

# Acute Care

# ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

## Mix-ups between the influenza (flu) vaccine and COVID-19 vaccines



Now that the 2021-2022 influenza (flu) vaccine is available, the Centers for Disease Control and Prevention (CDC) stated that both the flu and coronavirus disease 2019 (COVID-19) vaccines can be administered during the same visit, without regard to timing ([www.ismp.org/ext/784](http://www.ismp.org/ext/784)). In fact, the CDC encourages healthcare providers to offer both vaccines at the same visit to increase the probability that people will become fully vaccinated. Additionally, under an Emergency Use Authorization (EUA), the US Food and Drug Administration (FDA) has recommended a third COVID-19 vaccine for patients 12 and older who are moderately to severely immunocompromised. Recently, FDA amended the EUA to include a Pfizer-BioNTech COVID-19 vaccine booster for Pfizer-BioNTech vaccine recipients who completed their initial series at least 6 months ago and are 65 years or older, or 18 years or older if they are living in long-term care settings, have underlying medical conditions, or if they are living or working in high-risk settings.

### Mix-ups Between the Flu and COVID-19 Vaccines

Unfortunately, since the availability of the flu vaccine in September 2021, ISMP has received multiple reports, mostly from consumers, of mix-ups between the flu vaccine and COVID-19 vaccines. Most of the mix-ups occurred in patients who consented to a flu vaccine but received one of the COVID-19 vaccines instead; however, in two cases, patients received the flu vaccine instead of the intended COVID-19 vaccine. All of the events happened in community/ambulatory care pharmacies. The reported cases are highlighted below, and a discussion about possible causative factors and recommended strategies follows.

*A 23-year-old patient received the Pfizer-BioNTech COVID-19 vaccine instead of the flu vaccine. Afterwards, the patient was asked when she had received the first two COVID-19 vaccines, and the error was recognized. While the vaccine provider disclosed the error and apologized to the patient, the patient's request to get a flu vaccine was crossed out and replaced with "COVID (3<sup>rd</sup>)" in the documentation provided to the patient.*

*A 17-year-old visited a community pharmacy for a flu vaccine and was given a COVID-19 vaccine in error. The patient was called that evening and the error was disclosed; however, the patient's parents were upset because they were opposed to the COVID-19 vaccine.*

*A 26-year-old made an appointment at a local pharmacy for the flu vaccine. Upon arrival, the patient was given a screening form, consent form, and a Vaccine Information Statement (VIS) for the flu vaccine. However, a COVID-19 vaccine was administered in error. The error was immediately discovered, and the patient was given the flu vaccine. However, the pharmacy did not provide the patient with a record of the third COVID-19 vaccine.*

*A mother, son (10 years old), and daughter (6 years old) received the Moderna COVID-19 vaccine instead of the flu vaccine. When the mother experienced symptoms similar to those she experienced after receiving the Moderna COVID-19 vaccines, she called the pharmacist. After watching a video of the vaccination clinic, the pharmacist called the mother to report that she had received the Moderna COVID-19 vaccine in error, but her children had received the flu vaccine. After her daughter developed a local reaction at the vaccination site, the mother called the pharmacist and asked him to watch the video*

continued on page 2 — [Flu and COVID-19 vaccine mix-ups](#) >

## SAFETY briefs



### Trulicity pen should never be primed.

A health system received several reports about wasted **TRULICITY** (dulaglutide) pens because nurses tried to prime them prior to administration. Trulicity, a glucagon-like peptide-1 (GLP-1) receptor agonist, improves glycemic control in adults with type 2 diabetes mellitus, lowering hemoglobin A1c levels. It is available as a single-dose solution pen in 4 strengths. Nurses may not be familiar with Trulicity pens since weekly doses are designed for self-administration at home. While nurses are familiar with various types of pens that require priming, the Trulicity "pen" is more like an autoinjector with its own needle that does not require priming. Conversely, some of the other GLP-1 agonist medications, such as **VICTOZA** (liraglutide), **OZEMPIC** (semaglutide), and **BYETTA** (exenatide), require the attachment of a disposable needle and priming.

