2022–2023 Biannual Report

The **ISMP National Vaccine Errors Reporting Program** (ISMP VERP)

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

www.ismp.org

CONTENTS

ABSTRACT

Though immunization is one of the greatest public health achievements, continued success relies on the quality with which vaccines are prescribed, dispensed, stored, and administered. Analysis of 1,987 event reports submitted to the ***Institute for Safe Medication Practices (ISMP) National Vaccine Errors Reporting Program*** (ISMP VERP) from January 1, 2022, through December 31, 2023, shows that most of the reported errors reached the patient (82.3%, n = 1,635). Most of the reports were submitted by a practitioner working in the outpatient setting including medical clinics (42.9%, n = 853), public health immunization clinics (17.9%, n = 355), physician practices (17.0%, n = 338), and community pharmacies (8.7%, n = 173). The error types reported most frequently included the wrong vaccine (25.2%, n = 501) and expired vaccine (19.8%, n = 393). As vaccination programs seek to achieve high immunization coverage, more needs to be done to reduce the risk of vaccination errors since they can lead to inadequate immunity, increased cost, and reduced confidence in the healthcare delivery system.

INTRODUCTION

Over the past 35 years, vaccines have provided cost-effective and substantial advances in human health.[1] The Centers for Disease Control and Prevention (CDC) estimated that vaccines prevented more than 730,000 deaths and 322 million cases of illness among US children born between 1994 and 2013.[2] The World Health Organization specifies that, globally, immunization averts millions of deaths each year, offering protection from more than 20 life-threatening diseases.[3]

According to CDC's National Health Interview Survey, there was a modest increase in vaccination coverage for some vaccines (e.g., herpes zoster and hepatitis A vaccination) while other vaccine coverage decreased (pneumococcal vaccination) from 2017 to 2021.[4] A separate study in the United States compared prevaccine disease incidence to postvaccination disease incidence and found a reduction of greater than 99% and 98% for mumps and varicella, respectively.[5]

Vaccination successes together with advances in immunization technology and knowledge of diseases have spurred an ongoing stream of new vaccines.[6] In fact, the US Food and Drug Administration (FDA) has approved more than 100 vaccines.[7] To provide a uniform approach to vaccine references, the CDC provides a list (**Appendix A**, page 17) of standardized abbreviations or acronyms for these FDA-approved vaccines.[8]

With an increase in the number of vaccines, safe use becomes essential for the success of vaccination programs. As with medications, vaccination errors are known to occur.[9] Though preventable, each immunization represents a potential opportunity for vaccination-related errors.[10] Errors can occur during the scheduling, ordering, dispensing, preparation, and administration of vaccinations. Consequences of vaccination errors include inadequate immunological protection, increased cost, injury, inconvenience, and reduced confidence in the vaccine delivery system.[11]

In September 2012, ISMP partnered with the California Department of Public Health to develop the ISMP VERP which promotes ongoing learning about potentially preventable harm associated with pediatric and adult immunization.[12] Since then, ISMP has been receiving an overall increasing number of vaccine error reports (**Figure 1**, page 4). Although in recent years there has been a decrease in reported errors, likely related to the challenges associated with coronavirus disease 2019 (COVID-19) vaccination efforts, the overall trajectory remains higher. This report summarizes the analysis of vaccine error reports submitted to ISMP VERP during calendar years 2022 and 2023.

METHODS

Analysts queried the ISMP VERP database for events reported to ISMP from January 1, 2022, through December 31, 2023. The query yielded 1,987 vaccine error reports.

When submitting reports, reporters provided information for several questions, including event type, contributing factors, type of facility, type of practice, and practitioner type. For each question, the reporter

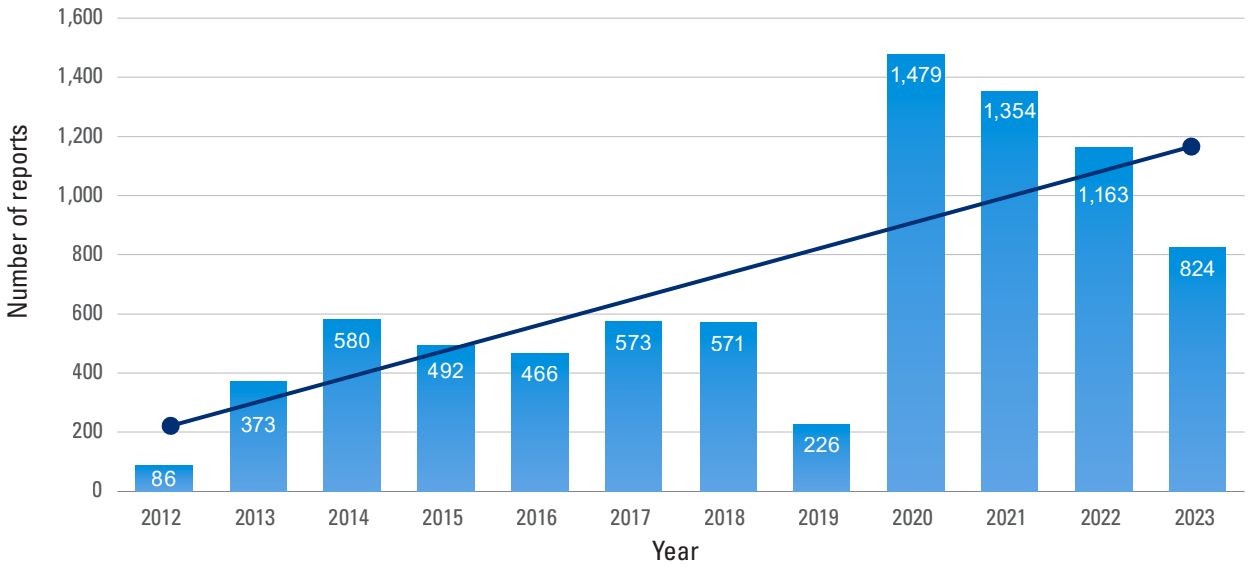


Figure 1. The reporting of vaccination errors to the ISMP VERP trends upward since the launch of the program in 2012.

had the option of selecting the "other" response to provide a free-text answer. Analysts reviewed the "other" categories to identify, when possible, characteristics of the events, including the primary event type, contributing factors, and setting.

Data for COVID-19 vaccinations were aggregated, as there were several variations (mRNA, adenovirus, bivalent, monovalent) approved to administer at one time or another. It was often difficult to discern which specific COVID-19 vaccine was involved in the reported error, so these results were aggregated and reported as COVID-19 vaccine errors.

RESULTS

Submission type

A breakdown by submission type indicated that most of the reported errors reached patients (82.3%, n = 1,635). This represents a slight decrease compared to the findings in the 2017-2018 ISMP VERP biannual report in which errors reached patients approximately 88% of the time (87.8%, n = 1,004).[13] The remainder of the reports in the 2022-2023 data set involved an error that occurred but did not reach the patient (14.0%, n = 278) or a hazardous condition or situation that warranted concern (3.7%, n = 74).

Facility

Given the fact that most children and adults receive their vaccines in the community, a majority (88.2%, n = 1,753) of reports were submitted by practitioners working in outpatient settings, such as medical clinics, physician practices, hospital (ambulatory), community pharmacy, and public health immunization clinics, similar to the 2017-2018 report (**Figure 2**, page 5). Also, regarding the COVID-19 pandemic, community pharmacies experienced an increase in the number of vaccinations provided. More than 8% (8.2%, n = 162) of reporters selected "other." Limitations in the submitted free-text data hampered analysts' ability to categorize the facility type for these reports.

Compared to data reported in ISMP's 2017-2018 biannual report,[13] more reports were reported by public health immunization clinics (17.9% in 2022-2023; 12.5% in 2017-2018) and community pharmacies (8.7% in 2022-2023; 3.9% in 2017-2018). Also, a lower percentage of events occurred in the hospital (ambulatory) (1.7% in 2022-2023; 13.8% in 2017-2018).

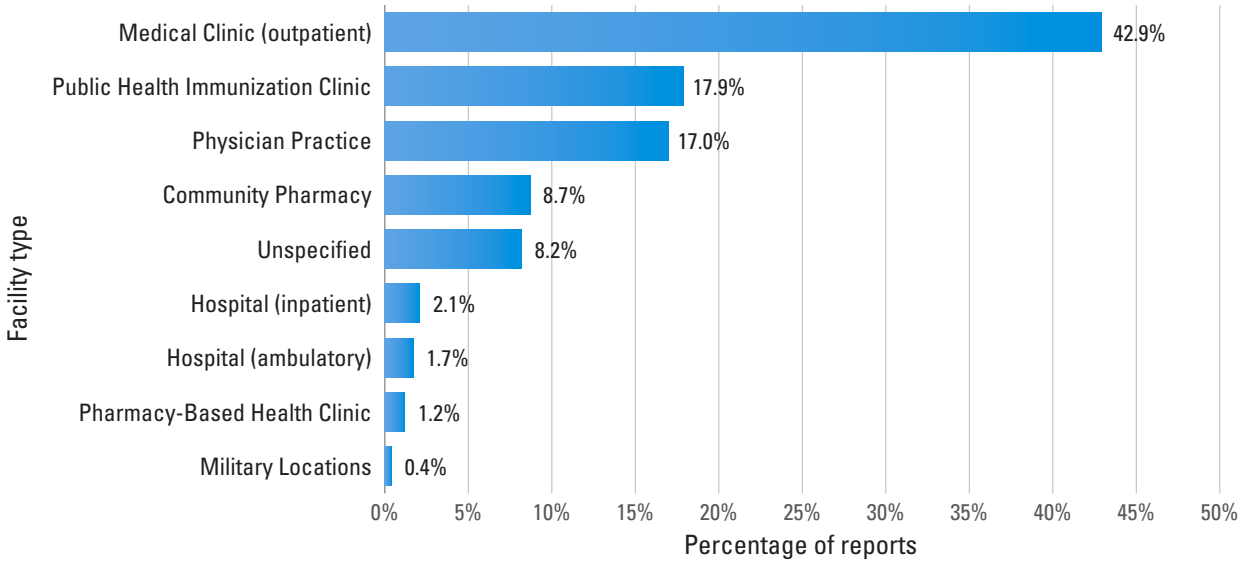


Figure 2. The types of facilities in which reported vaccination errors occurred (N = 1,987).

