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

ISMP National Vaccine Errors Reporting Program:

2020-2021 analysis focuses on age-related, non-COVID-19 vaccine errors

Problem: We recently looked at 1,440 events reported to the ***ISMP National Vaccine Errors Reporting Program*** (ISMP VERP) between June 2020 and December 2021. Of note, more than two-thirds (68%) of the vaccine events reported during this timeframe were related to coronavirus disease 2019 (COVID-19) vaccines. We excluded the COVID-19 vaccine events from our analysis since we recently published information about these errors, along with recommended error-prevention strategies (e.g., www.ismp.org/node/28619, www.ismp.org/node/32454, www.ismp.org/node/32703). Our analysis of the remaining reports during the 19-month timeframe showed that the most frequent types of vaccine events, other than those related to the COVID-19 vaccines, were:

- Wrong vaccine (24%)
- Expired vaccine or contamination/deterioration (14%)
- Wrong age (13%)
- Extra dose (10%)
- Wrong dose (9%)
- Vaccine/component omission (e.g., only diluent or a single component of a two-component vaccine administered) (8%)
- Wrong time or interval (7%)
- Wrong patient (4%)
- Wrong route (1%)
- Other (10%)

Since healthcare providers administer most vaccines in the outpatient setting, reported events occurred in medical clinics (49%), doctors' offices (20%), public health immunization clinics (11%), or community pharmacies (9%). In these outpatient settings, widespread barcode scanning prior to vaccine administration is often lacking. Only 3% of the events occurred in inpatient settings, and 8% occurred in other settings. Forty-two percent of the events involved registered nurses or nurse practitioners, 34% involved medical assistants, 14% involved pharmacists, and 14% involved other healthcare providers, such as physicians, physician assistants, emergency medical technicians, respiratory therapists, and nursing assistants (more than one practitioner type may have been included in a single report).

Focus on age-related vaccine events

Our focus for this vaccine event analysis is on age-related vaccine errors, which may also be associated with administering the wrong vaccine or the wrong dose. For example, a mix-up between a pediatric hepatitis A vaccine and an adult hepatitis A vaccine could result in an error classified as the wrong vaccine, the wrong dose, or the wrong age. One-third (33%) of the reported events involved the wrong vaccine or the wrong dose, which reporters often attributed to confusion between age-dependent vaccine formulations. Adding these vaccine events to wrong age vaccine events (13%) contributes to nearly half (46%) of all the vaccine errors reported to the *ISMP VERP* (excluding COVID-19 vaccine errors). Receiving a lower-than-intended vaccine dose for a patient's age can compromise the protection immunizations provide, leaving patients more vulnerable to diseases; whereas, receiving a higher-than-intended vaccine dose for a patient's age could result in adverse effects or the need for additional monitoring.

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SAFETY briefs

Bivalent COVID-19 vaccine vial label concerns. With the new Moderna and Pfizer-BioNTech COVID-19 bivalent booster formulations that target both the original coronavirus variant and omicron subvariants BA.4 and BA.5, it is predictable that mix-ups will occur, just as ISMP previously warned about with age-related COVID-19 vaccines (www.ismp.org/node/32454). The Moderna COVID-19 bivalent vaccine, authorized as a booster dose for patients 18 years and older, looks similar to the Moderna COVID-19 primary series vaccine for patients 6 through 11 years (also previously used as the conventional monovalent booster for patients 18 years and older). Both have dark blue caps with "BOOSTER DOSES ONLY" on the label (**Figure 1**), although the vaccine with the purple label should no longer be used for booster doses. Both the bivalent and primary series vaccine doses are 0.5 mL (50 mcg), but they are not equivalent. Although the Moderna bivalent booster label lists two doses, "0.5 mL or 0.25 mL based on age," it is only authorized as a 0.5 mL dose for patients 18 years and older at this time.

Figure 1. The new Moderna COVID-19 bivalent vaccine (left) and the primary series vaccine for patients 6 through 11 years (right) have dark blue caps and display "BOOSTER DOSES ONLY."