With the Trulicity pen, nurses should remove the base cap and throw it away, then place the clear base flat and firmly against the skin at the injection site (abdomen, thigh, or upper



**Figure 1.** Trulicity pen has an attached needle at the base and does not need to be primed before administration.

arm), turn the green bar to unlock the pen, then press and hold the green injection button ([www.ismp.org/ext/787](http://www.ismp.org/ext/787)) (**Figure 1**). After a click, continue to hold the clear base firmly against the skin for about 5-10 seconds until a second click, which happens as the needle starts retracting. Any attempt to "prime" a Trulicity pen by going through these steps and injecting contents into the air would empty its contents and waste the pen.

Trulicity is packaged for patient use in cartons of 4 pens for a 1-month supply. Although continued on page 3 — [SAFETY briefs](#) >

> **Flu and COVID-19 vaccine mix-ups** — continued from page 1  
again. A few days later, the pharmacist called the mother to say that both of her children had also received the COVID-19 vaccine instead of the flu vaccine.

A vaccinated 70-year-old patient received the Pfizer-BioNTech COVID-19 vaccine instead of the flu vaccine. He completed a consent form for the flu vaccine, but was told after administration that he now had his “COVID-19 booster.” He was then also given the flu vaccine and asked to provide consent for the COVID-19 vaccine he had received in error.

A 4-year-old child received the Pfizer-BioNTech COVID-19 vaccine instead of the flu vaccine. The Pfizer-BioNTech COVID-19 vaccine is not approved for EUA in a 4-year-old child. While the FDA is currently reviewing data submitted by Pfizer-BioNTech from a COVID-19 vaccine study in children 5-11, the dose is much smaller than that used for patients 12 years and older. Fortunately, the child suffered no ill effects from the vaccine.

A 22-year-old patient was scheduled to receive his first COVID-19 vaccine dose. The vaccinator assumed the patient was there to receive the flu vaccine and administered that instead. About 20 minutes after the patient left the pharmacy, he received a call informing him about the error. It is unclear if the patient returned to the pharmacy to receive the COVID-19 vaccine.

A 21-year-old patient was scheduled to receive a COVID-19 vaccine but was given the flu vaccine instead. Before the error was recognized, the patient had been given a COVID-19 vaccination card. The patient later noticed that the forms she had received from the pharmacy suggested that she had received the flu vaccine. She returned to the pharmacy, where the error was confirmed. The patient received her COVID-19 vaccine but no apology for the error.

A patient, who happened to be a pharmacist, scheduled an appointment at a local pharmacy to receive the flu vaccine, and his wife scheduled an appointment at the same time to receive both the flu vaccine and the Pfizer-BioNTech COVID-19 booster. Because there was a high-volume of patients receiving the COVID-19 booster, the pharmacist asked the vaccine provider to double check that he was only getting the flu vaccine (he had previously received a series of two Moderna COVID-19 vaccines, for which a booster has not yet been approved for EUA). After the vaccine provider confirmed that he was administering the flu vaccine, he grabbed the wrong syringe and gave the patient the Pfizer-BioNTech COVID-19 vaccine booster in error.

### Possible Causative Factors

Because most of the errors were reported by consumers, details about the contributing factors were not provided in many cases. However, the possible causative factors we have gleaned from the reports include the following:

**Increased demand and coadministration of the vaccines.** Flu season is already a busy vaccination time for community pharmacies. And, with the approval of the Pfizer-BioNTech vaccine booster and the surge in COVID-19, pharmacies are stretched even more to accommodate the demand in vaccination services. Also, the ability to administer the flu and COVID-19 vaccines during the same visit may be a causative factor.

**Syringes near each other.** Two vaccine providers indicated that they had picked up a COVID-19 vaccine syringe instead of the flu vaccine syringe, which were right next to each other in the vaccination area. Bringing both vaccines into a patient vaccination area when they are not needed sets the vaccine provider up for a possible mix-up.