Vaccines cited in error reports

Overall, errors with COVID-19 vaccines were the most frequently reported (44.3%, n = 880) followed by errors with diphtheria, tetanus and/or pertussis (12.7%, n = 252), hepatitis A and B (9.2%, n = 182), influenza (IIV3, IIV4, and LAIV) (6.4%, n = 127), and meningococcal vaccines (5.1%, n = 101). **Appendix B** (page 19) lists all of the vaccines cited in submitted reports along with the contributing factors selected by reporters.

All facility locations, with the exception of military locations, reported COVID-19 vaccine errors as most prevalent with medical clinics (outpatient) reporting the highest incidence of COVID-19 vaccine errors (38.8%, n = 331). The following are two examples of vaccine errors, one involving a COVID-19 vaccine and the other involving a diphtheria, tetanus, and pertussis vaccine:

A medical assistant administered an expired COVID-19 vaccine to a 9-year-old child. The medical assistant referred to the manufacturing expiration date printed on the vial and did not know that the vaccine should not be used beyond 10 weeks after thawed. Typically, the staff that receives the vaccine delivery enters the 10-week expiration into the computer system, but a new staff member was unaware of the shortened expiration date once thawed.

*A prescriber ordered the DTaP vaccine for a 15-month-old child. However, a practitioner who had newly graduated, administered **PEDIARIX** (DTaP-HepB-IPV) instead of the DTaP vaccine. When documenting vaccine administration, the practitioner discovered the error because the lot number on the vial did not match the lot number of the vaccine order in the electronic health record (EHR). The practitioner reviewed the vaccine carton and read "DTaP" but did not realize it was a combination product.*

In addition to the routine vaccines administered to both pediatric and adult patients, errors occurred with vaccines used to treat emerging diseases in addition to COVID-19. For example, practitioners reported errors when using the smallpox and monkeypox vaccine (**JYNNEOS**). In public health immunization clinics, the smallpox and monkeypox vaccine was cited in 24 error reports (6.8%, n = 24), second only to COVID-19 vaccines (44.8%, n = 159).

Practitioners

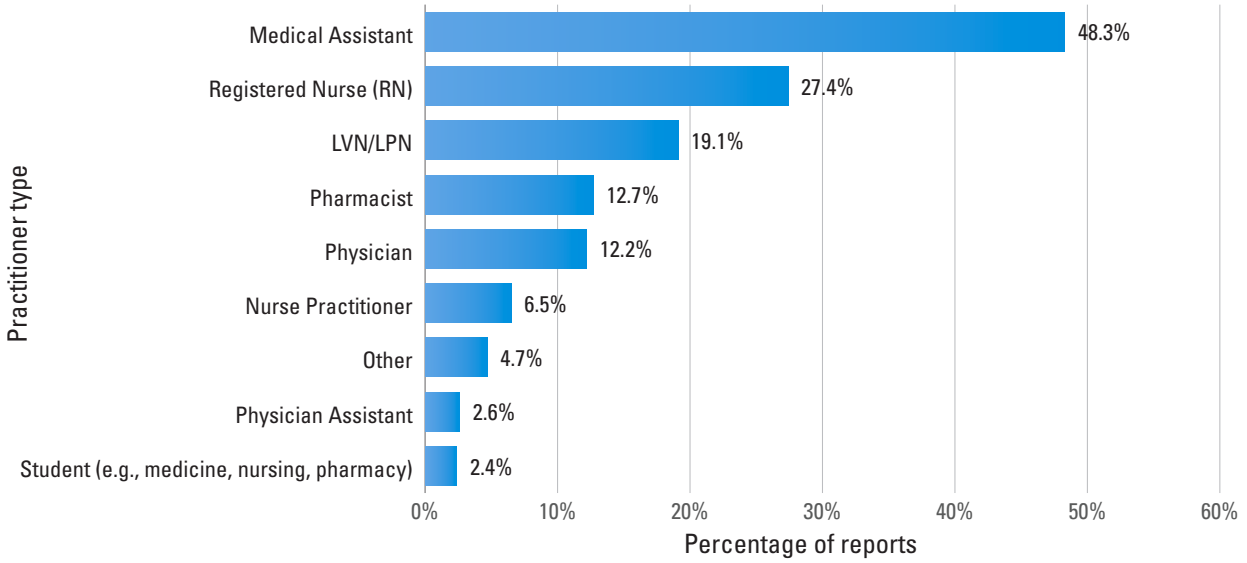
Medical assistants, registered nurses (RNs), and licensed vocational nurses/licensed practical nurses (LVNs/LPNs) were the most frequently mentioned type of practitioner involved in reported events (**Figure 3**, page 6).

The most reported errors occurred in medical clinics, public health immunization clinics, and physician practices where physicians are assisted in the preparation, administration, and documentation of vaccinations by

medical assistants[13] and nursing professionals, so it is not surprising that these healthcare practitioners are involved in vaccination errors. Medical assistants (61.8%, n = 527 of 853) and nurses (nurse practitioners, RNs, and LVNs/LPNs, 32.1%, n = 274 of 853) were most involved in events that occurred in medical clinics. Nurses were involved in over three quarters (88.4%, n = 314 of 355) of the reported errors that occurred in public health immunization clinics. The following is an example of an error involving HepA:

*A prescriber ordered a HepA vaccine for a 19-month-old patient. A nurse removed the HepA vaccine from the refrigerator, verified the label with the prescriber, and administered it. When the nurse attempted to document the administration in the patient's chart, the system did not allow documentation of the lot number. The nurse later identified that the patient had mistakenly received the HepA vaccine (**HAVRIX**) indicated for adults 19 years and older.*

Accompanying the rise in the number of events occurring in community pharmacy, a higher percentage of reports indicate that pharmacists were involved in events in 2022-2023 (12.7%) compared to 2017-2018 (4.9%).[13]



*Because some reported errors involve more than one practitioner type, the summed percentage may be greater than 100%.

Figure 3. The types of practitioners involved in reported vaccination errors (N = 1,987).

Provider type

Most of the providers involved in the reported vaccination errors were from family practice (36.7%, n = 729) and public health (21.8%, n = 433) (**Figure 4**, page 7). In fact, a higher percentage of reports involved public health providers in 2022-2023 than in 2017-2018 (13.4%).[13] Pharmacy providers were also cited in a larger percentage of reports in 2022-2023 (11.0%) than in 2017-2018 (4.6%).

The COVID-19 (37.0%, n = 270) and HepA and HepB (5.4%, n = 39 each) vaccines were most frequently involved in reported errors in the family practice setting while COVID-19 (47.0%, n = 205) and the smallpox and monkeypox (7.2%, n = 31) vaccines were involved in more errors in the public health clinics. The most commonly reported vaccine error with administration of smallpox and monkeypox vaccine was related to the absence of wheal formation (76.2%, n = 32) which required an extra dose to be administered. The following is an example of an error involving the smallpox and monkeypox vaccine:

A prescriber ordered Jynneos vaccine (0.1 mL) intradermally for a patient. However, the nurse administered the vaccine intramuscularly, along with other intramuscular vaccines that the prescriber had ordered. The patient identified that all of the vaccines were administered intramuscularly, and the error was identified.

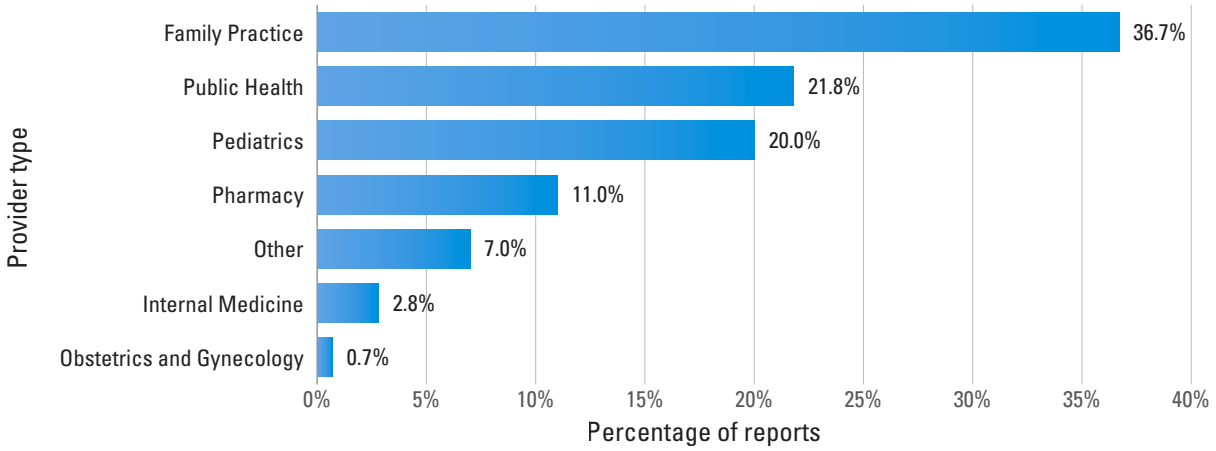


Figure 4. The types of providers (or practices) involved in the reported vaccination errors. (N = 1,987).

Event types

Reporters may select from one of 14 event types when they submit a report. Wrong vaccine, expired vaccine, and event type not listed accounted for 55% (n = 1,093) of all reported events (**Figure 5**). The most common contributing factors associated with each event type can be found in **Appendix C** (page 31). Also, **Appendix D** (page 35) presents a list of facility types with their associated reported event types.

When a reporter selects "event type not listed," they are prompted to specify the event type in the narrative field. Of the 199 events documented as "event type not listed," 56 (28.1%) were associated with contaminated, deteriorated, or expired vaccine (e.g., spillage, leakage, incorrect storage temperature), and 39 (19.6%) were associated with device malfunction or patient movement (e.g., bent needles, leaking syringes).

