October 2024 | Volume 23 ▪ Issue 10

ISMP
An ECRI Affiliate

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

ISMP National Vaccine Errors Reporting Program 2022-2023 analysis: New vaccines, new errors

Problem: Though immunization is one of the greatest public health achievements, continued success relies on the appropriateness with which vaccines are prescribed, dispensed, stored, and administered. We recently reviewed 1,987 events reported to the ***ISMP National Vaccine Errors Reporting Program*** (ISMP VERP) from January 1, 2022 through December 31, 2023, which showed that most of the reported events reached the patient (82%). The full analysis has been included in the recently published *2022-2023 Bi-Annual Report, The ISMP National Vaccine Errors Reporting Program (VERP)*. Unfortunately, vaccine errors are a widespread issue, especially in outpatient settings where barcode scanning prior to vaccine administration is often lacking. As vaccination programs seek to achieve high immunization rates, more needs to be done to reduce the risk of vaccination errors as they can lead to inadequate immunity, increased cost related to disease transmission and revaccination, increased risk of adverse effects and localized injection reactions if inappropriate duplicate vaccine doses are administered, and reduced confidence in the healthcare delivery system. Our analysis of the reports during the 24-month timeframe showed that the most frequent types of vaccine events reported were as follows:

- Wrong vaccine (25%)
- Expired vaccine or contamination/deterioration (20%)
- Wrong dose (overdosage and underdosage events) (12%)
- Wrong age (10%)
- Extra dose (9%)
- Wrong time or interval (7%)
- Vaccine/component omission (only diluent or a single component of a two-component vaccine was administered) (4%)
- Wrong route (2%)
- Wrong patient (1%)
- Other (10%)

Since most vaccines are administered in the outpatient setting, most reported events occurred in those settings: medical clinics (43%), public health immunization clinics (18%), doctors' offices (17%), or community pharmacies (9%). Forty-eight percent of the events involved medical assistants, 27% involved registered nurses, 19% involved licensed vocational nurses or licensed practical nurses, and 13% involved pharmacists. Other healthcare providers, such as physicians, nurse practitioners, physician assistants, and students (e.g., medical, nursing, pharmacy) were also involved in the events. (Note: more than one type of practitioner may be involved in the events.)

We completed a similar analysis between June 2020 and December 2021 and shared the results in our September 2022 newsletter. While the vaccine event types have not changed, additional vaccines have been marketed since and, in some cases, are indicated for vulnerable patient populations such as infants, pregnant women, and elderly patients. Therefore, the focus of this article is on the newer vaccines.

In 2023, the US Food and Drug Administration (FDA) approved two vaccines for respiratory syncytial virus (RSV) infection prevention in adults (ISMP. Don't confuse products used to prevent infections

continued on page 2 — VERP >

SAFETY briefs

Look-alike Simlandi cartons. In our July 2024 article, *Many adalimumab biosimilars may look similar*, we alerted practitioners to the fact that many of the cartons of adalimumab biosimilars (e.g., **AMJEVITA**, **YUFLYMA**, **HYRIMOZ**) look similar. Earlier this month, another practitioner shared that the cartons containing 1 and 2 autoinjectors of **SIMLANDI** (adalimumab-ryvk) 40 mg/0.4 mL are easy to mix up, which could result in a patient receiving too little or too much medication. The cartons have identical outer dimensions, graphics, and color schemes (**Figure 1**). Only the national drug codes (NDCs) and the small text on the front of each carton describing the contents provide a way to visually differentiate the two packages.

Figure 1. Simlandi cartons containing two autoinjectors (top) look similar to Simlandi cartons containing a single autoinjector (bottom) and may easily be confused for one another.

To help intercept selection errors, scan each carton during fulfillment. Clearly label storage bins, and if space permits, use separate storage locations for the different adalimumab products. Make sure staff are aware that the medications have been separated and where to locate them. Explore ways to differentiate the products to highlight critical information when they are

continued on page 2 — SAFETY briefs >

> VERP — continued from page 1

from respiratory syncytial virus. *ISMP Medication Safety Alert! Community/Ambulatory Care*. 2023;22[11]:3-4). **AREXVY** (respiratory syncytial virus vaccine, adjuvanted) was first approved for active immunization of adults 60 years and older. In June 2024, FDA expanded its approved use, which now includes patients 50 through 59 years old who are at increased risk. **ABRYSVO** (respiratory syncytial virus vaccine) is indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age, as well as individuals 60 years of age and older. Although not available for inclusion in the 2022-2023 data analysis, in May 2024, the FDA approved a third vaccine to prevent RSV infection, **MRESVIA** (respiratory syncytial virus vaccine, mRNA), to protect adults aged 60 years and older. Each year there are also updated formulas for the coronavirus disease 2019 (COVID-19) and influenza vaccines made by a variety of manufacturers. In addition, Merck now has a prefilled sterile diluent syringe used for reconstituting the **M-M-R II** (measles, mumps, and rubella), **VARIVAX** (varicella), and **PROQUAD** (measles, mumps, rubella, and varicella) live virus vaccines which has also led to errors.

