2017-2018 BIANNUAL REPORT

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

ISMP

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TABLE OF 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 1,143 event reports submitted to the Institute for Safe Medication Practices (ISMP) National Vaccine Errors Reporting Program (VERP) from January 1, 2017 through December 31, 2018 show that most of the reported errors reached the patient (87.8%, n = 1,004). Most of the reports were submitted by a practitioner working in the outpatient setting including medical clinics (36.5%, n = 417), physician practices (24.4%, n = 279), ambulatory areas of hospitals (13.8%, n = 158) and public health immunization clinics (12.5%, n = 143). The error types reported most often included wrong vaccine (24.2%, n = 277) and wrong age (17.4%, n = 199). A few (1.4% [n = 16 of 1,143]) of reports involved clusters of events. 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 (WHO) specifies that, globally, immunization averts about two to three million deaths each year.[3]

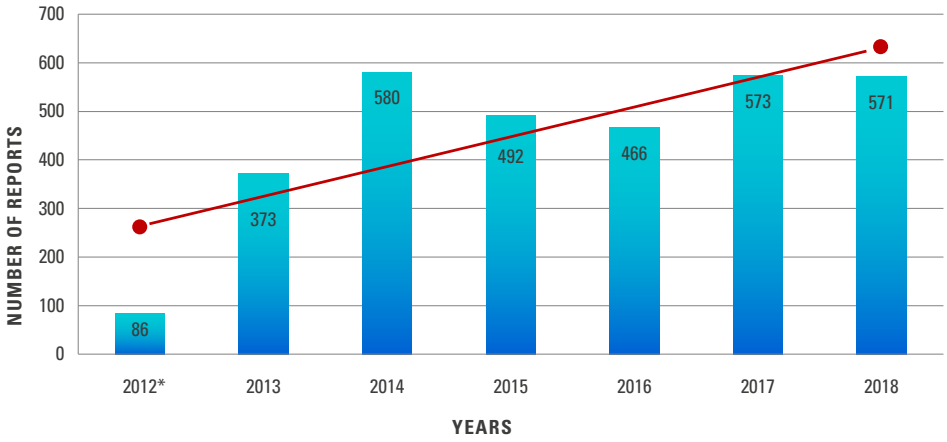
According to CDC's National Health Interview Survey (NHIS), there was a modest increase in vaccination coverage for some vaccines (e.g., pneumococcal vaccination in adults greater than 65-years, tetanus-diphtheria-pertussis (Tdap) in adults 19-years and older) in 2016.[4] More recently, WHO indicated that global vaccination coverage for children stalled at 86% during 2017.[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 United States Food and Drug Administration (FDA) has approved 80 vaccines for use in the United States.[7] To provide a uniform approach to vaccine references, the CDC Advisory Committee on Immunization Practices (ACIP) provides a list (**Appendix A**) 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 vaccines. Consequences of vaccination errors include inadequate immunological protection, increased cost, injury, inconvenience, and reduced confidence in the healthcare delivery system.[11]

In September 2012, the Institute for Safe Medication Practices (ISMP) partnered with the California Department of Public Health to develop the ISMP National Vaccine Errors Reporting Program (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**). This report summarizes the analysis of vaccine error reports submitted to the ISMP VERP during calendar years 2017 and 2018.

Figure 1: An overall increasing trend in reporting of vaccine errors to the ISMP VERP.



* Represents only a partial year (September 12, 2012 to December 31, 2012)

METHODS

Analysts queried the ISMP VERP database for events reported to ISMP from January 1, 2017, through December 31, 2018. The query yielded 1,143 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 had the option of selecting the "other" response to provide a free text answer. To assess if currently available selections needed alterations or new answer choices were warranted, analysts reviewed the "other" categories to identify, when possible, characteristics of the events, including the primary event type, contributing factor, and setting.

Some vaccine errors were reported in clusters (i.e., same error impacting multiple individuals at the same location or clinic). Each cluster report was considered as a single entry in the data analysis.

RESULTS

Submission type

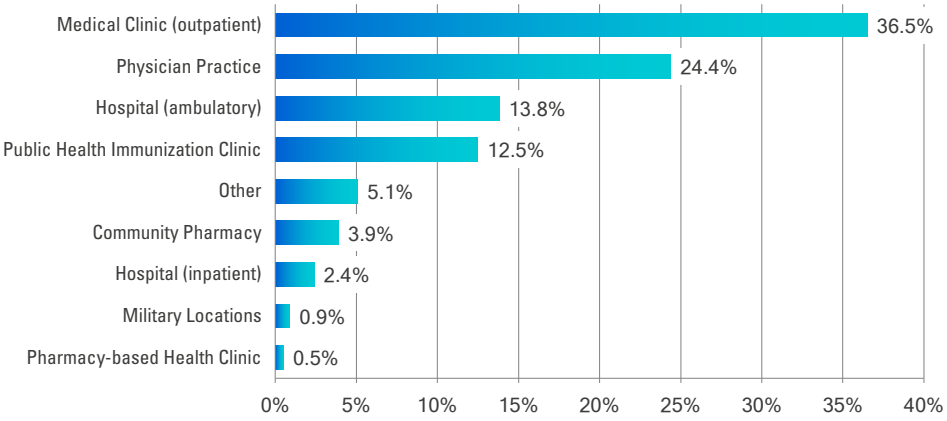
A breakdown by submission type indicated that most of the reported errors reached patients (87.8%, n = 1,004). The remainder of the reports involved an error that occurred but did not reach the patient (9.4%, n = 107) or a hazardous condition or situation that warranted concern (2.8%, n = 32).