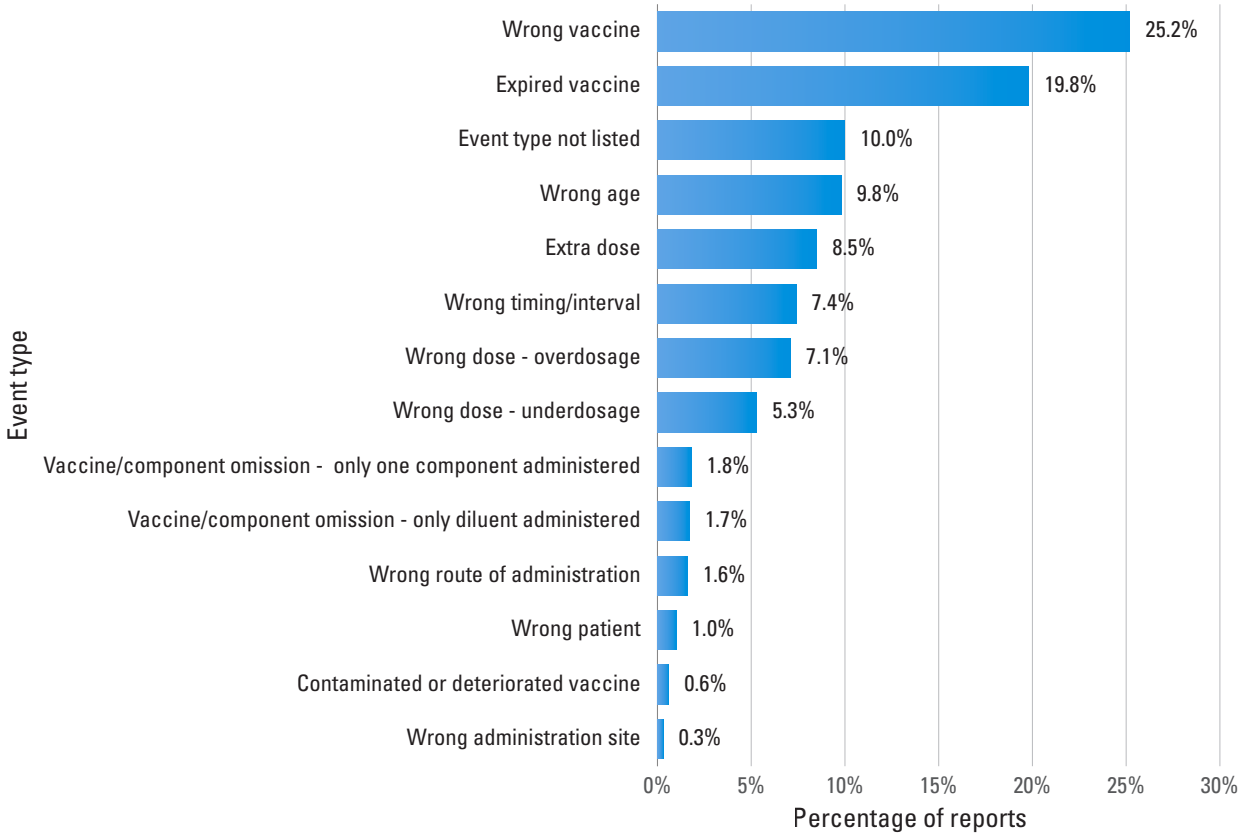


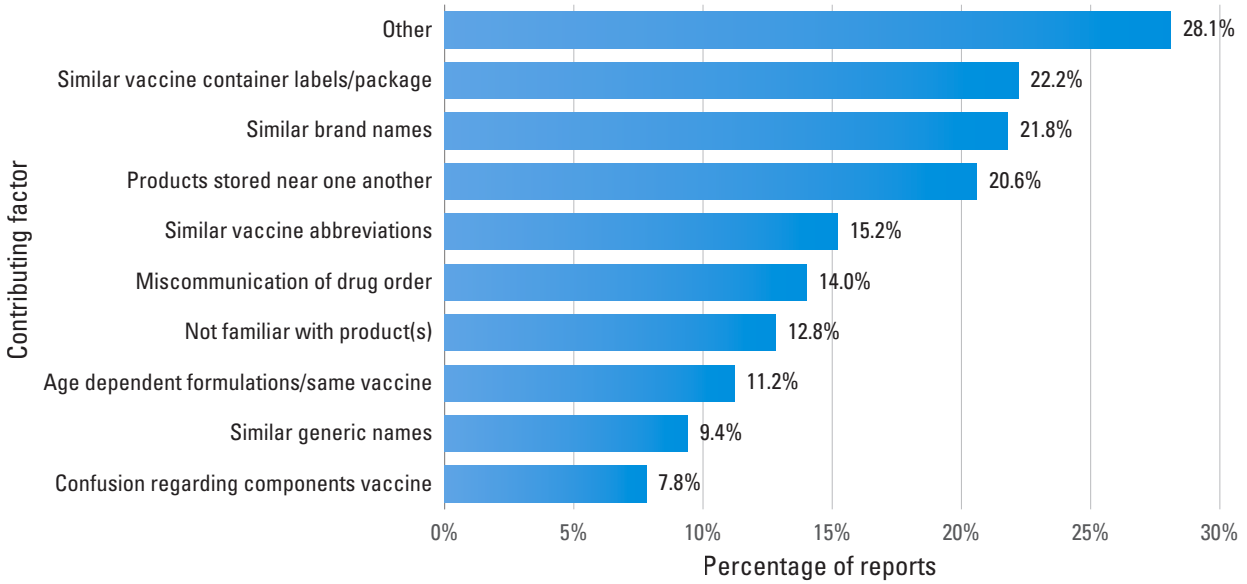
Figure 5. The vaccination error event types reported to ISMP VERP from January 1, 2022, through December 31, 2023 (N = 1,987).

Wrong vaccine

Reported errors predominantly involved the administration of a wrong vaccine (25.2%, n = 501).

An analysis of related contributing factors showed that similar packaging, names, abbreviations, and storage (79.6%, n = 399) resulted in the majority of events (**Figure 6**). The majority of naming conventions and abbreviation errors involved different COVID-19 vaccine preparations (17.2%, n = 86) and diphtheria and tetanus containing vaccines (Tdap, DTaP, DT, Td, and combination vaccines) (21.6%, n = 108). Though these vaccines are approved for different indications and/or populations, the CDC-approved abbreviations (**Appendix A**, page 17) for some of these vaccines differ only by letter casing (i.e., upper- versus lowercase). For example, DTaP and DT are indicated for children 6 months through 6 years of age while Tdap and Td are indicated for ages 10 and above (Td is indicated for patients who are at least 7 years old). The following is a mix-up between DTaP-IPV and DTaP-IPV/Hib:

*A provider ordered **KINRIX** (DTaP-IPV) for a 4-year-old patient, but the medical assistant administered **PENTACEL** (DTaP-IPV/Hib) in error. This resulted in the patient receiving an additional, unnecessary dose of Hib.*



*Respondents provided one or more contributing factors; so summed percentages may be greater than 1

Figure 6. The top 10 contributing factors reported for wrong vaccine errors (n = 501).

Similar brand names were one of the most commonly selected contributing factors for wrong vaccine errors. The most common brand name wrong vaccine errors (13.2%, n = 66) were associated with COVID-19 vaccines. The following is a mix-up between monovalent and bivalent formulations of COVID-19 vaccines:

A practitioner administered the monovalent Pfizer COVID-19 booster instead of the bivalent booster to six patients. The practitioner reported that the clinic had open boxes of both vaccines, and they selected the incorrect formulation due to similar packaging.

Similarities in manufacturer vials and cartons also contributed to vaccination errors. The following is an example of such an event:

*In anticipation of a high volume of patients, a nurse prepared vaccine doses for multiple patients in a clinic. One patient was prescribed **AREXVY** (respiratory syncytial virus vaccine, adjuvanted); however, the nurse mistakenly prepared and administered **SHINGRIX** (zoster vaccine recombinant, adjuvanted) prescribed for a different patient. Both vaccines are made by GSK and have a similar font and orange color on their labels (**Figure 7**, page 9).*

Figure 7. Similarities between Arexvy (respiratory syncytial virus vaccine, adjuvanted) and Shingrix (zoster vaccine recombinant, adjuvanted) can contribute to errors.

Expired vaccines

Almost 20% (19.8%, n = 393) of the reported events involved administration of an expired vaccine. Analysis of the contributing factors found that ambiguous or confusing expiration dates (51.9%, n = 204) and checks for expired products not routinely conducted (44.7%, n = 176) were responsible for the majority of these events. Most of these reports (71.0%, n = 279) involved COVID-19 vaccines followed by Hib (3.8%, n = 15) and HepA (3.1%, n =12) vaccines. These were reported primarily by medical clinics (49.6%, n = 195) and physician practices (21.6%, n = 85). Approximately one out of five (20.6%, n = 81) reported contributing factors as "other." The following are examples of expired vaccine events:

A provider misinterpreted the expiration date for the Pfizer-BioNTech COVID-19 vaccine for age 6 months to 4 years. The vaccine has a 10-week beyond use date, once thawed. Instead, the provider thought the product had a 10-week expiration date extension, and administered it beyond the 10 weeks to multiple patients.

A prescriber ordered multiple immunizations for a 16-year-old patient. After administering the vaccine doses, the nurse identified one of them, the meningococcal group b vaccine, had expired.

Wrong age

While the quality of care in immunization services requires age-appropriate ordering and administration of vaccines, many (9.8%, n = 194) of the reports submitted to the ISMP VERP involved the wrong age defined as "patient not correct age for vaccine given." Lack of familiarity with the indicated patient ages for products (36.6%, n = 71) was the most frequently identified contributing factor to these events.

Of the wrong age vaccine errors, COVID-19 vaccines (34.5%, n = 67) were the most frequently reported. The second most commonly reported wrong age errors were associated with various combination vaccines which target diphtheria, tetanus, and/or pertussis (24.7%, n = 48; Tdap, DTaP, DT, Td, and combination vaccines). Of these reports, over one third (35.4%, n = 17 of 48) involved the administration of DTaP-IPV either to a patient younger than 4 years or older than 6 years of age. The following is an example of a wrong age vaccine error involving Kinrix:

A prescriber ordered Kinrix (DTaP-IPV) for a 16-month-old patient. A medical assistant reviewed the order and vaccine syringe with the prescriber and administered the vaccine. The billing department later contacted the medical assistant to verify the patient's age since Kinrix is indicated for patients 4 to 6 years old, and the error was identified.

Another vaccine frequently involved in wrong age error reports related to lack of familiarity with indicated patient ages for the product and age-dependent formulations of the same vaccine was influenza virus vaccine (15.0%, n = 19 of 127). The following is a wrong age vaccine error involving influenza vaccine:

*A 4-month-old patient presented with his mother and two older siblings at a clinic to receive the influenza vaccine. A medical assistant mistakenly gave the 4-month-old patient **FLULAVAL** (IIV4) intramuscularly. However, Flulaval is recommended for patients who are 6 months or older.*

Extra dose

Though extra doses can also be categorized as wrong doses; it was not combined with under- and overdosage error reports as these latter event types have different contributing factors available for selection within the VERP reporting form. Extra dose accounted for 8.5% (n =169) of all vaccine errors reported to the ISMP VERP.