Perhaps an even greater concern for confusion exists between the Pfizer-BioNTech products. The bivalent vaccine is authorized

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Wrong age and wrong dose events

Wrong age and associated wrong dose errors occurred frequently between age-related formulations of influenza virus vaccines (31%); diphtheria, tetanus, and/or pertussis vaccines, including combination vaccines (23%); hepatitis A vaccines (16%); and hepatitis B vaccines (16%).The frequency of mix-ups between age-related formulations of these four vaccines has not improved much during the past decade. In fact, events related to these four vaccine types seem to be occurring for many of the same reasons previously noted in analyses of the *ISMP VERP* data between 2012 and 2016, and again in 2017 (www.ismp.org/ext/984), particularly for:

- Not differentiating age-dependent formulations of the same vaccine (44%)
- Failure to verify the patient's age before administration (16%)
- Lack of familiarity with the indicated ages for vaccines (16%)

The way vaccine labels portray the intended age group may contribute to some of these mix-ups. It is not surprising that practitioners continue to struggle with providing the correct vaccine based on the patient's age, given that several vaccines available in pediatric and adult formulations have similar packaging presentations and generic names—some even have the same brand name. Consider three recent vaccine event reports:

Figure 1. GSK manufactures two hepatitis A vaccines, one intended for children 12 months through 18 years (left), and the other for patients 19 years and older (right). The cartons do not specify "pediatric" or "adult" formulation, and the syringe labels (not pictured) do not include the recommended age range or state "pediatric" or "adult" formulation.

Case 1: A medical assistant administered an adult hepatitis A vaccine (1,440 ELISA units/mL, for patients 19 years and older) to a pediatric patient instead of the pediatric hepatitis A vaccine (720 ELISA units/0.5 mL, for children 12 months through 18 years). A coworker had pulled the adult formulation from the refrigerator, and a medical assistant confirmed what he thought was the correct vaccine and administered it. Both vaccines, manufactured by GSK, have the same brand name, **HAVRIX**, and the cartons have similar labeling (**Figure 1**). Although there appears to be plenty of empty space for larger fonts on the carton labels, the print is small and somewhat difficult to read. Also, once a healthcare provider removes a syringe from the carton, the syringe label does not include the recommended age range or specify "pediatric" or "adult" formulation.

Figure 2. GSK manufactures two hepatitis B vaccines, one intended for children from birth through 19 years (left), and the other for adults 20 years and older (right). The cartons do not specify "pediatric" or "adult" formulation, and the syringe labels (not pictured) do not include the recommended age range or state "pediatric" or "adult" formulation.

Case 2: A nurse administered the pediatric formulation of hepatitis B vaccine (recombinant), **ENGERIX-B** (10 mcg/0.5 mL), rather than the adult formulation (20 mcg/mL), to a 28-year-old patient. Both vaccines, manufactured by GSK, have the same brand name, Engerix-B, and the cartons have similar labeling, although the colors used on the left of the cartons are different (**Figure 2**). Also, the carton labels do not specify "pediatric" or "adult" formulation. Due to a stocking error, the pediatric doses had been stored in the adult bin in the clinic. Prior to administration, the nurse did not check the label, and the outpatient facility did not utilize barcode scanning technology.

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as a booster for patients 12 years and older, and the primary series vaccine is for patients 12 years and older. They both have gray caps and labels with gray borders (**Figure 2**).

Figure 2. The Pfizer-BioNTech bivalent vaccine (left) and the primary series vaccine for patients 12 years and older (right) have gray caps. The bivalent vaccine label does not specify its use as a booster.

In both cases, the manufacturer's name has become part of the vaccine name, which increase look-alike similarities. This means the vaccine name may wrap around the vial making it easier for practitioners to miss critical parts of the name. To help prevent errors, perhaps the lead word on the label should be bivalent or monovalent (e.g., Bivalent COVID-19 vaccine, Monovalent COVID-19 vaccine), rather than the company's name?

We have previously shared strategies to prevent vaccine mix-ups in look-alike situations like this (www.ismp.org/node/32454). Store vaccine formulations apart from one another in separate bins that are properly labeled with the corresponding age group or booster designation. Verify the patient's full name and actual age with the patient, parent, or caregiver, and ask which vaccine(s) were requested, including the brand name, company, and/or the dose (e.g., second primary vaccine, first bivalent booster). Prior to preparation, check the patient's vaccine card/medical record, and the immunization information system. Clearly label all syringes. During preparation and administration, use barcode scanning to confirm the correct vaccine. Only bring the intended and labeled vaccine syringe(s) for one patient into the vaccination area and vaccinate one patient at a time. Involve the parent, caregiver, or patient in verifying the correct vaccine by reading the label to confirm the vaccine, formulation, and dose.