Facility

Given the fact that most children and adults receive their vaccines in the community, a majority (87.2%, n = 997) of reports were submitted by practitioners working in outpatient settings such as medical clinics, physician practices, hospital (ambulatory), and public health immunization clinics (**Figure 2**).

Over 5.0% (5.1%, n = 58) of reporters selected "other." An analysis of this subset indicated that 48.3% (n = 28) were related to a type of community health center (e.g., Federally Qualified Health Centers [FQHC], rural health centers, tribal health centers) and 19.0% (n = 11) were related to an institutional setting (e.g., school, detention facility).

Figure 2. Types of facilities that submitted vaccination error reports (N = 1,143).



Vaccines cited in error reports based on facility type

A review of vaccines cited in error reports based on facility type can be found in **Table 1**. Overall, errors with diphtheria, tetanus and/or pertussis vaccines (Tdap, DTaP, DT, Td and combination vaccines) were reported most frequently (28.2%, n = 322) followed by errors with influenza virus vaccines (IIV3, IIV4 and LIAV [14.7%, n = 168]). More diphtheria, tetanus and/or pertussis vaccines (39.4%, n = 127 of 322) and influenza virus vaccine (32.1%, n = 54 of 168) errors occurred in medical clinics than any other setting. Following are two vaccine errors, one involving influenza vaccine and the other involving a diphtheria, tetanus and/or pertussis vaccine:

Pharmacy correctly entered, prepared and delivered 0.25 mL prefilled syringe of ***FLUZONE*** *Quadrivalent (indicated for children 6 to 35 months of age) for a 9-month-old child. Not realizing the pharmacy already prepared the vaccine, a nurse overrode the Automatic Dispensing Cabinet (ADC) and pulled 0.5 mL prefilled syringe of Fluzone Quadrivalent (indicated for children 3 years of age and older). Noticing the difference in dose volumes, nurse double checked the prescribing information to make sure it was the correct vaccine. Unfortunately, the prescribing information is the same for both the 0.25 mL and 0.5 mL prefilled syringes and the nurse didn't realize the volume difference between the two products. With the assumption that she had the right product, she drew up 0.25 mL from the 0.5 mL prefilled syringe and administered to child.*

⚠ *A 6-month-old child received a dose of* ***QUADRACEL*** *(DTaP-IPV) which is not CDC indicated until 4 years of age. The clinic was out of* ***PENTACEL*** *(DTaP-IPV/Hib) and the practitioner decided to administer Quadracel plus Hib. The error was not realized until after administering the vaccine because the order was placed after administration. [Our electronic health record (EHR)] alerted our staff that the vaccine is not indicated for children under 4 years of age.*

Errors related to other vaccines were more common in specific facilities based on the population served. For example, HepA vaccine was commonly reported in public health clinics and physician practices.

For a list of all reported vaccines with associated contributing factors see **Appendix B**.

Table 1. Facility types cited in error reports and top five associated vaccines.

Facility type (% of all reports, N = 1,143)	Vaccines involved	% within facility (n)
Medical Clinics (outpatient) (36.5%, n = 417)	DTaP-IPV	10.8% (n = 45)
	HepA	9.1% (n = 38)
	MMRV	8.4% (n = 35)
	Tdap	8.2% (n = 34)
	IIV4	6.5% (n = 27)
Physician Practice (24.4%, n = 279)	HepA	12.5% (n = 35)
	DTaP-IPV	10.4% (n = 29)
	9vHPV	9.0% (n = 25)
	DTaP-IPV/Hib	7.5% (n = 21)
	MMRV	6.1% (n = 17)
Hospital (ambulatory) (13.8%, n = 158)	IIV4	15.2% (n = 24)
	HepA	11.4% (n = 18)
	DTaP-IPV	8.9% (n = 14)
	IIV3	8.2% (n = 13)
	HepB	8.2% (n = 13)
Public Health Immunization clinic (12.5%, n = 143)	HepA	14.0% (n = 20)
	HepB	11.2% (n = 16)
	DTaP	9.1% (n = 13)
	MMRV	8.4% (n = 12)
	IIV3	7.0% (n= 10)
Community Pharmacy (3.9%, n = 45)	RZV	20.0% (n = 9)
	IIV3	20.0% (n = 9)
	PCV13	15.6% (n = 7)
	HepB	8.9% (n = 4)
	PPSV23	6.8% (n = 3)
	IIV4	6.8% (n = 3)
Hospital (inpatient) (2.4%, n = 27)	Tdap	33.3% (n = 9)
	IIV3	18.5% (n = 5)
	HepB	11.1% (n = 3)
	MMR	7.4% (n = 2)
	IIV4	7.4% (n = 2)
Military Locations (0.9%, n = 10)	Tdap	20.0% (n = 2)
	MMR	20.0% (n = 2)
	RZV, HepA, Smallpox, HepB, DTaP and IIV4 each	10.0% (n = 1)
Pharmacy-based Health clinic (0.5%, n = 6)	HepA	33.3% (n = 2)
	IIV3	16.7% (n = 1)
	PPSV23	16.7% (n =1)
	RZV	16.7% (n = 1)
	MMR	16.7% (n = 1)