Wrong vaccine events

Events related to patients receiving the incorrect vaccine continue to be the most frequently reported error type. The top reported underlying causative factors associated with wrong vaccine mix-ups noted by the reporters included the following:

- Similar vaccine container labels/package (22%)
- Similar brand names (22%)
- Products stored near one another (21%)
- Similar vaccine abbreviations (15%)

Consider these vaccine event reports involving the new RSV vaccines:

Case 1: In anticipation of a high volume of patients, a nurse prepared vaccine doses for multiple patients in a clinic. One patient was prescribed Arexvy; however, the nurse mistakenly prepared and administered **SHINGRIX** (zoster vaccine recombinant, adjuvanted) prescribed for a different patient. Barcode scanning was not available in the clinic. Both vaccines are made by GSK and have a similar font and orange color on their labels (**Figure 1**).

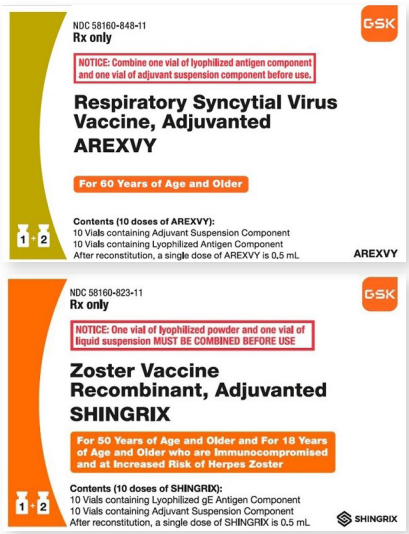

Figure 1. A patient was supposed to receive Arexvy (top), but a nurse prepared and administered Shingrix (bottom) in error.

Case 2: A mother brought her 4-day-old infant to a clinic for a newborn health examination. A prescriber gave a verbal order for the nurse to administer "the RSV vaccine" to the infant. The prescriber was confused about the new RSV products available and intended to prescribe a monoclonal antibody indicated to prevent RSV infection in infants, as opposed to an adult vaccine. The nurse administered Abrysvo, the only RSV vaccine available in the clinic. The nurse later identified that Abrysvo is not indicated for infants and notified the prescriber and parent.

Wrong dose events

The most common reported contributing factors associated with underdosage and overdosage events included the following:

- Age-dependent formulations of the same vaccine (39%)
- Not familiar with dosing of product (24%)

continued on page 3 — VERP >

>SAFETY briefs

continued from page 1

received from the supplier. Educate staff on the different products and the potential to mix them up.

Hurricane Helene IV Fluid update. ISMP has been in communication with Baxter and other organizations to help navigate the drug shortages in the aftermath of Hurricane Helene. On October 9, 2024, the FDA announced it is working to temporarily import some products to help meet patient needs. Multiple resources are available to help practitioners navigate these shortages:

- American Society of Health-System Pharmacists (ASHP) and the University of Utah: *Small- and Large-Volume Fluid Shortages – Suggestions for Management and Conservation*
- ECRI: Patient safety nonprofit releases guidance for navigating medical supply chain disruptions caused by Hurricane Helene
- End Drug Shortages Alliance: Alliance resources

Worth repeating...

More wrong patient errors!

We have written about wrong patient errors multiple times in this newsletter. In fact, we described two wrong patient errors during home delivery in the September 2024 issue. However, since the September issue was published, we have received more wrong-patient reports from both practitioners and consumers.

In one case, an infant was to receive **AUGMENTIN** (amoxicillin and clavulanate potassium), an oral antibiotic suspension. At the pharmacy, the child's parents were given a bag that was stapled shut with the medication inside. The prescription receipt stapled to the bag had the correct patient information. The parents began preparing a dose at home and noticed that the consistency, smell, and amount of medication were different from previous prescriptions of Augmentin. When they looked at the

continued on page 3 — Worth repeating >

> VERP — continued from page 2

The following is an example of a wrong dose error that occurred with the 2023-2024 Moderna COVID-19 vaccine (25 mcg/0.25 mL) (**Figure 2**), indicated for patients 6 months to 11 years of age under an emergency use authorization (EUA):

Case 1: A pediatric clinic reported that more than 200 children were administered the full vial of the Moderna COVID-19 vaccine before the error was identified. The vial is labeled as a 0.25 mL single-dose vial, but it contains double the dose as overfill. The dose of Moderna's **SPIKEVAX** (COVID-19 vaccine) for patients 12 years and older is 50 mcg/0.5 mL, and the volume (0.5 mL) is similar to several other childhood vaccines which could have also contributed to this event.