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Case 3: A nurse administered an adult hepatitis A vaccine (for patients 19 years and older) to a pediatric patient instead of the pediatric hepatitis A vaccine (for children 12 months through 18 years). The nurse caught the error when documenting the vaccine. Both vaccines, manufactured by Merck, have the same brand name, **VAQTA**, differing by the color, dose, and pediatric/adolescent or adult formulation designation on the carton, vial, and syringe (**Figure 3**). However, the indicated age range (pediatric/adolescent or adult) is listed below the vaccine name in similar font size and color, and in all uppercase letters. Practitioners generally identify the vaccine and then stop reading, so they may miss what is below the name and not see "pediatric/adolescent" or "adult."

Figure 3. Merck manufactures two hepatitis A vaccines, one intended for children 12 months through 18 years (left), and the other for patients 19 years and older (right). The labels specify pediatric/adolescent or adult, but this is displayed below the name of the vaccine in similar font size and can be easily overlooked.

Wrong vaccine events

Wrong vaccine events most often involve mix-ups between formulations for different age groups, such as diphtheria, tetanus, and/or pertussis vaccines, including combination vaccines (38%); influenza virus vaccines (17%); meningococcal vaccines (12%); measles, mumps, rubella, and/or varicella vaccines (10%); and hepatitis A vaccines (7%). Underlying causative factors associated with mix-ups among these products included the following:

- Not differentiating age-dependent formulations of the same vaccine (19%)
- Look-alike products stored near one another (16%)
- Similar brand names (15%)
- Similar vaccine abbreviations (7%)

Consider this recent vaccine event report:

Case 1: A prescriber ordered DTaP (**DAPTACEL**) to be administered to an infant. A nurse removed the Tdap formulation (**ADACEL**) from the refrigerator and administered a dose to the infant. Daptacel specifies "6 wks – 6 yrs," and Adacel specifies "Adolescent/Adult" on the top of the carton (**Figure 4**). Both products are made by Sanofi and are available in 0.5 mL doses.

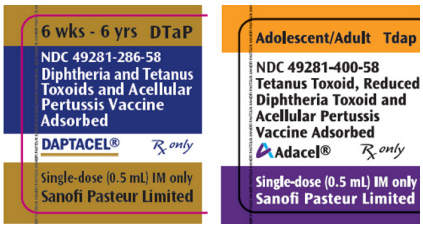

Figure 4. Daptacel, the DTaP formulation by Sanofi, is intended for patients 6 weeks through 6 years (left). Adacel, the Tdap formulation by Sanofi, is intended for patients 10 years through 64 years of age (right).

Unfortunately, confusion between DTaP and Tdap is among the most common of the age-related mix-ups reported to ISMP. Tdap vaccines contain less diphtheria toxoid and pertussis antigens per dose than DTaP vaccines. These products are easy to confuse due to their similar proper names and abbreviations. The uppercase letters, "D" and "P" in DTaP, correspond with a higher antigen quantity of the diphtheria and pertussis components, relative to Tdap and its lowercase letters. A larger amount of antigen is needed for initial immunization versus a booster shot. An adult who gets DTaP (higher amount of antigens) would not need to be revaccinated but would be more likely to experience adverse effects. But an infant/child who receives Tdap would have received a lesser amount of antigen and may not develop an adequate immune response.

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

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Avoid tearing the metal flange on the monkeypox vaccine vial. With the monkeypox outbreak, we are fortunate to have smallpox and monkeypox vaccine injection (**JYNNEOS** [US], **IMVAMUNE** [Canada], **IMVANEX** [Europe]). However, this vaccine comes in vials that have a closure typically used for oral preparations, where you tear off the metal flange and remove the stopper to pour out the liquid. The monkeypox vaccine is a parenteral injection and needs to be opened carefully. Unless you are aware

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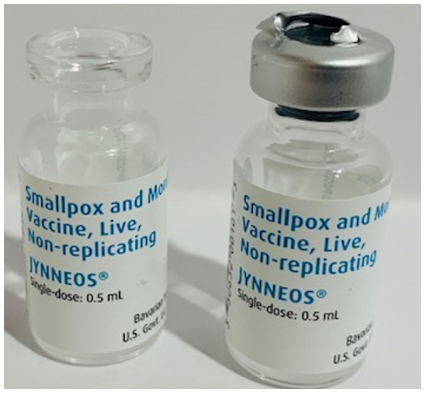

Figure 1. With improper removal of the yellow cap from the Jynneos vial, the entire metal flange and stopper can come off (left), or the metal flange can tear leaving sharp edges (right).