Practitioners

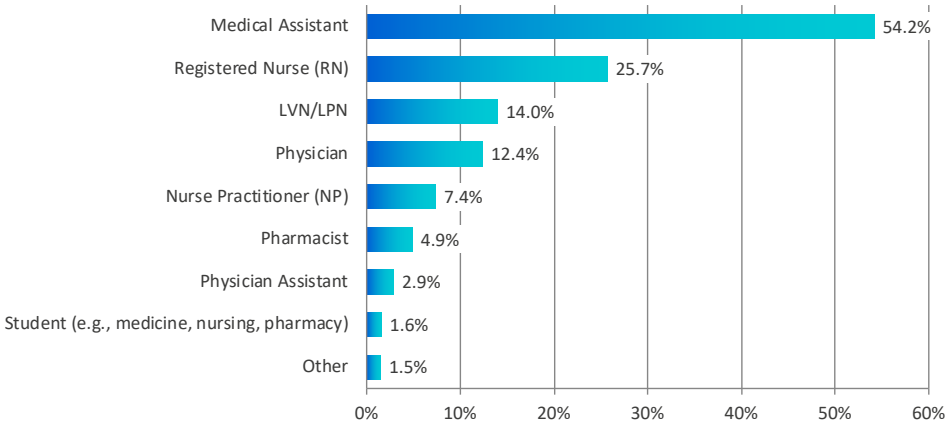
Medical assistants, registered nurses (RN), and licensed vocational nurses/licensed practical nurses (LVN/LPN) were the most frequently mentioned type of practitioner involved in reported events (**Figure 3**).

Given the fact that most reported errors occurred in medical clinics and physician practices where physicians are assisted in the preparation and administration of medications by medical assistants,[13] it is not surprising that medical assistants were involved in most reported vaccine errors. Medical assistants (70.3%, n = 489 of 696) and nurses (nurse practitioners [NP], RN and LVN/LPN, 30.8%, n = 270 of 696) were most often involved in events that occurred in medical clinics and physician practices. Nurses were involved in more than three quarters (97.9%, n = 140 of 143) of the reported errors that occurred in public health immunization clinics.

While the frequently reported errors involving medical assistants were related to DTaP-IPV and HepA vaccines, the most frequently reported errors involving nurses were related to MMRV, HepB and HepA vaccines. Following is an example of an error involving DTaP-IPV:

> ⚠ *An 11-year-old patient was brought to our office by his father to receive a Tdap vaccine. The provider recognized that the patient was due for IPV as well, so unaware of the age guidelines he decides to order a **KINRIX** (indicated for children 4 through 6 years of age). The vaccine was verified by the provider and given by a medical assistant.*

Figure 3. Practitioners involved in reported vaccination errors (N = 1,143).*



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

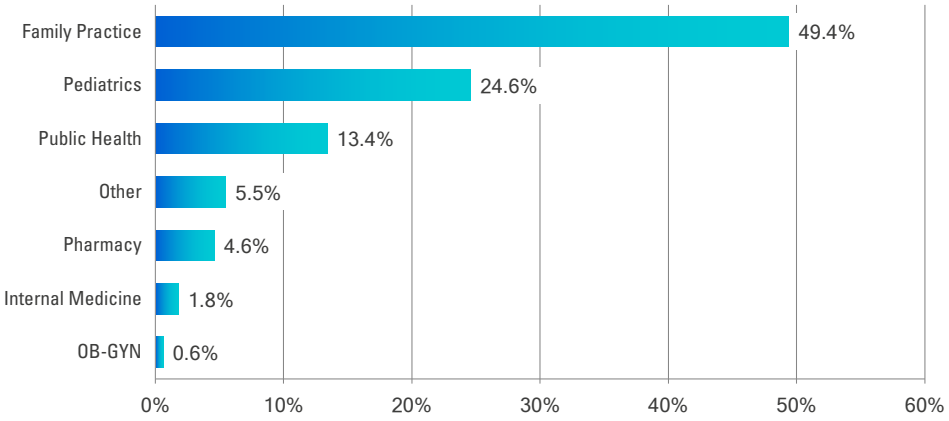
Provider type

Most of the providers involved in the reported vaccination errors were from family practice (49.4%, n = 565) and pediatrics (24.6%, n = 281) (**Figure 4**).