**Unlabeled syringes.** While many vaccine providers purchase the flu vaccine in manufacturer prefilled syringes, which are labeled, COVID-19 vaccines are available in multiple-dose vials and must be prepared in a syringe for administration to patients.

continued on page 3 — **Flu and COVID-19 vaccine mix-ups** >

## Meet our 2021-2022 Fellows

▶ **Sunny Ro, MS, PharmD**, is the **2021-2022 ISMP International Medication Safety Management Fellow**, supported by Novartis, Name Creation & Regulatory Strategy. She completed her Doctor of Pharmacy degree at Temple University School of Pharmacy and PGY1 pharmacy practice residency at Thomas Jefferson University Hospital in Philadelphia, PA. Prior to becoming a pharmacist, Sunny was a special education math teacher in Baltimore, MD. Through ISMP she hopes to unite, connect, and educate the world on medication safety.

▶ **Emily Holcomb, PharmD, BCPS**, is the **2021-2022 ISMP Safe Medication Management Fellow**, supported by the US Army. Emily is an active-duty US Army Officer and has most recently worked as the Deputy Chief, Pharmacy Services at Tripler Army Medical Center in Honolulu, HI. She received her Doctor of Pharmacy from Pacific University, in Forest Grove, OR. Prior to her appointment in Honolulu, she spent several years in clinical and managerial roles in other US military health facilities, where she developed an interest in medication safety.

▶ **Wykeem Parker, BS, PharmD**, is the **2021-2022 FDA/ISMP Safe Medication Management Fellow**. He completed his Bachelor of Science in Biology and Doctor of Pharmacy degrees at Temple University in Philadelphia, PA. Prior to the fellowship, Wykeem practiced as a clinical pharmacist at the Hospital of the University of Pennsylvania in Philadelphia, PA. During pharmacy school, he completed a medication safety track and rotation with ISMP, where he developed a passion for safety and quality improvement.

▶ **Samuel Suen, PharmD**, is the **2021-2022 FDA/ISMP Safe Medication Management Fellow**. He completed his Doctor of Pharmacy at the University of Maryland School of Pharmacy in Baltimore, MD, and completed a PGY1 pharmacy practice residency at MedStar Georgetown University Hospital in Washington, DC. Sam’s passion for medication safety emerged while serving on a hospital interdisciplinary medication safety committee.

> **Flu and COVID-19 vaccine mix-ups** — continued from page 2

It is possible that these prepared COVID-19 vaccine syringes were not labeled. Also, COVID-19 vaccine doses may be prepared in an unlabeled syringe by one healthcare provider and administered by another; as a result, the person who administers the vaccine may not visually verify the empty vial if it remains with the person who prepared the dose.

**Distractions.** After a vaccine mix-up, one vaccine provider told the patient that he had become distracted by their conversation. Interruptions and other distractions in a busy pharmacy could also lead to mix-ups.

**Staffing shortages.** Because most healthcare providers are experiencing staffing shortages, it is possible that current vaccine providers are multi-tasking and hurried/rushed, even when patients are scheduled for vaccinations. For example, a pharmacist who was working alone in a busy pharmacy recently told us that she needed to administer more than 50 vaccinations during her shift, in addition to dispensing prescriptions.

**Safe Practice Recommendations**

Implement these safety strategies during the multistep vaccination process to avoid errors, particularly mix-ups between the flu and COVID-19 vaccines:

**Provide staffing support.** Schedule vaccines for a dedicated block of time each day and ensure adequate staffing. Ideally, staff should not be expected to accomplish both vaccine administration and regular dispensing functions simultaneously. Explore the use of qualified and trained volunteers to assist in the vaccination process (as was done initially when the COVID-19 vaccines first became available) to relieve some of the stress associated with professional staffing shortages.

**Separate vaccination areas.** Provide a separate area for vaccine administration, away from distractions and interruptions.