Nearly half of the reports (49.1%, n = 83) involved the failure to either check the patient's chart or the state vaccine registry before administering the vaccine. One in seven reports (14.2%, n = 24) were related to the coadministration of two products, one being a combination vaccine, resulting in a second dose of a vaccine component being administered. Other reports also indicated that many patients received a combination vaccine when only one component was needed (e.g., HepA-HepB administered instead of HepA alone), or received a single vaccine when a combination vaccine is needed (e.g., IPV instead of DTaP-IPV). Eleven (6.5%) of these errors were associated with smallpox and monkeypox vaccination which required a second dose after the absence of wheal formation.

Wrong timing/interval

Some reported events (7.4%, n = 147) involved administration of a vaccine on the wrong vaccine interval (e.g., interval too short). Nearly half of reporters (49.1%, n = 86) indicated failure to check the patient's chart or state vaccine registry before vaccine administration as contributing factors to wrong vaccine timing errors. A lack of familiarity with the vaccination interval for the product (16.3%, n = 24) was also reported as a contributing factor. Most of the reports (55.8%, n = 48 of 86) related to failure to check the patient's chart or state vaccine registry involved COVID-19 vaccines (70.8%, n = 34 of 48) and HepA or HepB vaccines (29.2%, n = 14 of 48).

DISCUSSION

Errors in the vaccination process have not received a great amount of attention.[14,15] In fact, only 7% of reports submitted between 2000-2013 to the Vaccine Adverse Event Reporting System (VAERS) operated by the CDC and FDA were related to vaccination errors.[11] While vaccination errors usually do not appear to pose a substantial safety risk, they can have epidemiological (lack of immunization which can contribute to the propagation of disease or an epidemic), human (adverse events and overvaccination), financial, and other public health consequences.[14] To prevent these consequences, it is paramount to address the common contributing factors to vaccination errors.

The massive COVID-19 vaccination effort had an effect on the overall data analyzed for this report. The quantity of reports attributed to COVID-19 vaccination errors directly influenced the findings of this analysis. However, the results of this report demonstrate similar overall trends in the contributing factors and error types when compared to ISMP's previously published 2017-2018 biannual report.[13]

Setting

This study indicated that most of the reported vaccine errors were from medical clinics, public health immunization clinics, and physician practices. With pharmacists being authorized to administer vaccines in all states,[16] it was surprising to identify only 8.7% of vaccine reports from community pharmacies. However, this was an increase from the previous ISMP biannual report (2017-2018) which identified 3.9% of errors reported from the community pharmacy setting.[13] Many factors can increase the risks of human error including

high workload, insufficient staff, distractions, miscommunication, and stress. Healthcare practices, including community pharmacies, have experienced many of these risk factors throughout and following the effects of the COVID-19 pandemic. Given the increase in the number of vaccines administered in community pharmacies, it could be expected that a higher percentage of reports from this setting would have been reported to the ISMP VERP. However, pharmacists and others face barriers to reporting errors, which include a fear of punishment, no clear definition of what constitutes an error, and lack of time and resources.[17]

Staff education

As with previous ISMP VERP analysis, unlicensed medical assistants who may not have the training or knowledge to recognize and address challenges associated with the administration of vaccines were most often involved in reported events that occurred in outpatient settings such as medical clinics and physician practices. Nurses were most often involved in events that occurred in public health clinics.[12,13]

The scope of practice of medical assistants is state dependent. Most states now permit medical assistants to administer injections in at least some capacity.[18] While delegating authority for vaccination to medical assistants can increase immunization rates, these tasks should only be delegated to individuals who have received specialized education and demonstrate competency. There are many immunization training programs available to healthcare practitioners, including several from the CDC.[19]

Immunization history

All states and some local municipalities have developed immunization registries or immunization information systems (IIS) to collect vaccination history information.[20] IIS consolidates the immunization information from all providers within a state or local area to create a more complete and current record. Even though most health professionals endeavor to document immunizations, omissions and administration of extra doses have occurred.

A shortcoming of the use of IIS is that they are state or region specific and not integrated on a national scale. While the integration of IIS with EHRs provides an opportunity to exchange public health data with doctors and hospitals, it is difficult to track immunization records across states and within a mobile society.

Wrong vaccine, wrong dose, extra doses, or wrong time/schedule errors were reported due to erroneous documentation in the patient's medical record or the failure to check the IIS, medical, or vaccine record prior to administration. In fact, many practitioners have reported to ISMP that administration errors were discovered during documentation *after* the vaccine was administered.

Storage and handling of vaccines

Failure to adhere to best practices for storage and handling of vaccines can increase the risk of error and compromise the stability of the vaccine product. For example, most vaccines must be stored in a refrigerator or freezer and maintained within a specific temperature range. Also, many vaccines require protection from light. Excessive heat or cold—even a single exposure in some instances—can reduce vaccine potency.[21]

Similarities between vaccine names, packaging, and acronyms also introduce opportunities for errors. In fact, wrong vaccine errors related to vaccine name and abbreviation similarities have been reported to both ISMP and VAERS.[11]

FDA's requirements to list the generic name before the brand name can make it difficult to distinguish some vaccines. Errors have been reported with Havrix vials, due to nonprominent differentiation between the adult and the pediatric/adolescent formulations.[22]

It should also be noted that storing vaccines too close to other medications in a refrigerator or freezer also can lead to product selection and administration errors. Mix-ups between a vaccine and insulin (high-alert medication) have been reported.[23] Neuromuscular blocking agents (e.g., pancuronium) have also been inadvertently used to reconstitute vaccines or administered instead of vaccines. [24]

The availability of different brands of some vaccines that are not interchangeable (i.e., indications for different brands of the same vaccine type can differ, based on certain criteria) introduces complication and risk into management of series vaccines and adhering to the CDC immunization schedules. For example, **ABRYSVO**

(respiratory syncytial virus vaccine) is the only approved vaccine option for pregnant persons as a single dose from 32 to 36 completed gestational weeks. However, Arexvy was approved in the same year as Abrysvo, but only Abrysvo is approved for use in pregnant patients. Arexvy recently received approval for expanded use for adults aged 50-59 years old who are at increased risk of severe respiratory syncytial virus (RSV) outcomes.

Multivial vaccines

ISMP continues to receive errors related to the use of the wrong "diluent" to prepare vaccines. Currently, there are 20 vaccines with specific diluents[25] and five vaccines (**MENVEO** [MenA], **PENBRAYA** [MenABCWY], Pentacel [DTaP-IPV/Hib], Arexvy [RSV], and Shingrix [RZV]) have an active lyophilized vaccine powder that needs to be reconstituted with an "active" liquid component. Errors regarding these vaccines include neglecting to administer the manufacturer-supplied diluent or liquid component. The use of an inappropriate diluent—including those meant for different vaccines—to reconstitute the lyophilized vaccine powder have also been reported.[26] This is particularly dangerous since diluents are designed for the specific needs of each vaccine. Using the wrong diluent may result in incorrect doses and possible contamination.

Administration of an expired vaccine

Vaccine and diluent expiration dates printed on vials, prefilled syringes, and packages indicate when the product must be discarded. This is usually different from a recommended beyond-use date (BUD), which is usually required when manipulations to the vaccine are made, or changes are made to the storage environment.[27] Vaccines should be discarded when either the expiration date or, if manipulated, the manufacturer's BUD is reached, whichever occurs first. Reports indicate problems with BUD markings or labels which have obscured manufacturer expiration dates, especially when the original manufacturer's expiration date occurred prior to the BUD.

Reconstituted vaccines, multidose vials, and manufacturer-shortened expiration dates (when vaccine is exposed to inappropriate storage conditions) may require an earlier expiration or BUD date.[28] Additionally, multicomponent vials may have different expiration dates for each vial or syringe, despite being provided in the same package. After the expiration date, the product may lose its stability and potency[29] and should not be administered.

RISK-REDUCTION STRATEGIES

Organizations and healthcare facilities should strive to identify system-based causes of errors involving vaccines. These errors typically involve a number of key elements of the vaccine use system, such as patient and vaccine information; communication; vaccine labeling and packaging; vaccine storage, stock, standardization, and distribution; environmental factors; staff competency and education; patient education; and quality process and risk management.[30] To successfully prevent errors, multiple strategies targeting different parts of the system are required.[31]

Several reports described implementing a lower-leverage risk-reduction strategy, such as double checking by the same person, concentrating on a task at hand, or educating staff, to prevent recurrence of the error. While educating staff, students, and patients is a necessary component of a safety plan, it relies on human vigilance to prevent errors. A single strategy, particularly a low-leverage strategy such as education, is not enough to change behaviors and prevent vaccine errors. Instead, numerous high-leverage risk-reduction strategies that improve system reliability (**Figure 8**, page 13) must be layered together, on top of education, to create a more robust safety system. This is important for organizations in their quest to attain highly reliable outcomes.[22,32,33]

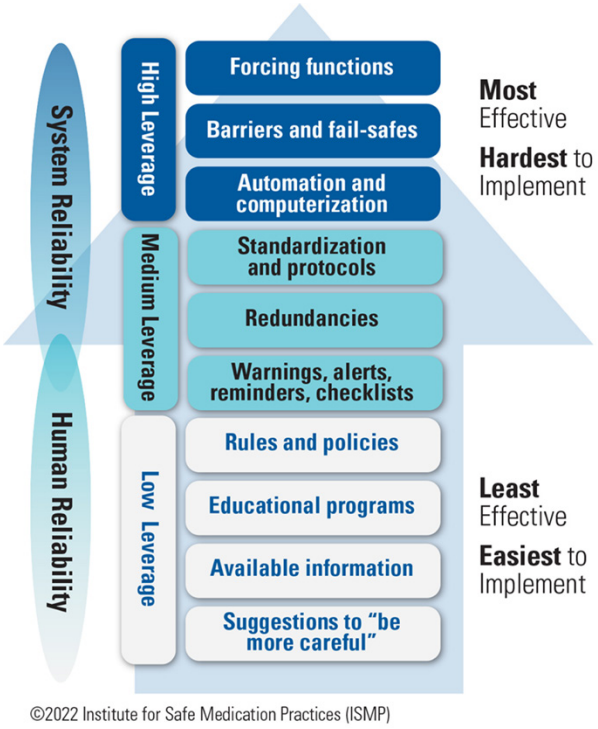


Figure 8. ISMP's hierarchy of error-reduction strategies.