DTaP-IPV (12.6%, n = 71 of 565) was the vaccine most frequently involved in reported errors in the family practice setting while HepA (12.5%, n = 35 of 281) was involved in more errors in pediatric settings than any other vaccine. Following is an example of an error involving HepA vaccine:

> ⚠ ***INFANRIX** was ordered by provider. HepA was allowed to be chosen in the EHR and administered to patient. There were no adverse reactions. Parents were notified. The EHR company was contacted to understand why one vaccine was ordered, yet another was allowed to be chosen from the order.*

Figure 4. Providers involved in reported vaccination errors (N = 1,143).



Event types

Reporters may choose one of 14 event types when they submit a report. Wrong vaccine, wrong age, and extra dose events accounted for 52.1% (n = 596) of all reported events (**Figure 5**). **Table 2** presents a list of facility types with the reported event types.

One of the 14 event type options available for selection by the reporter is "event type not listed." The reporter is asked to specify the event type in the narrative field. A small percentage (7.9%, n = 90) of reporters chose this option. More than a quarter (28.9%, n = 26 of 90) of these reports were related to damaged or deteriorated vaccines (e.g. spillage, broken vials, unused reconstituted vaccines) and 10.0% (n = 9) were related to giving vaccines from the wrong vaccine stock (i.e. administering vaccines from the Vaccines for Children Program [VFC] stock to adults).

The most common contributing factors with associated vaccines for each event type can be found in **Appendix C**.

Figure 5. Event types reported (N = 1,143).

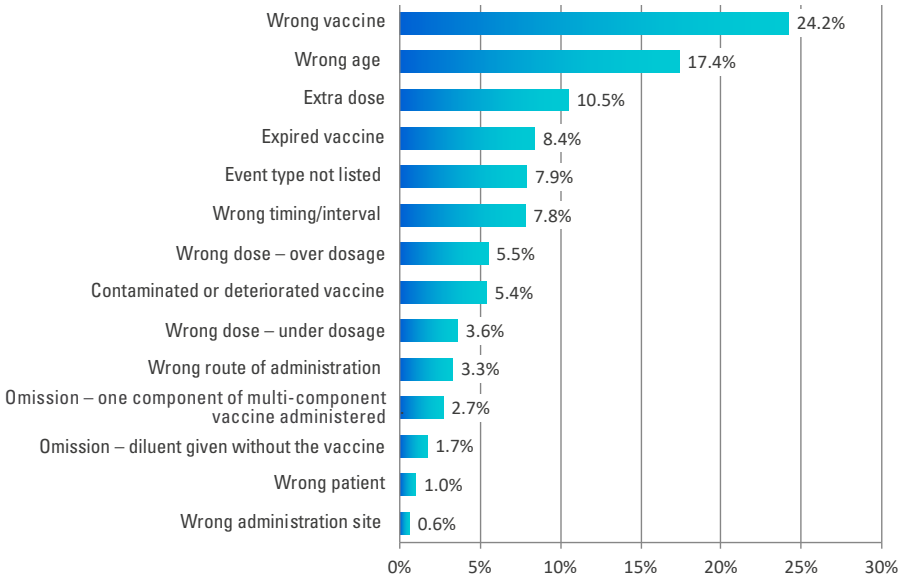


Table 2: Facility types with the top three associated event types

Facility type (% of all reports, N = 1,143)	Event types	% within facility (n)
Medical Clinics (outpatient) (36.5%, n = 417)	Wrong vaccine	25.2% (n = 105)
	Wrong age	15.3% (n = 64)
	Extra dose	12.7% (n = 53)
Physician Practice (24.4%, n = 279)	Wrong vaccine	21.9% (n = 61)
	Contaminated or deteriorated vaccine	19.4% (n = 54)
	Wrong age	16.8% (n = 47)
Hospital (ambulatory) (13.8%, n = 158)	Wrong vaccine	34.2% (n = 54)
	Wrong age	31.0% (n = 49)
	Expired vaccine	9.5% (n = 15)
Public Health Immunization clinic (12.5%, n = 143)	Wrong vaccine	23.1% (n = 33)
	Wrong age	17.5% (n = 25)
	Wrong timing/interval (e.g., interval too short)	11.9% (n = 17)
Community Pharmacy (3.9%, n = 45)	Extra dose	20.0% (n = 9)
	Event type not listed	15.6% (n = 7)
	Wrong vaccine	13.3% (n = 6)
	Wrong route of administration	13.3% (n = 6)
Hospital (inpatient) (2.4%, n = 27)	Wrong vaccine	22.2% (n = 6)
	Event type not listed	22.2% (n = 6)
	Wrong route of administration (e.g., IM vs. subcutaneous)	14.8% (n = 4)
	Wrong timing/interval (e.g., interval too short)	14.8% (n = 4)
Military Locations (0.9%, n = 10)	Expired vaccine	40.0% (n = 4)
	Wrong timing/interval (e.g., interval too short)	20.0% (n = 2)
	Extra dose	20.0% (n = 2)
Pharmacy-based Health clinic (0.5%, n = 6)	Wrong dose – over dosage	33.3% (n = 2)
	Wrong timing/interval (e.g., interval too short)	16.7% (n = 1)
	Extra-dose, Event type not listed each	16.7% (n = 1)
	Vaccine/component omission-diluent given without the vaccine	16.7% (n = 1)