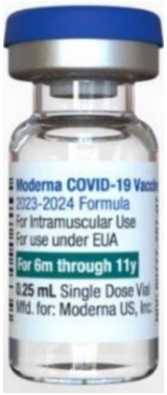

Figure 2. The label on the Moderna COVID-19 vaccine (2023-2024) for patients ages 6 months through 11 years states, "0.25 mL Single Dose Vial," but practitioners have administered the entire contents, which can contain up to 0.5 mL.

Vaccine/component omission events

Errors have been reported where only the diluent or a single component of a two-component vaccine was administered. The most commonly reported contributing factor was practitioners' lack of familiarity with how to prepare products (57%). Prefilled syringes that are not ready-to-administer may contribute to omission errors and create an increased risk of other errors.

Case 1: An outpatient clinic reported concerns with Merck's prefilled sterile diluent syringes (packaged separately) (**Figure 3**) for reconstituting a lyophilized powder vial of M-M-R-II, Varivax, and Proquad vaccines. The syringes are labeled "STERILE DILUENT FOR RECONSTITUTION OF MSD LIVE VIRUS VACCINES," but the instructions do not mention the need to relabel the diluent syringe with the vaccine name after reconstitution and prior to administration. The clinic reported concerns that someone could inadvertently pick up and inject an unmixed diluent syringe. A separate risk is if a practitioner does not know that a syringe was already used to reconstitute a vaccine, it could be used again, and a patient could get a double dose or two different vaccines.

Figure 3. Prefilled diluent syringe for use with Merck vaccines must be relabeled with the vaccine name after reconstitution.

Wrong diluent events

Among the "other" event types, wrong diluent events were also reported. This could include using the wrong diluent, using a diluent instead of a vaccine liquid component to reconstitute its lyophilized powdered component, or reconstituting one vaccine with another vaccine. Here is one example of such an event:

Case 1: A patient was to receive Abrysvo and **FLUZONE HIGH-DOSE** (influenza vaccine). During reconstitution, the nurse inadvertently connected the Fluzone High-Dose syringe to the Abrysvo powder for reconstitution (instead of the intended sterile water diluent for Abrysvo) (**Figure 4**). The error was caught prior to administration.

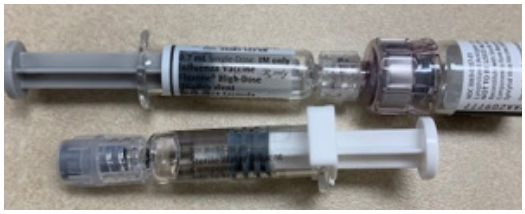

Figure 4. Rather than using an Abrysvo diluent syringe (bottom), a nurse connected the Fluzone High-Dose syringe (top) to the Abrysvo vial via an adapter for reconstitution.

Safe Practice Recommendations: Consider the following recommendations to prevent vaccine errors, foster herd immunity to prevent disease outbreaks, limit costly re-vaccination and overvaccination, and enhance the public's confidence in vaccines and the healthcare delivery system:

continued on page 4 — VERP >

>Worth repeating

cont'd from page 2

pharmacy label affixed to the bottle, they realized the medication was clo**NIDI**ne, an antihypertensive, for a different patient.

In a second case, a patient went to pick up **WEGOVY** (semaglutide), a glucagon-like peptide-1 (GLP-1) receptor agonist from the pharmacy. They were supposed to receive a Wegovy 1.7 mg pen; however, they received a Wegovy 1 mg pen labeled for a different patient. The pharmacy staff had retrieved the wrong prescription bag from the refrigerator. Then, instead of asking the patient for their date of birth and verifying that information in the computer system, they entered the date of birth printed on the pharmacy receipt and scanned out the prescription. The error was discovered a few days later when the patient whose Wegovy 1 mg pen had been dispensed in error arrived at the pharmacy to pick up her prescription.

In the third case, twins, who have similar names, use the same pharmacy for their prescription medications. When one of the twins went to the pharmacy to pick up their prescribed antibiotic, the pharmacy staff dispensed the other twin's blood pressure and hypothyroid medications.