**Label the syringes.** All individual syringes containing vaccines should be clearly labeled, by the manufacturer if prefilled syringes are used, or by the vaccine dose preparer if single- or multiple-dose vials are used. Be sure to provide vaccine preparers with any necessary labels to affix to the syringes to facilitate proper labeling.

**Separate the vaccines.** Only bring the intended and labeled vaccine syringe(s) for one patient into the vaccination area.

**Identify the patient and requested vaccine.** When the patient approaches the pharmacy counter to request a vaccination and immediately prior to vaccination, ask the patient to provide at least two patient identifiers—their full name and date of birth. Access to an electronic patient profile to assist with verifying the patient's identity is recommended. Also, be sure to ask the patient which vaccine(s) they have requested. Talking with the patient about their vaccines ahead of administration can reduce the risk of errors. Be sure to verify the vaccine(s) the patient requests with the patient's signed consent form(s).

**Involve the patient/parent in the checking process.** Ask the patient/parent to read the syringe label (and vial if present) to confirm that it is the correct vaccine. Have the patient/parent and the vaccine provider read the label and expiration date aloud. At a minimum, the vaccine provider should tell the patient exactly which vaccine is being given before administration.

**Document lot number/expiration date.** Document the vaccine lot number and expiration date prior to administration. (The vaccine lot number may signal a mix-up has occurred and prevent it from reaching a patient.) Then document vaccine administration afterward in the patient's profile, on vaccination records, and via state or other immunization registries.

continued on page 4 — **Flu and COVID-19 vaccine mix-ups** >

> **SAFETY briefs** cont'd from page 1

the carton includes a fold-out pamphlet with easy-to-understand instructions and sketches, there is only one pamphlet per carton, so it cannot be given to nurses for reference with each dispensed dose. Instead, the health system that reported this problem has designed information leaflets to include when dispensing Trulicity. Instructions in the package insert or the accompanying pamphlet may also be copied (color copying is preferred since the instructions use color to make them easy to understand). The health system is also adding comments to the medication administration record (MAR) that state, Do Not Prime the Trulicity Pen. This note will appear when the nurse opens the MAR, before administration.



**COVID-19 revaccination for refugees or immigrants.** The *ISMP National Vaccine Errors Reporting Program* (ISMP VERP) has received several reports of refugees or immigrants being revaccinated despite receiving the recommended doses of an FDA-approved or authorized coronavirus disease 2019 (COVID-19) vaccine or a World Health Organization (WHO)-emergency use vaccine, such as the AstraZeneca vaccine. According to the Centers for Disease Control and Prevention (CDC), these patients do not need additional doses; nor do those who need the second dose, but got only the first vaccine injection, need to restart the series ([www.ismp.org/ext/785](http://www.ismp.org/ext/785)). In addition, people who have not been vaccinated or have received a COVID-19 vaccine not currently approved or authorized for use in the US or by the WHO may be offered a complete FDA-approved or FDA-emergency use authorized (EUA) COVID-19 vaccine series.

As of October 5, 2021, the WHO has listed the following COVID-19 vaccines for emergency use ([www.ismp.org/ext/786](http://www.ismp.org/ext/786)):

- Oxford/AstraZeneca: AZD1222 (e.g., Vaxzevria)
- Janssen (Johnson & Johnson): Ad26.COV2.S (e.g., Ad26COVS1, JNJ-78436735) (also US EUA)
- Moderna: mRNA-1273 (e.g., Spikevax) (also manufactured by Takeda [TAK-919]) (also US EUA)
- Pfizer/BioNTech: BNT162b2 (e.g., Comirnaty [tozinameran]) (also US FDA-approved)

continued on page 4 — **SAFETY briefs** >



> **Flu and COVID-19 vaccine mix-ups** — continued from page 3

**Scan the barcode.** During the production and/or pharmacist verification phase of the dispensing process, scan the vaccine barcode to verify that the correct product has been retrieved from the refrigerator or freezer. Ideally, barcode scanning should be available at the point of administration, even in outpatient vaccine clinics, to once again confirm that the correct vaccine had been retrieved and prepared.