Figure 2. To use, flip off the yellow cap at the arrow (top) with your thumb at a 90-degree angle. Leave the yellow cap on the metal flange (bottom). Alternatively, flip the yellow cap all the way off but ensure the metal flange stays on the stopper/vial.

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Maximize technology

- Develop order sets based on the Centers for Disease Control and Prevention (CDC) immunization schedules to guide prescribers to the appropriate age-based formulations (www.ismp.org/ext/978).
- Along with the full generic name and CDC standard abbreviation, list vaccine brand names in the electronic health record (EHR) and outpatient pharmacy systems, as they may help to differentiate look-alike full vaccine names and combination vaccines.
- Confirm that clinical decision support will provide an alert if a practitioner orders a vaccine for a patient in an age group outside of its approved indication.
- Use barcode scanning technology for verification prior to vaccine administration. Expand the use beyond inpatient care areas to offer a greater layer of protection to ensure the patient receives the correct vaccine formulation, as recommended in the 2022-2023 ***ISMP Targeted Medication Safety Best Practices for Hospitals***, Best Practice #18 (www.ismp.org/node/160).

Purchase from different manufacturers

- Investigate purchasing differing age-specific formulations of the same vaccine from different manufacturers to help distinguish them.

Store separately

- Separate adult and pediatric vaccine storage 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., DTaP, Tdap, TD, Td) right next to each other.
- For vaccines that come in prefilled syringes, consider storing them in their carton, especially for age-dependent formulations that do not display the intended age range or age group (e.g., pediatric, adult) on the syringe.
- Assign a staff person to routinely go through the contents of the vaccine bins, opening each carton and making sure no vaccines were incorrectly returned to stock, confirming the intended formulations are still stored separately, and checking that the vaccines have not expired.

Verify identity, age, and vaccine(s) requested

- 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.
- 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 EHR.
- Check your state information immunization system prior to vaccination to ensure the patient requires the intended vaccine.

Label syringes

- For vaccines that do not come in prefilled syringes, clearly label all prepared syringes (e.g., vaccine name, dose).
- To facilitate labeling, print patient-specific labels with barcodes or provide practitioners who prepare the vaccines with strips of preprinted labels that differentiate adult or pediatric formulations and doses for each vaccine.

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. Providing the vaccine information statement (VIS) and reading the medication name and age formulation in the patient's, parent's, or caregiver's preferred language can provide an additional opportunity for both parties to stop and question if something does not seem right.

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of how to properly open these vials, you might tear the flange leaving an exposed sharp edge, or if the stopper is removed, it can affect sterility (**Figure 1**, page 3). We contacted Bavarian Nordic (Jynneos) and learned there are specific steps to follow to avoid damaging the flange (**Figure 2**, page 3). However, they did not explain why a parenteral vial has this closure system.

HIGH-ALERT

More on leaking ports with ExactaMix 2400 compounder. ISMP has received reports of leaking **EXACTAMIX** 2400 valve set ports beyond the issues that Baxter mentioned in its July 14, 2022, *Urgent Medical Device Correction* communication (www.ismp.org/ext/955). Baxter had previously received complaints of ports 1 and 2 leaking when in the closed position, resulting in unintended ingredient transfer into the compounded admixture. Baxter has focused on ports 1 through 4 for device corrections; however, we recently received reports from a hospital involving leaking ports beyond 1 through 4. We have shared this with Baxter. While these events may be due to using the device incorrectly (e.g., wrong syringes or vial sizes), we do not know if the other ports are leaking due to manufacturing issues like those previously reported. Baxter is investigating these additional reports, and the root cause of the suspected problem is currently unknown. Because parenteral nutrition (PN) ingredients are often colorless and the vials on automated compounders are replaced infrequently, practitioners are unlikely to identify individual small-volume ingredient discrepancies, which could result in patients receiving incorrect admixtures. In addition, we received a report regarding a missing valve in the valve set (**Figure 1**).

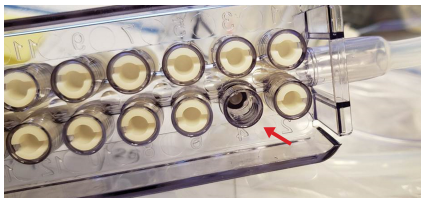

Figure 1. Valve 4 is missing from an ExactaMix 2400 valve set.