There are several strategies community pharmacies can implement to prevent wrong patient errors, including those outlined in *Best Practice #1* in the 2023-2024 ISMP ***Targeted Medication Safety Best Practices for Community Pharmacy***. We thought they were ***Worth* repeating** since we continue to receive reports of patients taking home another patient's medication by mistake.

Always ask the patient to provide at least two patient identifiers (e.g., their full name and date of birth) when picking up prescriptions or receiving vaccines. This is important even if you "know" your patients. Compare their answer to the information in the computer system or on the prescription receipt. Never ask a "Yes" or "No" question by reading aloud the patient's date of birth.

Employ technological enhancements at the point-of-sale (e.g., "blind" entry of patient's

continued on page 4 — *Worth* repeating >

> VERP — continued from page 3

Maximize technology

- Utilize standard orders, built into the electronic health record (EHR), based on the Centers for Disease Control and Prevention (CDC) immunization schedules to guide prescribers to the appropriate formulation based on the patient population (e.g., age, pregnancy status).
- Utilize the full generic name and brand name (if applicable) in the pharmacy computer system and EHR. Avoid the use of vaccine abbreviations.
- Ensure clinical decision support will provide an alert if a practitioner orders or selects a vaccine for a patient in an age group or documented pregnancy status outside of its approved indication.
- Use barcode scanning technology to verify the correct vaccine and dose are being administered to the correct patient prior to vaccine administration.

Ensure safe storage

- Store vaccines in separate bins or containers based on name and formulation.
- Store the components of each two-component vaccine together where storage requirements permit.
- Separate adult and pediatric vaccine storage (e.g., on different shelves in bins properly labeled with the corresponding age formulation).
- Do not store vaccines with similar names or abbreviations, or overlapping components (e.g., diphtheria, tetanus, and/or pertussis vaccines [DTaP, Tdap, TD, Td]) right next to each other.
- Assign a staff person to go through the contents of the vaccine bins on a regular schedule (e.g., weekly), opening each carton and making sure no vaccines were incorrectly returned to stock, confirming the different vaccine formulations are stored separately, and checking that the vaccines have not expired. Ensure vaccines that expire soonest are stored closest to the front to be used first.

Verify identity, age, and vaccine(s) requested

- Verify a patient's immune status (e.g., whether they are immunocompromised) as well as their immunization status (in the pharmacy computer system, EHR, and state and/or local immunization information systems) prior to providing vaccines.
- Ask patients and/or caregivers to bring up-to-date vaccination records/cards to their appointment so they may be reviewed and compared to the pharmacy computer system and/or EHR.
- If multiple patients are being vaccinated at the same time, separate them into distinct treatment areas; bring only one patient's vaccines into the treatment area at a time.
- When checking in a patient scheduled to receive a vaccine(s), ask the parent, caregiver, or patient to provide at least two patient identifiers—their full name and date of birth. Verify the patient's actual age with the patient, parent, or caregiver, and ask which vaccine(s) they have requested. Repeat this process immediately prior to vaccination.

Prepare and label syringes

- Use manufacturer prefilled syringes when available. If not available, prepare each vaccine dose immediately prior to administration and, if not administered immediately to the patient, label with the vaccine name, dose, and if appropriate, the indicated age range before it is set down.
- Prepare and label only one vaccine at a time.
- To facilitate labeling, print patient-specific labels with barcodes or provide practitioners who prepare the vaccines with preprinted labels that differentiate adult or pediatric formulations and doses for each vaccine.

continued on page 5 — VERP >

>Worth repeating

cont'd from page 3

date of birth) that require pharmacy staff to electronically verify the patient's identity before the register transaction can be completed.

At the point-of-sale, review the pharmacy labels and contents of each prescription container with the patient to check that the patient's name and medications are correct—even if this requires opening the bag. To facilitate this process, consider employing a will call system that uses clear plastic hanging bags to hold the prescription containers and receipts awaiting pick up, or do not staple the paper bag shut. However, this may not be appropriate when a friend picks up the prescription. In these cases, patients should be notified to open the package at home, check the contents before taking any of the medication, and call the pharmacist with any concerns or questions.

Counseling the patient about their medications can also reduce the risk of the patient taking home the wrong medication. Pharmacists should engage the patient in dialogue by asking open-ended questions. Patient education sessions should include a discussion of the medication's purpose to help ensure the correct medication is being dispensed to the correct patient. As mentioned before, patient counseling at the point-of-sale may not be possible if someone other than the patient is obtaining the medication(s), so important information must be conveyed to the patient via telephone.