Note: Items at the top of the list, such as forcing functions and automation, are more powerful strategies because they focus on systems. The tools in the middle attempt to fix the system yet rely in some part on human vigilance and memory. Items at the bottom, such as education, are tools that are important but focus on individual performance and therefore are weaker and ineffective when used alone.

To prevent errors, consider the following recommendations, based on events reported to the ISMP VERP, current guidelines and literature, and observations from ISMP.

Staff education

- Require all healthcare professionals who immunize patients or handle vaccines (procurement, inventory management, preparation for patients) to undergo initial and ongoing training, and demonstrate competencies related to the types of vaccines being administered.[23] Training should include content on proper storage, selection, administration, monitoring, and vaccine timing/spacing, especially for vaccines with complex schedules.[11,32]
- Promote a culture of safety by discussing vaccine errors that can and have occurred and how to prevent them with health professionals who prescribe, dispense, and administer vaccines.[15]
- Implement and enforce procedures to properly screen patients for contraindications before vaccine administration.[11]
- Utilize standard order sets to prescribe vaccines. Require an order prior to administration of any vaccine.[32] Integrate clinical decision support with the vaccine use process; include screening of the ordered vaccine against prior vaccinations to validate the correct time, sequencing, formulation(s), and type(s) of vaccine(s) for the patient's specific needs.
- Where possible, encourage staff to use point-of-care barcode scanning to verify that the correct vaccine and age-specific formulation have been selected and prepared for administration to the correct patient.[15,22]
- Educate staff to verify the patient's date of birth and compare it to the age limits of the CDC's Vaccine Information Statement (VIS) before administering age-dependent vaccines.[33,34]

Patient education

- Require staff to provide all patients, parents, or legal guardians with a VIS in their preferred language prior to vaccination. VIS documents are available on the CDC and the Immunize.org websites and have been translated into more than 40 languages.[23,31,34,35]
- Require staff to provide parents/caregivers, teens, and adults with easy-to-read immunization schedules so they know what vaccine(s) they or their child should be receiving during visits to a healthcare provider.[15]
- 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.[6]

Immunization history

- Always verify the patient's current immunization status by checking the patient's health record, pharmacy profile, and vaccination registry before vaccine administration.[15,32,34]
- Always submit complete vaccine administration information to the local or state IIS.[32,35]
- Document the national drug code (NDC), lot number, and expiration date of each vaccine container in the vaccination record or log before administration to confirm the selection or preparation of the correct vaccine or components of two-component vaccines. Documenting actual administration of the vaccine should always occur after it is given.[15,35]
- On vaccination records and medication administration records, list the vaccine brand name (if applicable) and the full nonproprietary name of the vaccines administered. In electronic formats, nonproprietary names may be provided by hovering over the vaccine abbreviation or acronym if space is an issue.[6,35]
- Use patient vaccination records with enough space to list full vaccine names.[6]

Storage and handling of vaccines

- Consult the CDC Vaccine Storage and Handling Toolkit[28] to ensure the use of proper vaccine storage units and equipment, temperature ranges, temperature monitoring, placement of vaccines in storage units, and recommended actions.
- Store vaccines in refrigeration and freezer units large enough for organized and labeled stock.[6] If possible, store vaccines in their own, dedicated refrigeration and freezer units. Separate vials and syringes into bins or other containers according to vaccine type and formulation.[32] Never store different vaccines in the same containers.[15]
- Label the specific locations where vaccines are stored to facilitate correct, age-specific selection and to remind staff to combine the contents of vials. Based on recommendations from the Advisory Committee on Immunization Practices, the CDC has published vaccine storage labels that can help staff quickly locate and choose the correct vaccine.[36] These labels could be affixed to containers or bins or directly attached to shelves where vaccines are placed.
- Separate pediatric and adult formulations of vaccines in storage areas and affix auxiliary labels to the vaccines and/or storage areas to help alert staff to the targeted ages for these vaccines.[15]
- Do not store vaccines with similar names or abbreviations, or overlapping component(s) (e.g., DTaP, DT, Tdap, Td) immediately next to each other.[6] Where possible, store vaccines with similar packaging or names on different refrigerator or freezer shelves.[15]
- Improve monitoring of vaccine storage temperatures and take immediate actions in response to temperature excursions.[15] Specify the storage requirements for each vaccine and diluent in your inventory. Use of a storage-unit-alarm system with wireless alerting capability for temperature fluctuations and power outages is recommended.
- Use CDC-approved checklists and forms for routine and emergency vaccine storage, handling, and transport. Store this information in an easily accessible area near the vaccine storage unit.
- List *Haemophilus influenzae* type b, meningococcal, and pneumococcal conjugate vaccines on automated dispensing cabinet screens, pharmacy labels, vaccination records, and electronic medication administration records, in a way that reduces the risk of identifying the conjugate antigen (e.g., tetanus toxoid, diphtheria, meningococcal protein) as the targeted vaccine.[35]

Administration

- Use prefilled syringes when available. If not available, prepare each vaccine dose immediately prior to administration and label with the vaccine name, dose, and if appropriate, the indicated age range.[32]
- If multiple adults and children 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.[32]
- Verify the patient's identity using at least two unique identifiers (e.g., full name and date of birth).[32]

Two-component vaccines

- Establish a process to keep two-component vaccines together, and to keep diluents and their corresponding vaccines together if storage requirements do not differ.[31] Dispense the products together in a bag with an auxiliary label to remind staff to use both vials.[15,37]
- Be sure staff understand the differences between two-component vaccines (vaccines with active liquid and lyophilized powder components) and vaccines packaged with specific diluents.[24]
- Only use the vaccine diluents supplied and packaged by the manufacturer with vaccines that require reconstitution. Vaccine diluents are not interchangeable, and unless specified by manufacturer, stock vials of sterile water or normal saline should not be used as a substitute.[21]
- Where technology is utilized, require barcode scanning of both components of two-component vaccines prior to mixing and administration.[24,38]

Expiration inventory management

- Check for expired vaccines weekly and immediately remove any expired vaccines or diluent.[15]
- Check expiration dates while counting stock and remove expired doses immediately.[21]
- Rotate the stock based on the expiration date to prevent unnecessary waste by placing vaccines first to expire in the front.[15]
- Remove expired vaccines from storage areas/refrigerators/freezers where viable vaccines are stored. Label the vaccines as expired and sequester them away from in-date medications and drug preparation areas.[15]
- Always check the expiration date on both the diluent/liquid component and lyophilized vaccine powder. Never use an expired diluent or vaccine.[28]
- Contact CDC or the vaccine manufacturer for further guidance if an expired vaccine was administered in error.

Vaccine manufacturers, FDA and other regulators

- Seek a federal regulatory change that allows the vaccine brand name to be listed first on vaccine labels, before the full generic names, which are often long and confusing.[22]
- Package two-component vaccines in redesigned vials that accommodate larger labels to reduce label crowding and increase the font size of important text.[37]
- When product stability and storage allow, employ integrated packaging that forces or facilitates proper mixing of the two components prior to administration, like the dual-chamber vial of **SOLU**-medrol.[37]
- Continue to improve labeling and packaging to differentiate age-dependent formulations of the same vaccine and vaccines with similar names or acronyms.[22,37]
- Establish a single, nationwide network of integrated immunization registries that promotes private and confidential exchange of immunization records with other immunization systems and health information systems. This can help prevent missed opportunities while reducing vaccine administration errors.
- Seek to reduce the complexity of the vaccination schedules.
- Provide clear directions for use and warnings to administer the contents of both vials of two-component vaccines on the front label of the carton, each vial, and on the vial caps.[37]

LIMITATIONS

The comprehensive nature of the predefined categories and contributing factors, as well as the use of a national database of reports are strengths of this review. However, in-depth analysis of vaccine errors is limited by the information provided in reports submitted through the ISMP VERP, including event descriptions. As with all voluntary reporting programs, the type, quantity, and quality of reports depends upon the reporter as well as the design and implementation of internal reporting systems. In addition, the reporting cultures and patterns in each practice site, and their interpretations of what occurrences are reportable, can lead to reporting variations. Finally, not all reports contained details describing how the event deviated from the standard operation or which factors contributed to the event.

CONCLUSION

Immunizations are one of the most effective disease prevention strategies. However, the effectiveness of vaccines depends on the handling and administration of the product. To reduce vaccination errors and improve patient safety, healthcare providers and manufacturers should adopt and layer multiple risk-reduction strategies, including those mentioned above, to target identified system failures.

ISMP thanks the many healthcare practitioners who have taken the time to report vaccine errors to the ISMP VERP. We encourage your continued reporting of vaccine errors or close calls to the ISMP VERP.

APPENDICES

Appendix A. Selected examples of CDC standard vaccine abbreviations and acronyms

Vaccine	Brand Name	CDC-Approved Abbreviation
Diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed	Daptacel	DTaP
	Infanrix	
Diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine	Kinrix	DTaP-IPV
	Quadracel	
Diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B and inactivated poliovirus vaccine	Pediarix	DTaP-HepB-IPV
Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and *Haemophilus influenzae* type b conjugate vaccine	Pentacel	DTaP-IPV/Hib
Diphtheria, tetanus, acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B combination vaccine	Vaxelis	DTaP-IPV-Hib-HepB
Haemophilus influenzae type b conjugate vaccine	PedvaxHIB	Hib
	Hiberix	
	ActHIB	
Hepatitis A inactivated and hepatitis B vaccine	Twinrix	HepA-HepB
Hepatitis A vaccine	Havrix	HepA
	Vaqta	
Hepatitis B vaccine	Engerix-B	HepB
	Recombivax HB	
	Heplisav-B	HepB-CpG
Human papillomavirus vaccine (9-valent)	Gardasil 9	9vHPV
Human papillomavirus vaccine (quadrivalent)	Gardasil	4vHPV
Inactivated influenza vaccine, trivalent	Afluria	IIV3
	Fluzone	
	Fluzone High-Dose	
	Flulaval	
Inactivated influenza vaccine, quadrivalent	Flublok Quadrivalent	IIV4
	Fluzone Quadrivalent	
Live, attenuated influenza vaccine	Flumist	LAIV
Measles, mumps, and rubella vaccine	M-M-R II	MMR
Measles, mumps, rubella, and varicella vaccine	Proquad	MMRV
Meningococcal conjugate vaccine, quadrivalent	Menomune	MCV4
Meningococcal conjugate vaccine, quadrivalent	MenQuadfi	MenACWY-TT
	Menveo	MenACWY-CRM
	Menactra	MenACWY-D
Pneumococcal conjugate vaccine (13-valent)	Prevnar 13	PCV13
Pneumococcal conjugate vaccine (20-valent)	Prevnar 20	PCV20
Pneumococcal polysaccharide vaccine (23-valent)	Pneumovax 23	PPSV23
Rotavirus vaccine (monovalent)	Rotarix	RV1
Rotavirus vaccine (pentavalent)	Rotateq	RV5

Serogroup B meningococcal vaccines	Bexsero	MenB-4C
	Trumenba	MenB-FHbp
Tetanus and diphtheria toxoids adsorbed	Tenivac	Td
Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed	Adacel	Tdap
	Boostrix	
Varicella vaccine	Varivax	VAR
Zoster vaccine live	Zostavax	ZVL
Zoster vaccine recombinant	Shingrix	RZV

List adapted from www.cdc.gov/vaccines/hcp/vaccines-us/abbreviations.html.