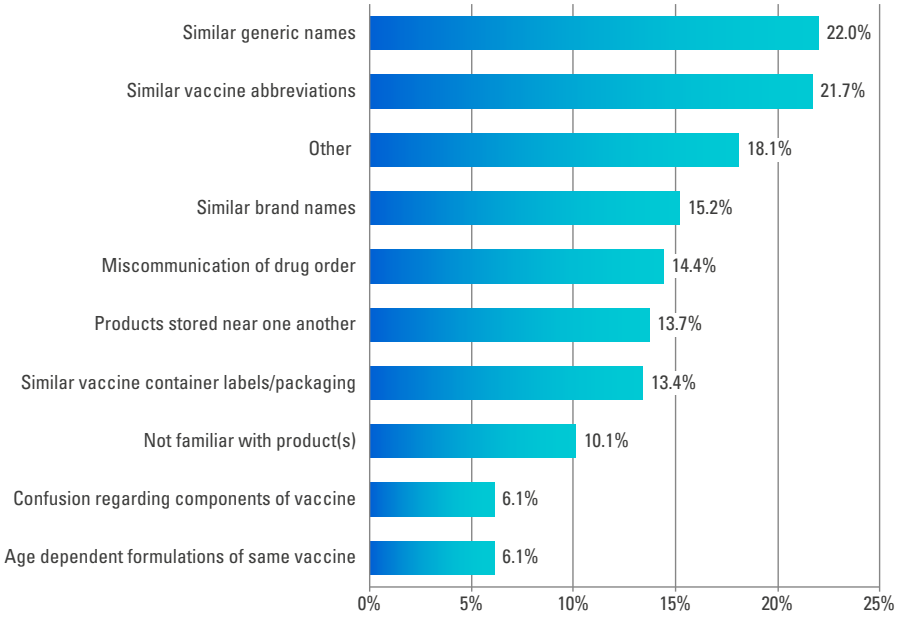
Wrong vaccines

Reported errors often involved the administration of a wrong vaccine (24.2%, n = 277). An analysis of related contributing factors showed that more than half (58.8%, n = 163 of 277) of the reported wrong vaccine events were associated with similarities in vaccine names or abbreviations (Figure 6). About a third (32.5%, n = 53 of 163) of mix-ups related to vaccine names or abbreviations involved diphtheria, tetanus and/or pertussis vaccines (Tdap, DTaP, DT, Td and combination vaccines). Though these vaccines are approved for different indications and/or populations, the CDC approved abbreviation (Appendix A) for some of these vaccines differ only by letter casing (i.e., upper versus lower case). 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 a minimum of 7 years). Following is a mix-up between Tdap and DTaP:

> ⚠ *After double checking the vaccine vial, a practitioner administered a Tdap vaccine to a 15-month-old baby thinking it was DTaP. Error was noted during documentation due to lot number mismatch.*

Similar generic names was one of the most commonly selected contributing factors for wrong vaccine errors. The most common (19.7%, n = 12 of 61) pairs of generic names mixed-up were Pneumococcal conjugate vaccine (13-valent; PCV 13) and Pneumococcal polysaccharide vaccine (23-valent; PPSV23).

Figure 6. Top ten contributing factors reported for wrong vaccine errors (n = 277).*†



*Respondents provided one or more contributing factors, so summed percentages may be greater than 100%.
†Percentages in the figure are based on n = 277. The number of events represented in the figure correspond to the top 10 contributing factors reported for wrong vaccine errors.