Special Announcement

New white paper: Reducing inappropriate polypharmacy

Polypharmacy is common among older adults. Age-related changes in medication metabolism can lead to side effects and adverse drug events, potentially resulting in inappropriate polypharmacy. ECRI's new white paper, *Reducing Inappropriate Polypharmacy through Deprescribing*, explores how to reduce polypharmacy risks in older adults and provides steps for healthcare leaders to take to protect patients now. To obtain a copy, click here.

> VERP — continued from page 4

Engage the patient

- Involve the parent, caregiver, or patient in verifying the vaccine, formulation, and dose by reviewing the label to confirm the correct vaccine.
- Provide patients, parents, and/or caregivers with vaccine information (e.g., Vaccine Information Statement [VIS]) in their preferred language prior to vaccination. Providing the VIS and reading the medication name and age formulation in the patient's preferred language can provide an additional opportunity for both parties to stop and question if something does not seem right.
- Give patients a copy of the larger, provider immunization record with full vaccine names, even if wallet-sized immunization cards with CDC abbreviations are provided.

Document the vaccine(s)

- Document the vaccine's national drug code (NDC) number, lot number, and expiration date prior to administration; this is often the step during which healthcare workers detect an error that can be mitigated.
- Document administration afterward in the pharmacy computer system, EHR, on vaccination records, and in state or local immunization information systems.

Educate Practitioners

- Provide vaccinators with ongoing education and competency assessment about vaccines and their appropriate storage, selection, preparation, administration, and monitoring.
- When bringing in new vaccine products, including during shortages, educate staff about the new vaccine product, highlighting its storage location, packaging, indication, and the intended patient population including age and pregnancy status.
- In locations where vaccines are prescribed, dispensed, and administered, provide resources that list the indication and schedules for routine and catch-up vaccinations.
- Share impactful stories and recognize staff for good catches, describing how the event was averted to prevent future close calls or actual events.

Report vaccine-related errors

- Report vaccine errors internally as well as to ISMP VERP, and adverse vaccine reactions to the Vaccine Adverse Event Reporting System operated by the FDA and CDC.

Recommendations for FDA and manufacturers

- We encourage manufacturers to review labeling strategies to reduce the risk of vaccine mix-ups. More can be done by regulators and manufacturers to reduce errors!
- Manufacturers should always first look to produce vaccines in ready-to-use prefilled syringes. For vaccines that do not come in ready-to-use prefilled syringes, manufacturers should provide preprinted labels (in the carton) that include the vaccine name, dose, and intended age group.
- We also encourage manufacturers to develop innovative packaging for component vaccines in order to prevent errors where only the diluent or a single component of a two-component vaccine are administered.

Welcome our newest staff members

Director of Consulting and Education

We are pleased to announce that **Jana O'Hara**, MSN, RN, CPHQ, CPPS has joined ISMP as the Director of Consulting and Education. Jana has worked in a variety of clinical quality, safety, and leadership roles. Most recently, she served as the Director of Marketplace Operations for a healthcare staffing company, leading clinical and non-clinical teams that support clinical staff across the country. Prior to that she served as the Director of Patient Safety for University Health in San Antonio, TX, overseeing patient safety across the entire healthcare system including inpatient, ambulatory, ambulatory surgery centers, dialysis, and correctional facilities.

2024-2025 FDA/ISMP Safe Medication Management Fellow

Desiré Johnson, PharmD, is the ***2024-2025 FDA/ISMP Safe Medication Management Fellow***. She received her Doctor of Pharmacy degree at Mercer University College of Pharmacy in Atlanta, GA and completed a PGY-1 acute care residency at AdventHealth Altamonte Springs in Altamonte Springs, FL. She will spend the first 6 months of her Fellowship at ISMP and the second half of the year at the US Food and Drug Administration (FDA). Desiré aspires to become a servant leader in medication safety and aims to increase awareness of the importance of establishing safe medication-use processes.

Please join us in welcoming our new staff members!

To subscribe: www.ismp.org/ext/1369

ISMP An ECRI Affiliate

ISMP Medication *Safety Alert!* Community/Ambulatory Care (ISSN 1550-6290)

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.

Tuesday, December 10, 2024

Civic Theatre – New Orleans, LA

The Cheers Awards honor the amazing abilities of individuals and organizations that have advanced medication safety.

Show Your Support:

www.ismp.org/cheers-awards

Demonstrate your commitment to medication error prevention with sponsorship of our **ONLY** annual fundraising event!

Captivate Your Audience

Other benefits of Cheers sponsorship:

- Branding as a prominent champion of patient safety
- Positioning as a strategic partner with ISMP
- Networking with patient safety leaders from varied practice settings

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

To show your support, visit
www.ismp.org/cheers