January 2024 | Volume 23 ■ Issue 1

ISMP An ECRI Affiliate

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Prevent errors with RSV vaccines in pregnant and pediatric patients

Problem: ISMP has received reports of four different events in which pregnant women, 32 through 36 weeks gestational age, have received injections of **AREXVY** (respiratory syncytial virus vaccine, adjuvanted) (**Figure 1**) instead of **ABRYSVO** (respiratory syncytial virus vaccine) (**Figure 2**). Three of these events occurred in community pharmacies with the fourth taking place in a hospital. At the time of the reports, no outcome data were shared.

In addition, a January 22, 2024 Centers for Disease Control and Prevention (CDC) *Clinician Outreach and Communication Activity, Information on Respiratory Syncytial Virus (RSV) Vaccine Administration Errors in Young Children and Pregnant People* (www.ismp.org/ext/1296) warned that several errors have been reported through the Vaccine Adverse Event Reporting System (www.ismp.org/ext/592) operated by the US Food and Drug Administration (FDA) and CDC. This includes 25 reports involving children younger than 2 years who received Abrysvo or Arexvy (adult vaccines), and 128 reports of pregnant women mistakenly getting Arexvy (not approved during pregnancy). Most events occurred in outpatient settings where barcode scanning prior to vaccine administration is often lacking.

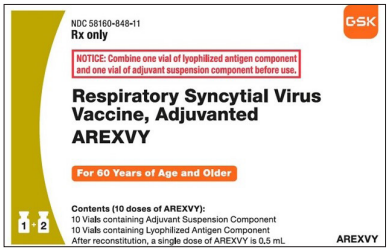


Figure 1. Arexvy is for the active immunization of adults 60 years and older. After reconstitution, a single dose is 0.5 mL.

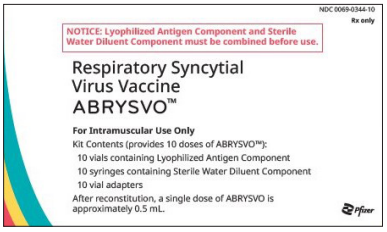


Figure 2. Abrysvo is for the active immunization of pregnant individuals at 32 through 36 weeks gestational age, as well as individuals 60 years of age and older. After reconstitution, a single dose is 0.5 mL.

The FDA approved both Arexvy and Abrysvo for RSV prevention in adults in 2023. However, Arexvy is only indicated for active immunization of adults 60 years and older. Abrysvo is for active immunization of pregnant individuals at 32 through 36 weeks gestational age, as well as individuals 60 years of age and older. Both Arexvy and Abrysvo need to be reconstituted prior to administration. Arexvy is prepared by reconstituting the lyophilized antigen component with the accompanying adjuvant suspension. Abrysvo is prepared by reconstituting the vial of lyophilized antigen component using the included prefilled syringe of sterile water for injection and vial adapter. The volume of vaccine administered is the same for both products (0.5 mL) and both are injected intramuscularly.

Safe Practice Recommendations: Implement strategies now to help prevent these errors. Clinics and medical offices should create order sets to guide practitioners in selecting the appropriate product and dosage based on the indication and the patient's pregnancy status and/or age. Consider noting or highlighting the vaccine's intended patient population(s) on vaccine packages and storage locations. Confirm that computerized clinical decision support (CDS) will provide an alert if a practitioner orders a vaccine for a patient in an age group outside of its approved indication. Explore ways to collect and document a patient's pregnancy status that would allow CDS to provide alerts when a vaccine is ordered for a patient with a pregnancy status outside of the vaccine's approved indication. If a patient of child-bearing age requests an RSV vaccine, verify the patient's pregnancy status prior to entering and administering Abrysvo. Clearly label prepared vaccine syringes (e.g.,

continued on page 2 — RSV vaccines >

SAFETY briefs

Wrong quantity of Ovidrel entered into pharmacy system. A prescription was written for two prefilled syringes of **OVIDREL** (choriogonadotropin alfa) injection. Ovidrel is a gonadotropin indicated for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle stimulating hormones as part of an assisted reproductive technology (ART) program. At a specialty pharmacy, the prescription was entered into the pharmacy computer system for #2 as the written and dispense quantity. However, the billing unit for Ovidrel 250 mcg/0.5 mL is mL, so the entry of 2 as the dispense quantity

continued on page 2 — SAFETY briefs >

IMPORTANT! Read and utilize the Community/Ambulatory Care 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, selected items from the **September – December 2023** issues of the ***ISMP Medication Safety Alert! Community/Ambulatory Care*** newsletters have been selected and prepared for you and your staff to stimulate discussion and collaborative 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 date to locate additional information.