**Provide the intended vaccine.** If a mix-up occurs, apologize to the patient and provide the intended vaccine (since both the flu and COVID-19 vaccines can be given at the same visit), either before they leave the vaccination area or by asking the patient to return to the vaccination site.

**Report vaccine errors.** Report all vaccine errors internally as well as to the FDA Vaccine Adverse Event Reporting System (VAERS, <https://vaers.hhs.gov/>), which is mandatory for errors with the COVID-19 vaccines available under an EUA. ISMP also asks providers to report vaccine errors to the **ISMP National Vaccine Errors Reporting Program** (ISMPVERP, [www.ismp.org/VERP](http://www.ismp.org/VERP)).

## Worth repeating...

### Nucala vial is overfilled for ease of reconstitution

A hospital had a close call due to confusion involving the package label for **NUCALA** (mepolizumab), which is used for severe eosinophilic asthma. This was the first time preparing a dose of Nucala for both a pharmacist and technician. The product's carton is labeled "100 mg/vial," but each vial contains approximately 144 mg of the drug to facilitate dose preparation (**Figure 1**). Instructions on the back of the carton and package insert state to dilute the lyophilized powder with 1.2 mL of sterile water for injection for a final concentration of 100 mg/mL. Healthcare practitioners generally expect that the amount of drug listed on the label matches the total amount contained in the vial. Such confusion could lead to an overdose of this medication if the entire amount within the vial, after reconstitution, is drawn into a syringe and administered.

In the recently reported case, the medication was reconstituted, and the entire volume in the vial (which exceeded 1 mL) was placed into a syringe and dispensed. An experienced nurse questioned the excess volume as she was used to only administering 1 mL. After further investigation, it was discovered that only 1 mL (100 mg) was to be administered to the patient. This situation is similar to previous events with Nucala that were described in **SAFETY briefs** published in the June 28, 2018, and September 6, 2018, issues of this newsletter. In those incidents, staff also reported that they were confused by the vial label statement, "100 mg/vial."

We previously asked the manufacturer to revise the container labeling to reflect the contents of each vial, and to refer users to the package insert for preparation and dosing instructions. The current label mentions, "Single-dose vial. Discard unused portion." But an asterisk after the "100 mg/vial" statement in the green band, followed by an asterisk before the statement below the strength that says, "Reconstituted solution contains 100 mg/mL," could give this important label information more visibility. Otherwise, that information is easily missed. Pharmacies should make sure compounding instructions clearly state the volume (i.e., 1 mL for 100 mg and 0.4 mL for 40 mg) to be withdrawn from the reconstituted vial to ensure the proper dose. Consider including preparation instructions, such as, "CAUTION: Vial contains overfill. Reconstitute with 1.2 mL of sterile water for final concentration of 100 mg/mL." As an alternative, use the 100 mg/mL autoinjector or prefilled syringe to ensure dosing accuracy.



**Figure 1.** Nucala's front label notes "100 mg/vial" when each vial actually contains 144 mg after reconstitution with sterile water. The volume excess is to facilitate dose preparation.

> **SAFETY briefs** cont'd from page 3

- Serum Institute of India: Covishield (Oxford/AstraZeneca formulation)
- Sinopharm (Beijing): BBIBP-CorV (Vero Cells) (e.g., Covilo) (also manufactured by G42 Healthcare [Hayat-Vax])
- Sinovac: CoronaVac

## Special Announcements

### Deadline extended for survey

We have extended the deadline to **November 19, 2021**, for participating in our survey on **disrespectful behavior in healthcare**. Disrespectful behavior is defined as: any overt or covert interaction (or lack of interaction) between healthcare professionals that may result in either an intended or unintended reluctance to speak up about concerns, question patient care, or share an opinion on a subject. To complete the survey, which we estimate will take 15 minutes, please visit: [www.ismp.org/ext/761](http://www.ismp.org/ext/761).