Appendix B. Vaccines cited in reported errors with contributing factors

Vaccine (% all vaccine reports, N = 1,987)	Contributing Factors	% (per specific vaccine)
mRNA COVID-19 vaccine (COV-mRNA) (43.4%, n = 863)	Ambiguous/confusing expiration date	20.5
	Age-dependent formulations/same vaccine	12.9
	Check for expired products not conducted	11.5
	Similar brand names	7.6
	Similar vaccine container labels/package	7.2
	Miscommunication of drug order	6.7
	Patient age not verified before administration	4.2
	Not familiar with dosing of product	4.1
	Not familiar with product(s)	3.2
	Patient chart not checked before administration	2.9
	Products stored near one another	2.9
	Similar generic names	2.3
	Confusion regarding components of vaccine	2.2
	Similar vaccine abbreviations	1.6
	State vaccine registry not checked before administration	1.6
	Not familiar with patient ages for product	1.0
	Incorrect or crowded storage area	0.8
	Patient did not recall previous vaccine	0.7
	Prior vaccination not documented	0.6
	Not familiar with vaccination interval	0.6
	State vaccine registry not checked	0.5
	Vaccine drawn and confused with another	0.5
	Patient information missing/wrong	0.3
	Follow-up vaccine(s) not scheduled	0.3
	Not familiar with how to prepare product	0.3
	Vaccine drawn into a syringe not labeled	0.3
	Dose split between visits	0.2
	Similar packaging	0.1
	Vaccine stored at high temperature	0.1
	Vaccine drawn up into a syringe mislabel	0.1
	Vaccine stored at low temperature	0.1

IIV4 (4.8%, n = 95)	Age-dependent formulations/same vaccine	14.7
	Patient chart not checked before administration	11.6
	Miscommunication of drug order	8.4
	Products stored near one another	7.4
	Patient did not recall previous vaccine	6.3
	Not familiar with patient ages for product	6.3
	Patient information missing/wrong	5.3
	Check for expired products not conducted	4.2
	Similar brand names	4.2
	Patient age not verified before administration	4.2
	Vaccine stored at low temperature	4.2
	Not familiar with product(s)	3.2
	State vaccine registry not checked before administration	2.1
	State vaccine registry not checked	2.1
	Similar vaccine container labels/package	2.1
	Similar generic names	1.1
	Confusion regarding components of vaccine	1.1
	Not familiar with vaccination interval	1.1
	Ambiguous/confusing expiration date	1.1
HepA (4.3%, n = 85)	Age-dependent formulations/same vaccine	29.4
	Check for expired products not conducted	9.4
	State vaccine registry not checked before administration	9.4
	Patient chart not checked before administration	7.1
	Miscommunication of drug order	3.5
	Not familiar with product(s)	3.5
	State vaccine registry not checked	3.5
	Products stored near one another	2.4
	Similar vaccine container labels/package	2.4
	Not familiar with dosing of product	2.4
	Similar generic names	2.4
	Similar vaccine abbreviations	2.4
	Incorrect or crowded storage area	2.4
	Two patient identifiers not used	2.4
	Not familiar with patient ages for product	1.2
	Patient did not recall previous vaccine	1.2
	Patient age not verified before administration	1.2
	Similar brand names	1.2
	Vaccine stored at low temperature	1.2
	Language barrier	1.2
	Not familiar with route administration for product	1.2

HepB (4.2%, n = 83)	Age-dependent formulations/same vaccine	25.3
	Products stored near one another	13.3
	Not familiar with dosing of product	13.3
	Similar vaccine container labels/package	10.8
	Incorrect or crowded storage area	8.4
	Similar brand names	7.2
	Miscommunication of drug order	6.0
	Similar vaccine abbreviations	6.0
	Patient chart not checked before administration	4.8
	State vaccine registry not checked	3.6
	Not familiar with patient ages for product	3.6
	Similar generic names	2.4
	Check for expired products not conducted	1.2
	State vaccine registry not checked before administration	1.2
	Not familiar with product(s)	1.2
	Patient age not verified before administration	1.2
	Patient information missing/wrong	1.2
	Ambiguous/confusing expiration date	1.2
MMRV (3.6%, n = 71)	Products stored near one another	14.1
	Similar vaccine abbreviations	12.7
	Similar vaccine container labels/package	11.3
	Not familiar with patient ages for product	11.3
	Patient age not verified before administration	9.9
	Similar brand names	5.6
	Similar generic names	5.6
	Age-dependent formulations/same vaccine	4.2
	Miscommunication of drug order	4.2
	Not familiar with product(s)	4.2
	Patient did not recall previous vaccine	4.2
	Vaccine stored at high temperature	4.2
	Patient chart not checked before administration	2.8
	State vaccine registry not checked	2.8
	Check for expired products not conducted	2.8
	Confusion regarding components of vaccine	2.8
	Incorrect or crowded storage area	1.4
	State vaccine registry not checked before administration	1.4
	Ambiguous/confusing expiration date	1.4
	Not familiar with route administration for product	1.4
	Not familiar with vaccination interval	1.4
	Similar packaging	1.4
	Label misleading/difficult to read	1.4

Tdap (3.3%, n = 65)	Similar vaccine abbreviations	18.5
	Miscommunication of drug order	13.8
	Products stored near one another	12.3
	Similar vaccine container labels/package	9.2
	Similar brand names	7.7
	Age-dependent formulations/same vaccine	7.7
	Patient chart not checked before administration	6.2
	Patient age not verified before administration	4.6
	Not familiar with product(s)	4.6
	Patient did not recall previous vaccine	4.6
	Check for expired products not conducted	4.6
	State vaccine registry not checked before administration	4.6
	Not familiar with patient ages for product	3.1
	Similar generic names	3.1
	Confusion regarding components of vaccine	3.1
	Vaccine drawn and confused with another	3.1
	State vaccine registry not checked	1.5
	Incorrect or crowded storage area	1.5
	Not familiar with route administration for product	1.5
	Not familiar with vaccination interval	1.5
	Two patient identifiers not used	1.5
DTaP-IPV (3.0%, n = 60)	Not familiar with patient ages for product	20.0
	Age-dependent formulations/same vaccine	16.7
	Miscommunication of drug order	10.0
	Products stored near one another	10.0
	Not familiar with product(s)	8.3
	Similar brand names	6.7
	Similar vaccine abbreviations	5.0
	Ambiguous/confusing expiration date	5.0
	Similar vaccine container labels/package	3.3
	Patient did not recall previous vaccine	3.3
	Check for expired products not conducted	3.3
	Similar generic names	3.3
	Confusion regarding components of vaccine	3.3
	Not familiar with vaccination interval	3.3
	Patient chart not checked before administration	1.7
	Patient age not verified before administration	1.7
	State vaccine registry not checked before administration	1.7
	State vaccine registry not checked	1.7
	Not familiar with dosing of product	1.7
	Language barrier	1.7

Smallpox and Monkeypox Vaccine (2.5%, n = 49)	Not familiar with route administration for product	12.2
	Not familiar with dosing of product	4.1
	Miscommunication of drug order	2.0
	Ambiguous/confusing expiration date	2.0
	Patient chart not checked before administration	2.0
	Not familiar with correct administration site	2.0
DTaP (2.4%, n = 48)	Similar vaccine abbreviations	16.7
	Not familiar with patient ages for product	14.6
	Check for expired products not conducted	12.5
	Patient chart not checked before administration	10.4
	Similar vaccine container labels/package	10.4
	Products stored near one another	8.3
	Miscommunication of drug order	6.3
	Not familiar with product(s)	4.2
	Similar brand names	4.2
	Similar generic names	4.2
	Age-dependent formulations/same vaccine	2.1
	Patient age not verified before administration	2.1
	State vaccine registry not checked before administration	2.1
	Vaccine stored at low temperature	2.1
	Similar patient names	2.1
MMR (2.4%, n = 48)	Check for expired products not conducted	16.7
	Products stored near one another	8.3
	Similar vaccine abbreviations	6.3
	Not familiar with vaccination interval	6.3
	Not familiar with how to prepare product	6.3
	Patient chart not checked before administration	4.2
	Similar vaccine container labels/package	4.2
	Miscommunication of drug order	4.2
	Not familiar with dosing of product	4.2
	Ambiguous/confusing expiration date	4.2
	Not familiar with product(s)	2.1
	Similar brand names	2.1
	Age-dependent formulations/same vaccine	2.1
	State vaccine registry not checked before administration	2.1
	Patient did not recall previous vaccine	2.1
	Confusion regarding components of vaccine	2.1
	Two patient identifiers not used	2.1
	Similar packaging	2.1
	Label misleading/difficult to read	2.1
	Patient information missing/wrong	2.1
	Prior vaccination not documented	2.1