Another type of mix-up reported involved the conjugate polysaccharide antigen name listed on some vaccine labels and the target vaccine name. Some vaccines such as Haemophilus influenza type b, meningococcal, and pneumococcal are connected to polysaccharide antigens that trigger the immune system to respond. The three common proteins used to conjugate polysaccharide antigens include tetanus toxoid, diphtheria, and meningococcal protein. Including the name of the protein used to conjugate the polysaccharide antigens introduces an opportunity for error.[14] Following is a mix-up between a polysaccharide antigen and a target vaccine name:

> ⚠ *A provider ordered meningococcal vaccine (**MENACTRA**) and the medical assistant administered Haemophilus b conjugate vaccine (**PEDVAXHIB**) because PedvaxHIB vaccine's manufacturer carton displays "Meningococcal Protein Conjugate"(**Figure 7**).*

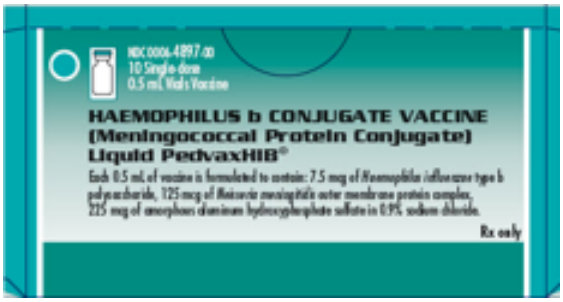


Figure 7: PedvaxHIB vaccine label displays "[Meningococcal Protein Conjugate]" sandwiched between the generic and brand name.[15]

Wrong age

While quality of care in immunization services requires age-appropriate ordering and administration of vaccines, many (17.4%, n = 199) of the reports submitted to the ISMP VERP involved wrong age defined as "patient not correct age for vaccine given." Lack of familiarity with the indicated patient ages for products (38.2%, n = 76) often contributed to these events (**Figure 8**).

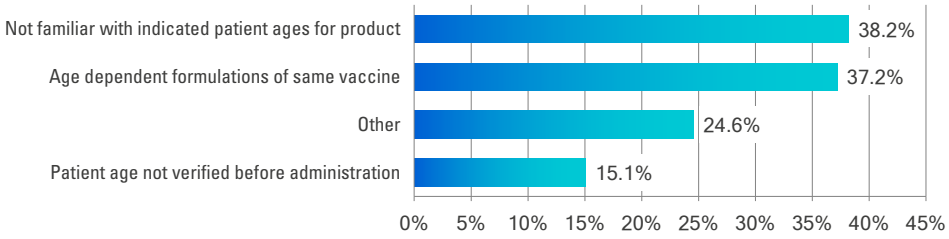
Of the reported wrong age vaccine errors related to lack of familiarity with indicated patient ages for products and age dependent formulation of the same vaccine, 45.3% (n = 68 of 150) involved various combinations of vaccines that target diphtheria, tetanus and/or pertussis (Tdap, DTaP, DT, Td and combination vaccines). Of these reports, 63.2% (n = 43 of 68) involved the administration of DTaP-IPV either to a patient younger than 4 years or older than 6 years of age. Following is a wrong age vaccine error involving Kinrix:

> ⚠ ***PEDIATRIX*** *(DTaP-HepB-IPV) recommended at 2, 4 and 6 months was ordered for a 4-month-old infant and a nurse practitioner inadvertently administered Kinrix (DTaP-IPV). Patient developed a large persistent bump at the injection site which lasted for about one month.*

Another vaccine frequently involved in wrong age error reports related to lack of familiarity with indicated patient ages for product and age dependent formulation of the same vaccine was influenza virus vaccine (IIV3, IIV4 and LIAV; 22.0%, n = 33 of 150). Following is a wrong age vaccine error involving influenza vaccine:

Verbal order from provider to give influenza vaccine to 18-month-old; usual supply of flu vaccine in pre-filled syringe not available, asked a nurse in the medication room which one to give, pointed to bottom shelf and removed ***FLUCELVAX****. Administered to child and when reviewing, noted it was indicated for 4 years and above, not 18-month-old. Primary care provider, patient's mother, and manufacturer notified. No untoward reaction.*

Figure 8. Contributing factors for reported wrong age errors (n = 199).*



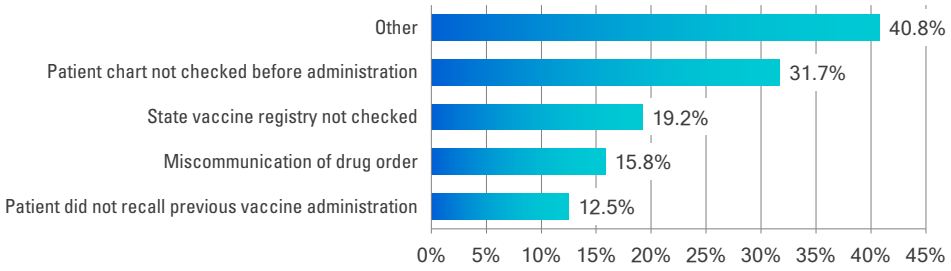
*Respondents provided one or more contributing factors; so summed percentages may be greater than 100%.