To prevent inaccuracies due to device setup, always use BD 50 mL syringes and medication vials that are 10 mL or larger, per the *Operator Manual*. As Baxter investigates the recent reports, periodically observe the pumping process and the ingredient source

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Document the vaccine(s)

- Document the lot number and expiration date prior to vaccine administration; this is often the step during which healthcare workers detect an error that can be mitigated. Document administration afterwards in the patient's profile, on vaccination records, and in state or other immunization information databases.

Educate practitioners

- 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 age group.
- In locations where vaccines are prescribed, dispensed, and administered, provide resources that list the indication and schedules for routine and catch-up vaccinations.
- Use trained providers with demonstrated vaccination competencies to educate staff prior to allowing them to vaccinate patients.
- Consider focusing on a "vaccine of the month" during staff meetings and/or huddles to draw attention to the vaccine. During this time, review the storage location, packaging, indication, and intended age group, highlighting when there are pediatric and adult formulations. Gather feedback from staff by asking them how this vaccine has caused confusion and led to errors, and make adjustments as needed.
- Share impactful stories and recognize staff for good catches, describing how the event was averted to prevent future close calls or actual events.
- Use this document, ***Staff Educational Topics and Teaching Points to Prevent Errors During Vaccine Administration*** (www.ismp.org/ext/55), as a teaching tool.

Report vaccine-related errors

- Report vaccine errors internally as well as to the Vaccine Adverse Event Reporting System (https://vaers.hhs.gov) operated by the US Food and Drug Administration (FDA) and CDC. ISMP also asks providers to report vaccination errors to the *ISMP VERP* (www.ismp.org/report-medication-error).

Additional resources

- Please see our past newsletters for additional recommendations to prevent vaccine errors (www.ismp.org/node/592; www.ismp.org/node/584; www.ismp.org/node/268; www.ismp.org/node/208; www.ismp.org/node/226; www.ismp.org/node/1102).

Recommendations for FDA and manufacturers

- We encourage manufacturers to review labeling strategies to reduce the risk of age-related vaccine mix-ups. More can be done by regulators and manufacturers to reduce errors!
- Prominently display **PEDIATRIC** or **ADULT** (or **ADOLESCENT/ADULT** or **PEDIATRIC/ADOLESCENT**) formulations in a different color bold font on the top of the cartons, vials, and on syringe labels.
- For vaccines and other biologics, government regulations require manufacturers to place the product's proper (generic) name above the brand name (www.ismp.org/ext/988). The font size and typeface of the proper name must be at least as prominent as the font size and typeface used in designating the trademark and trade name. However, when reading a label, people generally start from the top, and once they think they have identified the product, they tend to stop reading. Thus, healthcare workers can overlook critical information, including the vaccine's brand name. While not supported by FDA, for vaccines that have different brand names for vaccine formulations, displaying the brand name prominently and higher on the carton label and vial could help differentiate the various formulations when vaccines have similar generic names.
- For vaccines that do not come in ready-to-use prefilled syringes, provide pharmacists and vaccine administration staff with preprinted labels (in the carton) that include the vaccine name, dose, and intended age group.

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container levels to ensure their volumes are not consumed faster than expected. When replacing a valve set, visually check that all valves are present. Report all incidents to FDA, Baxter, ECRI, and ISMP. When reporting to Baxter, follow the instructions outlined in the field action letter and hold the suspect unit(s) until you receive instructions from Baxter. Our affiliate and safety partner, ECRI, published an ***ECRI Hazard Report***, which can be found here: www.ismp.org/ext/985.

Special Announcements

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Don't miss the opportunity to register for one of our unique 2-day ***ISMP Medication Safety Intensive (MSI)*** workshops in 2022. We have two more virtual sessions planned before the end of the year: **October 6 & 7** and **December 1 & 2**. For more information and to register, visit: www.ismp.org/node/127.

Free webinar from FDA

The US Food and Drug Administration's (FDA) Division of Drug Information is presenting a **FREE** webinar, ***FDA Drug Topics: Development and US Regulation of Preventative Vaccines***, on **September 27, 2022**. Healthcare professionals will receive **1 hour of continuing education (CE) credit** for attending. For more information, visit: www.ismp.org/ext/30. To register, visit: www.ismp.org/ext/31.

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