VAR (2.4%, n = 47)	Check for expired products not conducted	14.9
	Not familiar with vaccination interval	6.4
	Not familiar with route administration for product	6.4
	Products stored near one another	4.3
	Patient chart not checked before administration	4.3
	Prior vaccination not documented	4.3
	Similar vaccine abbreviations	2.1
	Miscommunication of drug order	2.1
	Not familiar with product(s)	2.1
	Patient did not recall previous vaccine	2.1
	Confusion regarding components of vaccine	2.1
	Similar packaging	2.1
	Label misleading/difficult to read	2.1
	Not familiar with correct administration site	2.1
MenACWY-CRM (2.1%, n = 41)	Not familiar with how to prepare product	19.5
	Similar packaging	7.3
	Check for expired products not conducted	4.9
	Patient chart not checked before administration	4.9
	Similar vaccine abbreviations	4.9
	Miscommunication of drug order	4.9
	Not familiar with product(s)	4.9
	Age-dependent formulations/same vaccine	4.9
	Patient age not verified before administration	4.9
	Products stored near one another	2.4
	Prior vaccination not documented	2.4
	Label misleading/difficult to read	2.4
	Ambiguous/confusing expiration date	2.4
	Similar brand names	2.4
	State vaccine registry not checked before administration	2.4
	Two patient identifiers not used	2.4
	Not familiar with patient ages for product	2.4
	Similar generic names	2.4
	State vaccine registry not checked	2.4
	Incorrect or crowded storage area	2.4

RZV (2.0%, n = 40)	Not familiar with how to prepare product	25
	State vaccine registry not checked	17.5
	Patient did not recall previous vaccine	17.5
	Patient chart not checked before administration	15
	Miscommunication of drug order	7.5
	Not familiar with route administration for product	7.5
	Products stored near one another	5.0
	State vaccine registry not checked before administration	5.0
	Incorrect or crowded storage area	5.0
	Similar vaccine container labels/package	5.0
	Vaccine drawn into a syringe not labeled	5.0
	Patient age not verified before administration	2.5
	Not familiar with patient ages for product	2.5
	Similar patient names	2.5
	Follow-up vaccine(s) not scheduled	2.5
	Components of vaccine mixed improperly	2.5
Hib (2.0%, n = 39)	Ambiguous/confusing expiration date	23.1
	Check for expired products not conducted	17.9
	Products stored near one another	7.7
	Miscommunication of drug order	5.1
	Not familiar with patient ages for product	5.1
	Confusion regarding components of vaccine	5.1
	Not familiar with how to prepare product	2.6
	State vaccine registry not checked	2.6
	Patient chart not checked before administration	2.6
	Age-dependent formulations/same vaccine	2.6
	Label misleading/difficult to read	2.6
	Two patient identifiers not used	2.6
	Vaccine drawn and confused with another	2.6

9vHPV (1.9%, n = 38)	Patient chart not checked before administration	10.5
	Check for expired products not conducted	7.9
	Miscommunication of drug order	7.9
	Not familiar with vaccination interval	7.9
	Products stored near one another	5.3
	Not familiar with patient ages for product	5.3
	State vaccine registry not checked	5.3
	Two patient identifiers not used	5.3
	State vaccine registry not checked before administration	5.3
	Prior vaccination not documented	5.3
	Not familiar with how to prepare product	2.6
	Age-dependent formulations/same vaccine	2.6
	Patient did not recall previous vaccine	2.6
	Patient age not verified before administration	2.6
	Similar patient names	2.6
	Similar vaccine abbreviations	2.6
	Similar generic names	2.6
	Language barrier	2.6
	Wrong patient selected in computer system	2.6
DTaP-IPV/Hib (1.9%, n = 37)	Not familiar with how to prepare product	35.1
	Check for expired products not conducted	5.4
	Similar vaccine abbreviations	5.4
	Confusion regarding components of vaccine	5.4
	Label misleading/difficult to read	5.4
	Not familiar with dosing of product	5.4
	Patient chart not checked before administration	2.7
	Miscommunication of drug order	2.7
	Products stored near one another	2.7
	Age-dependent formulations/same vaccine	2.7
	Similar generic names	2.7
	Incorrect or crowded storage area	2.7
	Similar vaccine container labels/package	2.7
	Not familiar with product(s)	2.7
	Similar brand names	2.7
	Patient information missing/wrong	2.7

IIV3 (1.4%, n =27)	Patient chart not checked before administration	18.5
	Not familiar with patient ages for product	14.8
	Age-dependent formulations/same vaccine	11.1
	Miscommunication of drug order	11.1
	Products stored near one another	11.1
	Patient did not recall previous vaccine	11.1
	Patient age not verified before administration	7.4
	Check for expired products not conducted	3.7
	State vaccine registry not checked before administration	3.7
	Similar vaccine container labels/package	3.7
	Similar generic names	3.7
	Confusion regarding components vaccine	3.7
	Not familiar with dosing of product	3.7
	Not familiar with route administration for product	3.7
	Not familiar with correct administration site	3.7
DTaP-HepB-IPV (1.2%, n = 24)	Similar vaccine container labels/package	20.8
	Products stored near one another	16.7
	Similar vaccine abbreviations	12.5
	Confusion regarding components of vaccine	12.5
	Miscommunication of drug order	12.5
	Incorrect or crowded storage area	12.5
	Not familiar with product(s)	12.5
	Similar generic names	8.3
	Age-dependent formulations/same vaccine	4.2
	Similar brand names	4.2
	Not familiar with vaccination interval	4.2
	Not familiar with patient ages for product	4.2
	State vaccine registry not checked	4.2
MenB-4C (1.1%, n = 22)	Check for expired products not conducted	22.7
	Products stored near one another	9.1
	Similar vaccine abbreviations	9.1
	Incorrect or crowded storage area	9.1
	Miscommunication of drug order	4.5
	Not familiar with product(s)	4.5
	Similar generic names	4.5
	Age-dependent formulations/same vaccine	4.5
	Not familiar with patient ages for product	4.5
	Ambiguous/confusing expiration date	4.5
Inactivated polio vaccine (1.1%, n = 21)	Miscommunication of drug order	14.3
	State vaccine registry not checked	9.5
	Patient chart not checked before administration	9.5
	Not familiar with product(s)	4.8
	Age-dependent formulations/same vaccine	4.8
	Not familiar with patient ages for product	4.8
	Patient did not recall previous vaccine	4.8

PCV13 (1%, n = 19)	Patient chart not checked before administration	10.5
	Miscommunication of drug order	5.3
	State vaccine registry not checked	5.3
	Age-dependent formulations/same vaccine	5.3
	Not familiar with patient ages for product	5.3
	Similar vaccine abbreviations	5.3
	Similar generic names	5.3
	Similar brand names	5.3
	Wrong patient selected in computer system	5.3
MenACWY-TT (1%, n = 19)	Similar vaccine abbreviations	10.5
	Patient chart not checked before administration	10.5
	Patient age not verified before administration	10.5
	Confusion regarding components vaccine	10.5
	Products stored near one another	5.3
	Not familiar with product(s)	5.3
	Two patient identifiers not used	5.3
	Patient did not recall previous vaccine	5.3
	Not familiar with vaccination interval	5.3
MenACWY-D (0.8%, n = 15)	Age-dependent formulations/same vaccine	13.3
	Not familiar with vaccination interval	6.7
	Patient chart not checked before administration	6.7
	Miscommunication of drug order	6.7
	Patient did not recall previous vaccine	6.7
	Not familiar with patient ages for product	6.7
	Similar vaccine abbreviations	6.7
	Not familiar with product(s)	6.7
	Similar vaccine container labels/package	6.7
PPSV23 (0.7%, n = 14)	Check for expired products not conducted	21.4
	Ambiguous/confusing expiration date	21.4
	Similar brand names	21.4
	Miscommunication of drug order	7.1
	Patient did not recall previous vaccine	7.1
	Similar vaccine abbreviations	7.1
	Not familiar with product(s)	7.1
	Similar vaccine container labels/package	7.1
	Products stored near one another	7.1
	Similar generic names	7.1

Respiratory Syncytial Virus (0.6%, n = 12)	Similar vaccine abbreviations	16.7
	Similar generic names	16.7
	Patient age not verified before administration	16.7
	Similar brand names	8.3
	Miscommunication of drug order	8.3
	Similar vaccine container labels/package	8.3
	Age-dependent formulations/same vaccine	8.3
	Not familiar with patient ages for product	8.3
	Confusion regarding components vaccine	8.3
	Not familiar with dosing of product	8.3
	Patient information missing/wrong	8.3
COVID-19 vaccine, adenovirus (COV-Adenovirus) (0.6%, n = 12)	Patient age not verified before administration	16.7
	Ambiguous/confusing expiration date	8.3
	Check for expired products not conducted	8.3
RV5 (0.6%, n = 12)	Patient age not verified before administration	16.7
	Not familiar with patient ages for product	16.7
	Check for expired products not conducted	16.7
	Patient chart not checked before administration	8.3
Td (0.5%, n = 10)	Ambiguous/confusing expiration date	20.0
	Check for expired products not conducted	20.0
	Similar brand names	10.0
	Products stored near one another	10.0
	Miscommunication of drug order	10.0
	Patient chart not checked before administration	10.0
	Similar generic names	10.0
	Not familiar with dosing of product	10.0
	Two patient identifiers not used	10.0
RV1 (0.5%, n = 10)	Patient age not verified before administration	20.0
	Not familiar with patient ages for product	10.0
	Miscommunication of drug order	10.0
	Not familiar with dosing of product	10.0
	Not familiar with route administration for product	10.0
DTaP-IPV-Hib-HepB (0.5%, n = 9)	Similar brand names	22.2
	Similar vaccine container labels/package	11.1
	Products stored near one another	11.1
	Miscommunication of drug order	11.1
	Not familiar with product(s)	11.1
	Age-dependent formulations/same vaccine	11.1
	Not familiar with patient ages for product	11.1
	Patient age not verified before administration	11.1

