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Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

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

The Fall and Winter months are typically busy with seasonal demand for influenza (flu) vaccines, treatment of respiratory infections (including flu), and symptomatic relief of cold symptoms. However, this year it is even busier with the addition of coronavirus disease 2019 (COVID-19) vaccinations. The Centers for Disease Control and Prevention (CDC) has stated that both the flu and COVID-19 vaccines can be administered during the same visit, without regard to timing (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 dose of the Pfizer-BioNTech or Moderna COVID-19 vaccines for patients who are moderately to severely immunocompromised. FDA also has amended the EUAs to include a Pfizer-BioNTech or Moderna COVID-19 vaccine booster for all COVID-19 vaccine recipients who completed their initial series at least 6 months ago and are 65 years or older, or 18 years or older and at high risk of severe COVID-19 or live or work in high-risk settings. In addition, a single dose booster of the Janssen (Johnson and Johnson) COVID-19 vaccine may be administered to those 18 years or older, at least 2 months after receiving the single-dose regimen.

Mix-ups Between the Flu and COVID-19 Vaccines

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 a couple cases, patients received the flu vaccine instead of the intended COVID-19 vaccine. All of the events happened in community/ambulatory care pharmacies. Some of the reported cases are highlighted below, and a discussion about possible causative factors and recommended strategies follow.

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 (3rd)" 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, 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.

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SAFETY briefs

Trulicity pen should never be primed.

A health system received several reports about wasted **TRULICITY** (dulaglutide) pens, a glucagon-like peptide-1 (GLP-1) receptor agonist used to improve glycemic control in adults with type 2 diabetes mellitus. This happened because nurses tried to prime the pens prior to administration. However, 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.

For the Trulicity pen, the user 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 arm), turn the green bar to unlock the pen, then press and hold the green injection button (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 is heard, 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.

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

Trulicity is packaged in cartons of 4 pens for a 1-month supply. Although the carton includes an *Instructions for Use* pamphlet with easy-to-understand instructions and sketches, there is only one pamphlet per carton, so it cannot be given to nurses for

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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 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 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. Soon after the patient left the pharmacy, he received a call informing him about the error. It is unclear if he 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 was given a COVID-19 vaccination card. She later noticed that the forms she received at 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, and at the time of the event, the Moderna COVID-19 vaccine EUA had not been updated to allow a booster dose of the Moderna COVID-19 vaccine). 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. With the approval of COVID-19 vaccine boosters for certain populations, and the likely approval of a pediatric COVID-19 vaccine, pharmacies are stretched even more as demand for vaccination services increases. 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

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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 *Instructions for Use* may also be copied (color copying is preferred since color is used to aid understanding). 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.

When the pens are prescribed and dispensed directly to patients, prescribers and pharmacists must educate the patient on how to use these devices. Consider making this education mandatory. Use the teach-back method, which incorporates a return demonstration by the patient, to verify that the patient can use the pen correctly.

Storage error with Trulicity pens. An ambulatory care clinic provider recently increased a patient's weekly dose of **TRULICITY** (dulaglutide) 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. The use of expired pens is thought to have contributed to the lack of therapeutic effect.

Trulicity, a glucagon-like peptide-1 receptor agonist, is administered once weekly to improve glycemic control in adults with type 2 diabetes mellitus. It is available as a single-dose pen in four strengths. Four pens of the same strength are packaged in a single carton for a 1-month supply. The pens should be stored in the refrigerator. If needed, a pen can be kept at room temperature for a total of 14 days.

While the storage information is listed on the back panel of each Trulicity carton and at the end of the *Instructions for Use*, patients may miss the information. This could happen if the pharmacy label covers the storage information listed on the carton or if the patient does not open the carton and read the *Instructions for Use* before storing the medication. Pharmacists and

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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. 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 distractions could lead to errors.

Staffing shortages. Because most healthcare providers are experiencing staffing shortages, it is possible that current vaccine providers are multi-tasking and hurried, 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.

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prescribers must teach patients how to properly store and use Trulicity pens. Community pharmacists should consider marking Trulicity prescriptions for mandatory patient education. In addition, a process should be established to ensure pharmacists and pharmacy technicians affix an auxiliary label to the medication carton to alert the patient to store the medication in the refrigerator. Ideally, pharmacies should leverage technology such that the pharmacy computer system automatically includes the appropriate auxiliary warning message(s) as part of the pharmacy label.

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 a US Food and Drug Administration (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). 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 23, 2021, the WHO has listed the following COVID-19 vaccines for emergency use (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)
- Serum Institute of India: Covishield (Oxford/AstraZeneca formulation: AZD1222)

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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.

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*** (ISMP VERP, www.ismp.org/VERP).

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.

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- Sinopharm (Beijing): BBIBP-CorV (Vero Cells) (e.g., Covilo) (also manufactured by G42 Healthcare [Hayat-Vax])
- Sinovac: CoronaVac

CDC asks providers to recommend v-safe to patients. The Centers for Disease Control and Prevention (CDC) is asking vaccine providers to encourage vaccine recipients to register for **v-safe** after receiving the coronavirus disease 2019 (COVID-19) vaccine (www.ismp.org/ext/801). V-safe is a smartphone-based monitoring tool from CDC that provides a personalized health "check in" after COVID-19 vaccination so patients can easily report any vaccine side effects and adverse reactions. CDC uses the information collected through v-safe as part of their COVID-19 vaccine safety surveillance program.

Provide patients with a v-safe information sheet (www.ismp.org/ext/802) at the time of vaccination and encourage them to register during the 15 minute post-vaccine administration observation period. The information sheet explains what v-safe is and provides step-by-step instructions on how to sign up. COVID-19 vaccine recipients can use the quick response (QR) code or the link on the information sheet to sign up. V-safe posters (www.ismp.org/ext/802) are also available to promote v-safe at vaccination sites and help remind vaccine providers to encourage patients to register with the program.

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