Extra dose

Though extra doses can also be categorized as wrong doses; it was not combined with under and over-dosage error reports due to differences in the contributing factors. Extra dose accounted for 10.5% (n = 120) of all vaccine errors reported to the ISMP VERP.

Half (50.8%, n = 61) of the reports involved the failure to check either the patient's chart or the state vaccine registry before administering the vaccine (**Figure 9**). Some (16.7%, n = 20) extra doses were given because the provider inadvertently administered both the vaccine and a combination product containing the same component. For example, there were several reports (65.0%, n = 14 of 20) involving the administration of MMRV and VAR. 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).

Figure 9. Contributing factors for reported extra dose errors (n = 120).*



* Respondents provided one or more contributing factors; so summed percentages may be greater than 100%.

Expired vaccines

Almost 9% (8.4%, n = 96) of the reported events involved administration of an expired vaccine. Analyses of the contributing factors found that 57.3% (n = 55) of the events involved a failure to routinely check for expired vaccines. Most of these reports (32.7%, n = 18 of 55) involved DTaP, PCV13 and MMR vaccines and 61.1% (n = 11 of 18) were reported by physician practices and medical clinics. More than a third (34.4%, n = 33) of reporters did not select a contributing factor. Following are examples of expired vaccine events:

Expired vaccines stored in the fridge of another building without notifying the vaccine coordinator was inadvertently administered to a patient.

A patient was mistakenly administered an expired vaccine because the nurse entered the wrong vaccine lot number into the state vaccine registry which failed to identify the vaccine error.

Wrong timing/interval

Some reported events (7.8%, n = 89) involved wrong vaccine interval (e.g., interval too short). More than a third (40.4%, n = 36) of reporters indicated failure to check the patient's chart or state vaccine registry before vaccine administration as contributing factors to wrong vaccine timing errors. Miscommunication of drug order and lack of familiarity with vaccination interval for product were also reported contributing factors. Most of the reports (33.3%, n = 12 of 36) related to failure to check patient's chart or state vaccine registry involved HepA and HepB vaccines.

Contaminated or deteriorated vaccine

Of the 5.4% (n = 62) reports in this event type, 91.9% (n = 57) were reports of vaccines stored at temperatures greater than recommended storage temperature. More than half (56.1%, n = 32 of 57) of these reports involved 9vHPV, HepA and MenB-4C which all require refrigeration. Most of these reports were submitted in clusters from single facilities. Following is an example of deteriorated vaccines reported through the ISMP VERP:

> ⚠ *Forty three children were administered varicella virus vaccine from a shipment that was stored out of the refrigerator for 5 days.*

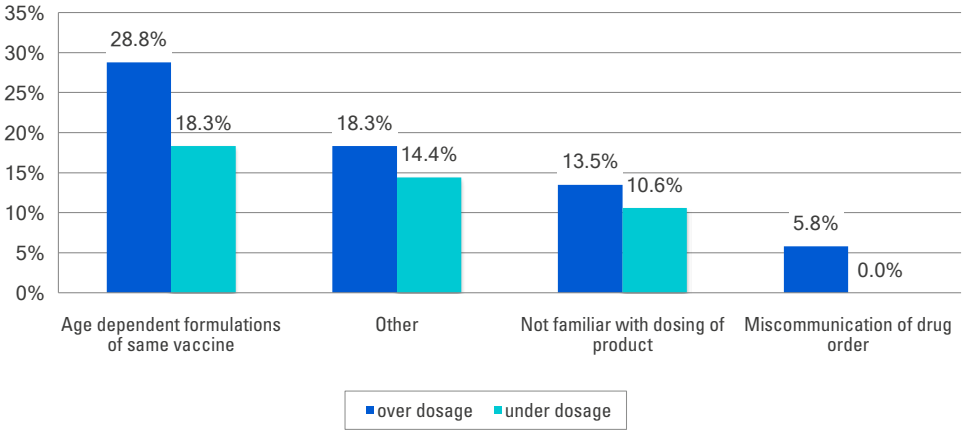
Wrong dose (over or under dosage)

In some instances, the right vaccine was given but at the wrong dose (over and under dose; n = 104). More than 5% (5.5%; n = 63 of 1,143) of all reports involved over dosage while 3.6% (n = 41 of 1,143) involved under dosage. The total wrong dose errors presented another scenario where age dependent formulations of the same vaccine contributed to the reported vaccine errors (47.1%, n = 49 of 104) Over a third (32.7%, n = 34 of 104) of reports combined did not include a contributing factor (**Figure 10**).