The **Action Agenda** is available for download as an Excel file at: www.ismp.org/node/120402.

> RSV vaccines — continued from page 1

vaccine name, dose). Ensure barcode scanning is used prior to dispensing and at the time of administration. Educate staff about the differences in indication, preparation, and dosage. Prior to administration, confirm with the patient the product(s) they are expecting to receive.

The CDC communication also provides recommendations for practitioners who have administered incorrect RSV vaccine products to their patients. For children who are recommended to receive nirsevimab (**BEYFORTUS**), a monoclonal antibody, but received either the Abrysvo or Arexvy vaccine in error, administer a dose of nirsevimab. For pregnant patients who have received Arexvy in error, do not give a dose of the Abrysvo; the infant (if younger than 8 months) should receive nirsevimab during RSV season (October through March in most of the continental United States).

Worth repeating...

Ensure medications are properly reconstituted

We have published several cases of medications being dispensed to patients before they were properly reconstituted (February 2007, February 2008, February 2013, June 2015, May 2017, and January 2023). Most of the cases involved pediatric patients who received overdoses of antibiotics when their parents administered the drug powder to their children. Other cases involved oral suspensions that had been inappropriately mixed; most often not enough diluent was used to reconstitute the medication powder. Unfortunately, we continue to receive reports of this type of error.

In one recent case, the pharmacy dispensed amoxicillin for oral suspension as a powder. Thankfully, the child's parent, who is a nurse, recognized that the medication needed to be reconstituted prior to administering a dose. When the parent called the pharmacy to inform them of the error, the pharmacy hung up on them. In fact, the child's parent had to make multiple phone calls to the pharmacy before they were able to speak to someone. The pharmacy staff indicated that the pharmacy was getting ready to close and therefore the child's parent could not speak to a pharmacist. As a result of the error, the child had to wait until the next day to start their antibiotic.

In another recent case, a 10-month-old child was prescribed amoxicillin with the instructions to give 4.7 mL twice a day for 10 days. At home, the child's parents were following the instructions but ran out of medication after just 6 days. When they returned to the pharmacy to report the situation, they were informed that the pharmacy's machine that is supposed to dispense the correct amount of water for reconstitution was not calibrated correctly. As a result, the patient's amoxicillin had been reconstituted with less water than indicated, producing a suspension with a higher drug concentration. The parents reported that the patient was experiencing dark, loose stools; fussiness; nausea; and poor appetite.

It is critical that pharmacies take steps to safeguard the dispensing of oral suspensions that require reconstitution. Because we continue to receive reports of these same errors, over and over again, we think reviewing strategies that can help prevent these errors from reaching patients is ***Worth* repeating**:

- Incorporate technology at the point-of-sale that will alert pharmacy staff that the prescription needs to be reconstituted. Explore options to have the alert be interactive, requiring the staff person to confirm that the medication has been reconstituted.
- Add a note or label to the prescription receipt, or use some other distinct visual cue (e.g., brightly colored "Need to mix" card) indicating that the medication needs to be reconstituted prior to dispensing.

continued on page 3 — *Worth* repeating >

>*SAFETY* briefs

cont'd from page 1

represents 2 mL or four syringes. As a result, the prescription was prepared with four prefilled syringes. Instead, the prescription should have been entered with a dispense quantity of 1 mL, or two syringes. Thankfully, the error was discovered with the patient at the point-of-sale. The prescription was corrected and only two syringes were dispensed. However, if the pharmacy had dispensed the greater (incorrect) quantity and the patient had used all four syringes, they would have been at increased risk of experiencing excessive ovarian response, including the risk of ovarian enlargement or ovarian hyperstimulation syndrome.

Not all specialty pharmacies may be familiar with fertility treatment and medications. If your pharmacy dispenses fertility treatments, it is important to provide staff with education about this area of therapy. Pharmacies may use dispensing software notes to alert the team to the correct package size for specific products (e.g., quantity of 1 = 2 syringes). Explore adding a default package size to the dispensing software and setting the system to print labels to match the required number of packages. Prescribers should include the units (mL vs. syringe vs. kit) with the quantity to minimize pharmacy staff confusion.

Paxlovid contraindicated in patients taking flecainide. An older adult was prescribed **PAXLOVID** (nirmatrelvir and ritonavir) to treat coronavirus disease 2019 (COVID-19). However, the patient was also taking the antiarrhythmic flecainide. The concomitant use of Paxlovid with flecainide is contraindicated. Flecainide is metabolized by various cytochrome P450 enzymes, including CYP2D6 and CYP1A2; however, Paxlovid inhibits CYP2D6, primarily from its ritonavir component. Thus, concomitant use of Paxlovid and flecainide may increase the serum concentration of flecainide which could result in arrhythmias or other serious adverse effects.