### Two-day program for industry

Healthcare practitioners who work in the pharmaceutical industry are invited to join us on **October 13 and 14, 2021**, for a live, virtual program, **FDA, ISMP, and Industry Partners: Symbiosis for Medication Safety**. The program will provide an understanding of how products are impacted during dispensing and administration through the use of technology. Participants will have a greater understanding of the importance of safe product design. For details, visit: [www.ismp.org/node/25772](http://www.ismp.org/node/25772).

To subscribe: [www.ismp.org/node/10](http://www.ismp.org/node/10)



**ISMP Medication Safety Alert! Acute Care** (ISSN 1550-6312) © 2021 Institute for Safe Medication Practices

(ISMP). Subscribers are granted permission to redistribute the newsletter or reproduce its contents within their practice site or facility only. Other reproduction, including posting on a public-access website, is prohibited without written permission from ISMP. This is a peer reviewed publication.

### Report medication and vaccine errors to ISMP:


Call 1-800-FAILSAFE or visit our website at: [www.ismp.org/report-medication-error](http://www.ismp.org/report-medication-error). ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.


**Editors:** Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Ann Shastay, MSN, RN, AOCN; Russell Jenkins, MD; Kelley Shultz, MD. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org); Tel: 215-947-7797; Fax: 215-914-1492.

# ISMP Medication Safety Alert!® Action Agenda


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 items from the **July – September 2021** issues of the *ISMP Medication Safety Alert! Acute Care* have been prepared for leadership to use with an interdisciplinary committee or with frontline staff to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue number to locate additional information. Look for our high-alert medication icon under the issue number if the agenda item involves one or more medications on the *ISMP List of High-Alert Medications* ([www.ismp.org/node/103](http://www.ismp.org/node/103)). The Action Agenda is also available for download in a Microsoft Word and Excel format ([www.ismp.org/node/27795](http://www.ismp.org/node/27795)) that allows expansion of the columns in the table designated for organizational documentation of an assessment, actions required, and assignments for each agenda item. Continuing education credit is available for nurses at: [www.ismp.org/nursing-ce](http://www.ismp.org/nursing-ce).



Key:  — ISMP high-alert medication

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
<b>Disconnect discontinued or paused infusions to avoid tragic errors</b>					
(13, 17) 	Discontinued or paused infusions of norepinephrine and oxytocin were not disconnected from patients, resulting in inadvertent boluses of the infusions and leading to harm that required treatment. In another case, a physician discontinued a fentaNYL infusion, which a nurse stopped but left connected to the patient's primary line. Another nurse mistakenly restarted the fentaNYL infusion while replacing the primary infusion bag. Unfortunately, the patient developed hypotension and died.	Discontinued infusions should be removed from the infusion pump, disconnected from the patient, and discarded. Paused infusions should be removed from the pump, disconnected from the patient, and discarded within a reasonable timeframe if not restarted. Access lines should be labeled with the drug name and route, and traced from the solution to the patient before starting an infusion. During shift changes, oncoming nurses should trace the lines and verify the pump settings and infusion labels.			
<b>Tubing misconnection leads to accidental intraventricular administration of intravenous (IV) contrast media</b>					
(15)	A patient with a brain mass had an external ventricular device (EVD) placed and underwent a magnetic resonance imaging (MRI) study. Contrast media was inadvertently administered via the EVD instead of IV, resulting in serious harm. Lack of communication with the radiology team, unfamiliarity with an EVD, close proximity of the EVD and midline IV tubing, lack of tracing the lines prior to administration, and common tubing with Luer connectors contributed to this error. Similar events have been published in the literature.	Use warning labels to distinguish EVD tubing from other medical tubing, cap all EVD ports, and position the EVD lines away from IV lines. Clear communication about the EVD should be reported during handoffs, and safety strategies, such as a "time out" and line tracing, should be utilized prior to drug administration. When possible, staff familiar with EVDs should stay with patients during procedures and be involved in the checking process. Become familiar with the signs and symptoms of inadvertent intraventricular administration and the appropriate response.			

