-acting" stickers and remind patients to always read the label before use.			
Proper dosing instructions for EPIPEN and EPIPEN JR (EPINEPHrine injection)					
10/20 ⚠	A parent was confused regarding the proper dose of EpiPen Jr for her child. The instructions, "Inject 0.3 mL intramuscularly one time as needed for anaphylaxis" were printed on the pharmacy label, but the carton highlighted 0.15 mg on the principal display panel (although the side panel indicated 0.3 mL). So, the parent assumed she would need to use both pens contained in the carton for the dose (2 x 0.15 = 0.3).	Review how your pharmacy relays instructions for EpiPen, EpiPen Jr, and other autoinjectors and prefilled pens that indicate the dose in mg. Pharmacies should create patient instructions, those printed on the pharmacy label, that clearly explain how to take (or give) the medication and match the dosing units the patient will find on the device. Ensure that patients and caregivers know how to use these products properly by using the "teach-back" method during patient counseling.			

Issue	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Confusion between fentaNYL patch duration of drug delivery and strength					
09/20 ⚠	During order entry, pharmacy staff misread a prescription for "fenta**NYL** patch 72 hour 50 mcg/hr transdermal, one patch to the skin every 48 hours" and dispensed transdermal fenta**NYL** 75 mcg per hour patches to the patient. The staff member read "fenta**NYL** patch 72" which led him to mistakenly select the 75 mcg per hour patch instead of the 50 mcg per hour patch.	The duration of controlled drug delivery (i.e., 72 hours) should not be included within the product description, which should include the release rate per hour. Evaluate how these patches and similar products appear in your pharmacy computer system and reach out to your drug information vendor to determine if the appearance can be changed if necessary.			
Warn patients to keep topical fluorouracil away from pets					
11/20 ⚠	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. The product labels on fluorouracil do not alert users about this risk.	Practitioners who prescribe or dispense topical fluorouracil should discuss this risk with their patients who have pets. Consider creating and adding an auxiliary label to warn patients of this toxicity to pets. Always remind patients to safely and securely store their medication up and away and out of sight of children and pets.			
Package labeling of PIQRAY (alpelisib) may cause confusion during dispensing					
12/20 ⚠	Piqray is usually prescribed at 300 mg daily (two 150 mg tablets) to treat advanced or metastatic breast cancer. The carton's principal display panel notes, "two 14-day blister packs each containing 28 tablets" and "28-day supply." The label also prominently displays the daily dose (300 mg) but not the individual tablet strength (150 mg); it also does not specify the total number of tablets per package (56). Pharmacy staff saw "28-day supply" on the carton and assumed they needed two cartons to reach the intended quantity of 56 tablets.	Ensure that computer systems indicate the correct tablet strength, daily dose, and quantity per carton. Educate staff about potential confusion around the correct quantity and dose. Use flags or reminders to indicate that one box contains 56 tablets and that only one box is needed for a 28-day supply. Piqray is available in other monthly carton configurations and tablet strengths to accommodate dose reductions for certain adverse effects. Review drug listings in computer systems and explore potential confusion with these cartons, too.			
New American Society for Parenteral and Enteral Nutrition (ASPEN) recommendations for in-line filters for parenteral nutrition (PN)					
12/20 ⚠	In-line filters are critical during the administration of PN. However, prior recommendations to use two separate filters with different pore sizes has led to confusion, variations in practice, and errors.	ASPEN now recommends (www.ismp.org/ext/586) the use of a 1.2 micron in-line filter for administration of total nutrient admixtures (TNAs), dextrose-amino acid admixtures, and lipid injectable emulsion (ILE).			