PCV20 (0.4%, n = 8)	Patient chart not checked before administration	37.5
	Check for expired products not conducted	12.5
	Similar brand names	12.5
	Products stored near one another	12.5
	Not familiar with route administration for product	12.5
	Age-dependent formulations/same vaccine	12.5
	Patient did not recall previous vaccine	12.5
HepA-HepB (0.4%, n = 7)	Check for expired products not conducted	57.1
	Similar brand names	14.3
	Not familiar with product(s)	14.3
HepB-CpG (0.4%, n = 7)	Patient chart not checked before administration	28.6
	Similar brand names	14.3
	Not familiar with product(s)	14.3
	Products stored near one another	14.3
	Age-dependent formulations/same vaccine	14.3
	Patient did not recall previous vaccine	14.3
	Miscommunication of drug order	14.3
	Incorrect or crowded storage area	14.3
	State vaccine registry not checked before administration	14.3
Undetermined (0.4%, n = 7)	Similar brand names	28.6
	Check for expired products not conducted	14.3
	Ambiguous/confusing expiration date	14.3
	Two patient identifiers not used	14.3
	Not familiar with vaccination interval	14.3
COVID-19 vaccine, adjuvanted (COV-Adjuvanted) (0.3%, n = 5)	Miscommunication of drug order	20.0
	Patient chart not checked before administration	20.0
LAIV (0.3%, n = 5)	Not familiar with patient ages for product	20.0
	Check for expired products not conducted	20.0
Rabies Vaccine (0.2%, n = 4)	Not familiar with vaccination interval	25.0
	Patient chart not checked before administration	25.0
MenB-FHbp (0.2%, n = 3)	Miscommunication of drug order	33.3
	Similar vaccine abbreviations	33.3
4vHPV (0.1%, n = 1)	Similar patient names	100.0
Anthrax Vaccine Absorbed (0.1%, n = 1)	Check for expired products not conducted	100.0
MCV4 (0.1%, n = 1)	Miscommunication of drug order	100.0
	Similar vaccine abbreviations	100.0
Typhoid Vi Polysaccharide Vaccine (0.1%, n = 1)	Miscommunication of drug order	100.0

Appendix C. Top three contributing factors and associated vaccines for each event type

Event Type (% of all reports, N = 1,987)	Top Reported Contributing Factors (% within event type)	Top Reported Vaccines (% per contributing factor)
Wrong vaccine (25.2%, n = 501)	Similar vaccine container labels/package (22.2%, n = 111)	COV-mRNA (55.9%, n = 62)
		MMRV (7.2%, n = 8)
	Similar brand names (21.8%, n = 109)	COV-mRNA (60.6%, n = 66)
		HepB (5.5%, n = 6)
	Products stored near one another (20.6%, n = 103)	COV-mRNA (24.3%, n = 25)
		HepB (10.7%, n = 11)
Expired vaccine (19.8%, n = 393)	Ambiguous/confusing expression of expiration date (51.9%, n = 204)	COV-mRNA (86.8%, n = 177)
		Hib (4.4%, n = 9)
	Routine check for expired products not conducted (44.8%, n = 176)	COV-mRNA (56.3%, n = 99)
		HepA and MMR each (4.5%, n = 8)
Wrong age (9.8%, n = 194)	Not familiar with indicated patient ages for product (36.6%, n =71)	DTaP-IPV and IIV4 each (16.9%, n = 12)
		COV-mRNA (12.7%, n = 9)
	Patient age not verified before administration (36.1%, n = 70)	COV-mRNA (51.4%, n = 36)
		MMRV (10.0%, n = 7)
	Age-dependent formulations of same vaccine (28.9%, n = 56)	COV-mRNA (41.1%, n = 23)
		HepA (12.5%, n = 7)

Extra dose (8.5%, n = 169)	Patient chart not checked before administration (30.8%, n = 52)	IIV4 (21.2%, n = 11)
		COV-mRNA (9.6%, n = 5)
	Patient did not recall previous vaccine (23.7%, n = 40)	IIV4 and RZV each (17.5%, n = 7)
		COV-mRNA (15.0%, n = 6)
	State vaccine registry not checked (18.3%, n = 31)	RZV (22.6%, n = 7)
		COV-mRNA (12.9%, n = 4)
Wrong timing/interval (7.4%, n = 147)	Patient chart not checked before administration (32%, n = 47)	COV-mRNA (42.6%, n = 20)
		9vHPV, DTaP, HepA, and Tdap each (6.4%, n = 3)
	State vaccine registry not checked (26.5%, n = 39)	COV-mRNA (35.9%, n = 14)
		HepA (20.5%, n = 8)
	Not familiar with vaccination interval for product (16.3%, n = 24)	COV-mRNA (20.8%, n = 5)
		9vHPV, MMR, and VAR each (12.5%, n = 3)
Wrong dose—over dosage (7.1%, n = 141)	Age-dependent formulations of same vaccine (44.7%, n = 63)	COV-mRNA (63.5%, n = 40)
		HepA (12.7%, n = 8)
	Not familiar with dosing of product (25.5%, n = 36)	COV-mRNA (80.6%, n = 29)
		HepA (5.6%, n = 2)
	Miscommunication of drug order (14.9%, n = 21)	COV-mRNA (57.1%, n = 12)
		9vHPV, DTaP-HepB-IPV, DTaP-IPV, DTaP-IPV/Hib, HepA, Hib, IIV4, MenACWY-D, and POL each (4.8%, n = 1)

Wrong dose—under dosage (5.3%, n = 105)	Age-dependent formulations of same vaccine (32.4%, n = 34)	COV-mRNA (50.0%, n = 17)
		HepB (29.4%, n = 10)
	Not familiar with dosing of product (21.9%, n = 23)	HepB (43.5%, n = 10)
		COV-mRNA (26.1%, n = 6)
	Miscommunication of drug order (16.2%, n = 17)	COV-mRNA (47.1%, n = 8)
		HepB (17.6%, n = 3)
Vaccine/component omission—only one component of multicomponent vaccine administered (1.8%, n = 36)	Not familiar with how to mix or prepare product (58.3%, n = 21)	DTaP-IPV/Hib (33.3%, n = 7)
		MenACWY-CRM (28.6%, n = 6)
	Carton/container label misleading or difficult to read (8.3%, n = 3)	DTaP-IPV/Hib, Hib, and MenACWY-CRM each (33.3%, n = 1)
	Similar packaging (5.6%, n = 2)	MenACWY-CRM (100%, n = 2)
Vaccine/component omission—diluent given without the vaccine (1.7%, n = 33)	Not familiar with how to mix or prepare product (54.5%, n = 18)	RZV (44.4%, n = 8)
		DTaP-IPV/Hib (33.3%, n = 6)
	Similar packaging (15.2%, n = 5)	COV-mRNA, MenACWY-CRM, MMR, MMRV, and VAR each (20.0%, n = 1)
	Carton/container label misleading or difficult to read (12.1%, n = 4)	DTaP-IPV/Hib, MMR, MMRV, and VAR each (25.0%, n = 1)
Wrong route of administration (e.g., IM vs. subcutaneous) (1.6%, n = 32)	Not familiar with route of administration for product (56.3%, n = 18)	POX (33.3%, n = 6)
		RZV and VAR each (16.7%, n = 3)

Wrong patient (1.0%, n = 20)	Two patient identifiers not used (55%, n = 11)	9vHPV and HepA each (18.2%, n = 2)
		Hib, MenACWY-CRM, MenACWY-TT, MMR, Td, and Tdap each (9.1%, n = 1)
	Similar patient names (20%, n = 4)	4vHPV, 9vHPV, DTaP, and RZV each (25%, n = 1)
	Language barrier (15%, n = 3)	9vHPV, DTaP-IPV, and HepA each (33.3%, n = 1)
Contaminated or deteriorated vaccine (0.6%, n = 11)	Vaccine stored at temperature lower than recommended (63.6%, n = 7)	IIV4 (57.1%, n = 4)
		COV-mRNA, DTaP, and HepA each (14.3%, n = 1)
	Vaccine stored at temperature greater than recommended (36.4%, n = 4)	MMRV (75.0%, n = 3)
		COV-mRNA (25%, n = 1)
Wrong administration site (e.g., gluteus maximus rather than the deltoid) (0.3%, n = 6)	Not familiar with correct administration site for product (50%, n = 3)	IIV3, POX, and VAR each (33.3%, n = 1)

Appendix D. Facility types with the top three associated event types

Facility Type (% of all reports, n = 1,987)	Event Types	% within Facility (n)
Medical clinics (outpatient) (42.9%, n = 853)	Wrong vaccine	27.4% (n = 234)
	Expired vaccine	22.9% (n = 195)
	Extra dose and wrong age (each)	10.7% (n = 91)
Public health immunization clinic (17.9%, n = 355)	Wrong vaccine	20.8% (n = 74)
	Event type not listed	13.2% (n = 47)
	Wrong age	12.4% (n = 44)
Physician practice (17.0%, n = 338)	Expired vaccine	25.1% (n = 85)
	Wrong vaccine	21.6% (n = 73)
	Event type not listed	14.8% (n = 50)
Community pharmacy (8.7%, n = 173)	Wrong vaccine	34.1% (n = 59)
	Expired vaccine	27.2% (n = 47)
	Wrong dose—over dosage	9.2% (n = 16)
Other (8.2%, n = 162)	Event type not listed	21.0% (n = 34)
	Wrong vaccine	17.9% (n = 29)
	Wrong timing/interval	14.2% (n = 23)
Hospital (inpatient) (2.1%, n = 41)	Wrong vaccine	34.1% (n = 14)
	Event type not listed	22.0% (n = 9)
	Expired vaccine and wrong age (each)	12.2% (n = 5)
Hospital (ambulatory) (1.7%, n = 34)	Wrong vaccine and expired vaccine (each)	29.4% (n = 10)
	Event type not listed	23.5% (n = 8)
	Wrong timing/interval	8.8% (n = 3)
Pharmacy-based health clinic (1.2%, n = 24)	Wrong vaccine	25.0% (n = 6)
	Wrong dose—over dosage	16.7% (n = 4)
	Wrong dose—under dosage, expired vaccine, and wrong route (each)	12.5% (n = 3)
Military locations (0.4%, n = 7)	Expired vaccine	42.9% (n = 3)
	Wrong vaccine	28.6% (n = 2)
	Event type not listed	28.6% (n = 2)

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ABOUT ISMP

The Institute for Safe Medication Practices (ISMP) is the only 501c (3) nonprofit organization devoted entirely to preventing medication errors. During its more than 30-year history, ISMP has helped make a difference in the lives of millions of patients and the healthcare professionals who care for them.

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Among its many initiatives, ISMP runs the only national voluntary practitioner medication error reporting program, publishes newsletters with real-time error information read and trusted throughout the global healthcare community, and offers a wide range of unique educational programs, tools, and guidelines.

In 2020, ISMP formally affiliated with ECRI to create one of the largest healthcare quality and safety entities in the world. The affiliation allows both organizations to work more closely together for the benefit of providers, patient advocates, governments, and most importantly, patients.

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