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
<b>Screening for dihydropyrimidine dehydrogenase (DPD) deficiency in fluoropyrimidine chemotherapy patients may prevent harm</b>					
(14, 15) 	<p><b>XELODA</b> (capecitabine), a fluoropyrimidine chemotherapy drug, was prescribed for a cancer patient, who quickly developed serious adverse effects including severe mucositis, hand and foot desquamation, delirium, and prolonged leukopenia. The patient became unresponsive and died within a month of starting treatment. It was later determined that the patient had a rare DPD deficiency and could not properly clear the drug, which led to the fatal toxicity.</p>	<p>Testing is available to screen patients for DPD deficiency, but it is costly. Although European agencies have provided screening guidelines, the National Comprehensive Cancer Network (NCCN) does not support it, noting a possible delay in care and reduced efficacy (<a href="http://www.ismp.org/node/27796">www.ismp.org/node/27796</a>). However, screening can be completed in a few days. Furthermore, the question regarding the efficacy of a reduced dose for DPD-deficient patients is unresolved. Oncology providers may want to reconsider their position on screening.</p>			
<b>Tips for increasing error reporting</b>					
(17)	<p>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.</p>	<p>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.</p>			
<b>Keep up to date with the US Food and Drug Administration (FDA) Emergency Use Authorization (EUA) Fact Sheet changes</b>					
(17, 18)	<p>The FDA has received reports of incorrect doses of <b>REGEN-COV</b> (casirivimab and imdevimab) administered to coronavirus disease 2019 (COVID-19) patients. Since EUA approval in November 2020, there have been several updates to the EUA <i>Fact Sheet</i> and the packaging and labeling to reflect new uses, dosing, and administration. The dosing errors may be due to the rapidly changing therapy options.</p>	<p>Review your inventories and formulary to determine which medications are under EUA. Evaluate your process for receiving/retrieving the updates on these medications and assign at least one pharmacy staff member to communicate the relevant updates and action items to all involved staff. Regularly check the <i>Fact Sheets</i> for the most current information and keep all electronic health record (EHR) systems updated.</p>			

© 2021 ISMP

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
<b>New packaging for REGEN-COV (casirivimab and imdevimab) monoclonal antibodies (Roche) may add confusion</b>					
(19)	To increase availability during the pandemic, Regeneron will introduce co-packaged cartons (from Roche) that contain individual vials of casirivimab and imdevimab in a single carton. The co-packaged carton labeling may cause some to mistakenly believe the vials contain co-formulated product (both drugs in a single vial), which is also being distributed. Other labeling features (e.g., absent barcodes) may lead to errors.	Practitioners need to be hypervigilant when ordering, selecting, preparing, and administering REGEN-COV due to the multiple packaging forms and changing administration and dosing requirements. Facilities are encouraged to access and be familiar with the information in the <i>Fact Sheet</i> ( <a href="http://www.ismp.org/ext/779">www.ismp.org/ext/779</a> ) for REGEN-COV (the package leaflet in the co-packaged carton is not approved for US use).			
<b>Inadvertent intra-arterial promethazine administration leads to serious injury</b>					
(15) 	Administration of parenteral promethazine has once again led to severe tissue damage. A patient with pancreatitis inadvertently received promethazine intra-arterially instead of intravenously (IV). The patient experienced hand pain, redness, and swelling, which progressed to gangrene requiring possible amputation of some digits.	There are safer therapeutic alternatives; thus, a recommendation to remove promethazine from the formulary is in the ISMP 2020-2021 <i>Targeted Medication Safety Best Practices for Hospitals</i> ( <a href="http://www.ismp.org/node/160">www.ismp.org/node/160</a> ). We have previously asked the US Food and Drug Administration (FDA) to eliminate IV administration from the product labeling.			
<b>Shared glucometers, fingerstick devices, and insulin pens increase the risk of infection transmission</b>					
(13)	Outbreaks of infectious diseases have occurred when healthcare workers have used a shared glucometer that was not cleaned and disinfected, or used a shared fingerstick device or insulin pen. Not following basic infection control practices led to the outbreaks.	<u>Never</u> share insulin pens with multiple patients, and <u>never</u> use a fingerstick device for more than one person. Shared glucometers must be cleaned <u>and</u> disinfected per the manufacturers' recommendations between patient use. Monitor to ensure that these practices are followed.			
<b>Eliminate bulk bottles of high-strength phenol, also known as carbolic acid</b>					
(19)	High-strength phenol is available in bulk bottles. The National Health Service in England has called for elimination of these bottles, which are used primarily during a matricectomy (treatment for an ingrown toenail), due to more than 30 harmful events (e.g., serious burns).	If bottles of high-strength phenol are stored in your facility, determine why it is being used and replace it with safer alternatives (e.g., prepackaged phenol applicators). Be prepared with polyethylene glycol 300 (PEG 300) solution to treat unintended phenol skin exposures.			