The error originated at an urgent care facility associated with the patient's primary care office. Medical personnel missed the flecainide entry in the patient's electronic

continued on page 3 — *SAFETY* briefs >

© 2024 Institute for Safe Medication Practices (ISMP). All rights reserved. Redistribution and reproduction of this newsletter, including posting on a public-access website, beyond the terms of agreement of your subscription, is prohibited without written permission from ISMP.

>Worth repeating continued from page 2

- Place the actual product container that requires reconstitution in a separate area (e.g., not with other medications in the will-call area awaiting pick up, not bagged with other prescriptions for the patient).
- Ensure that admixture technologies (e.g., FillMaster) are tested and calibrated on a regular basis and according to manufacturer recommendations.
- Establish a process to verify that the correct amount of liquid has been measured and used to reconstitute drugs.
- After the product is reconstituted, the product should be given to the pharmacist, along with any other prescriptions, to counsel the patient on how to measure the medication. Use the teach back method when educating patients. Have the caregiver or patient demonstrate how they will measure and administer the dose to validate learning.
- Include specific product descriptions on the prescription label (e.g., orange flavored, white, opaque liquid) that will cue the consumer that they should be receiving an oral liquid product.
- At the point-of-sale, open the bottle with the patient or caregiver to check that the contents have been reconstituted. Review with the patient or caregiver the label, storage requirements, route of administration, directions for use, and how many days of therapy the medication should be taken. Shake the bottle to demonstrate how to mix the suspension prior to administration.
- Ensure that an appropriate metric dosing device, which corresponds to the instructions on the label, is provided with the product.

It is also important for practitioners to approach all patients reporting actual or potential medication errors with transparency and empathy. See our February 2021 article, *Excuse me, I think there is an error with my prescription: practitioners should respond with empathy and honesty* (www.ismp.org/node/23867), for recommendations on preparing your pharmacy and staff to support patients who report errors.

Just Culture Scholarship recipient and runners-up announced

ISMP has awarded the 2024 ***Judy Smetzer Just Culture Champion Scholarship*** to a team from **Great River Health**, a regional healthcare system with three hospital campuses and more than 40 ambulatory clinics serving residents of southeast Iowa, west-central Illinois, and northeast Missouri. The scholarships, which are being offered in cooperation with The Just Culture Company, include enrollment in a certification course that helps healthcare practitioners work to advance fair accountability and system improvement.

This year for the first time two runner-up teams also were chosen in recognition of their outstanding applications and will receive free tuition for The Just Culture Company's *Just Culture Conduct Course for Healthcare Managers and Influencers* and a 50% discount on the certification course. The 2024 runner-up teams were **St. Luke's Hospital** in Kansas City, MO, and **UCI Health Medical Center** in Orange, CA.

For more about the scholarship benefits, candidate requirements, and application process, visit: www.ismp.org/node/30840.

>SAFETY briefs cont'd from page 2

health record. The error was perpetuated by a community pharmacy which dispensed Paxlovid. According to the report, the pharmacy dispensing system did not alert the pharmacist about the contraindication. The patient took three doses of Paxlovid while continuing flecainide. The patient discovered the error when they read more about Paxlovid and learned that flecainide was on the list of drugs that are contraindicated with Paxlovid use. Thankfully, no patient harm was reported.

Paxlovid is not a drug that should be prescribed without reviewing the patient's current medication list for potential drug-drug interactions. Prescribers and pharmacists should test their computer systems to ensure they provide alerts for this and other drug-drug interactions. The US Food and Drug Administration's (FDA) *Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers* (www.ismp.org/ext/921) can be used for screening.

Special Announcement

Virtual MSI workshop

Join us for our first ***ISMP Medication Safety Intensive (MSI)*** workshop in 2024. The unique 2-day virtual program will be held **March 7 and 8, 2024**. Please visit: www.ismp.org/node/127.

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

ISMP An ECRI Affiliate

ISMP Medication *Safety Alert!* Community/Ambulatory Care (ISSN 1550-6290) **© 2024 Institute for Safe Medication Practices (ISMP)**. All rights reserved. Redistribution and reproduction of this newsletter, including posting on a public-access website, beyond the terms of agreement of your subscription, is prohibited without written permission from ISMP. This is a peer-reviewed publication.

Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

Editors: Michael J. Gaunt, PharmD; Shannon Bertagnoli, PharmD; Ann Shastay, MSN, RN, AOCN; Rita K. Jew, PharmD, MBA, BCPPS, FASHP. ISMP, 5200 Butler Pike, Plymouth Meeting, PA 19462. Email: ismpinfo@ismp.org; Tel: 215-947-7797.