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
<b>Improved safety needed for pediatric pegfilgrastim (NEULASTA) and its biosimilars</b>					
(14, 16)	Neulasta and its biosimilars are available in 0.6 mL (6 mg) prefilled syringes. The package insert provides dosing for pediatric patients under 45 kg, which requires using less than 0.6 mL. The syringes are not graduated, and the label states that the syringes are not designed to administer doses less than 0.6 mL. In the outpatient setting, this leads to the risky removal of partial doses from the prefilled syringe. Parents have accidentally given their child the full 6 mg dose.	The US Food and Drug Administration (FDA) sent letters to manufacturers, asking them to conduct studies on the ability to measure pediatric doses, and to consider manufacturing the product in a vial or prefilled syringe for pediatric patients. Meanwhile, some pharmacies have been providing parents/patients with an empty sterile vial into which to inject the syringe contents, an empty syringe/needle to withdraw the smaller dose, and standardized instructions.			
<b>Confusion with Bluetooth-connected “smart” INPEN (insulin aspart or insulin lispro) devices</b>					
(13) 	A technician mistakenly ordered InPen for use with <b>HUMALOG</b> (insulin lispro) instead of <b>NOVOLOG</b> or <b>FIASP</b> (insulin aspart) cartridges due to confusion with the color descriptions of the pens on the wholesaler’s website. The two presentations come in three colors each, and the technician assumed any pen would work for the different types of insulin.	Add warnings in the computer to remind staff to verify the compatibility of the InPen with the required insulin cartridges. Link each InPen in the computer with the compatible insulin cartridge(s). Educate pharmacy staff about the availability of these pens and the packaging differences between the devices that hold compatible cartridges.			
<b>Mix-ups between KETALAR (ketamine) and ketorolac</b>					
(13) 	A paramedic accidentally administered ketorolac (25 mg) instead of Ketalar, despite a double check. The confusion may be related to name similarity between Ketalar and ketorolac. Both names share the letters K,E,T,A,L, and R.	Apply auxiliary labels to these products. If ketamine is generically available, remove the brand name from drug databases/search functions. Enter at least five letters when searching for or selecting medications in electronic systems.			
<b>Look-alike topiramate and traZODone tablets (Zydus Pharmaceuticals) and lack of safety checks lead to a robot misfill</b>					
(16)	Topiramate and traZODone 50 mg tablets look similar and are packaged in nearly identical 500-count bottles. When refilling a robot with traZODone, one of the two bottles used contained topiramate, but only the bottle containing traZODone was scanned to fill the robot.	When multiple bottles of tablets are needed to refill a robot, require barcode scanning of <u>each</u> bottle and an independent double check. Use unopened stock bottles to ensure that the national drug code (NDC) number, lot number, and expiration date match for all tablets.			

© 2021 ISMP