The most common (42.9%, n = 21 of 49) vaccine involved in these errors related to age dependent formulations of the same vaccine was HepA. HepB vaccine was also often cited in error reports related to age dependent formulations of the same vaccine (22.4%, n = 11 of 49). Following is a wrong dose event:

> ⚠ *During a **RECOMBIVAX HB** (5 mcg/0.5 mL) shortage, a pharmacy received an ordered for **ENGERIX-B** (10 mcg/0.5 mL) for newborn infants. Not very familiar with this product, the pharmacist inadvertently gave half the dose of Engerix-B (5 mcg/0.25 mL) in an attempt to convert Engerix-B to the 5 mcg/0.5 mL dose of Recombivax HB. This led to the under dosing of several dozens of babies.*

Figure 10. Contributing factors for reported wrong dose errors (n = 104).



Wrong route of administration

More than 3% (3.3%, n = 38) of reports involved erroneous administration of vaccines via the wrong route. Lack of familiarity with route of administration for product was commonly (57.9%, n = 22) cited as a contributing factor to wrong route of administration errors. More than one-third (39.5%, n = 15 of 38) of reports involved the administration of a vaccine via the subcutaneous route rather than the intramuscular route; more than half (60.0%, n = 9 of 15) of these errors involved the shingles vaccine (**SHINGRIX**).

Following is an example of a near miss involving wrong route of administration:

> ⚠ *Patient was aware that Shingrix should be given IM. Just before staff member in physician office administered it, patient asked staff member how she was going to give it. Staff responded subcutaneous. Patient told staff it's an IM injection. Staff checked the vial, apologized for being wrong, and then correctly administered it.*

Some wrong administration route errors reported in a hospital setting involved the erroneous administration of vaccines intravenously (IV) rather than IM. Following is an example of vaccine administration via the IV route:

> ⚠ *Patient was inadvertently given **PNEUMOVAX-23** intravenously rather than IM. RN had drawn up multiple medications including some IV medications and Pneumovax 23, when RN went to administer medications patient was combative and Pneumovax 23 was mistakenly administered via IV route.*

A few reports involved mix-ups in which vaccines were administered intradermally due to confusion with purified protein derivative (PPD) used to test for tuberculosis.

Vaccine/component omission

More than 4 % (4.4%; n = 50) of reported errors were related to either the administration of one component of a multi-component vaccine or diluent without the vaccine. More than a third (38.0%, n = 19) of reporters indicated a lack of familiarity with how to prepare these products. Following are examples of vaccine/component omission:

> ⚠ *A nurse failed to reconstitute the lyophilized powder component (Hib) of Pentacel and mistakenly administered only the liquid component (DTaP-IPV) to a 4 month-old-infant.*

> ⚠ *Two healthcare personnel, RN and NP, reviewed the patient's vaccine schedule and removed the applicable vaccinations from storage (varicella and DTaP). RN drew up the vaccines into their syringes. RN handed the DTaP materials to NP, who verified the DTaP syringe was filled, and the vial empty. NP then went with the DTaP into the administration room with RN, to perform 2-person simultaneous vaccine administration. DTaP administered to right deltoid, varicella to left arm. Upon completion of administration, during cleanup of materials, RN realized that only the diluent had been administered, and that she had not mixed in the varicella vaccine.*

Another example of this type of event included instances where the diluent of one vaccine was used to reconstitute another vaccine. Following is an example of such an event:

> ⚠ *A practitioner mistakenly reconstituted the active lyophilized Men A powder conjugate vaccine component of **MENVEO** with an MMR diluent (sterile water) instead of the accompanying Men CYW-135 liquid conjugate vaccine component.*

Wrong patient

Wrong patient was selected in 1.0% (n = 11) of reports received by ISMP VERP. Similar patient names were most commonly (27.3%, n = 3) reported as a contributing factor for wrong patient errors. Following is an example of a wrong patient error:

> ⚠ *The patient came in with his 2 siblings to receive vaccines for school. The mother did not bring in shot records for the patients therefore, they were looked up in the state registry. When we check to see what vaccines are needed, we put them onto the immunization record to advise the providers what vaccines are needed. Two of the patients were mixed up. One of the patients was 5-year-old and the other was 12-year-old and have similar names. The 12-year-old received the correct vaccines, but the 5-year-old received a **GARDASIL** vaccine and meningococcal conjugate vaccine along with a DTAP which was one of the vaccines that he required. We did not realize that the patient had received the wrong vaccines until the mother had already left.*

Clustered reports

A small number (1.4% [n = 16 of 1,143]) of reports involved clusters of events. All clusters involved different types of errors with the highest number of individuals affected by wrong administration site and wrong dose-underdose errors (more than 100 patients per cluster). Other types of events included the administration of a wrong dose to several dozen infants and contaminated or deteriorated vaccines administered to almost 50 children. Some cluster entries did not provide the number of patients affected but used phrases such as several, dozens, and many. Following are examples of the same error impacting multiple individuals at the same location or clinic:

> ⚠ *In one facility, about 100 patients were administered **HAVRIX**, while almost a quarter of patients were administered Engerix-B intramuscularly via the gluteal site instead of the preferred deltoid site.*

> ⚠ *Medical clinic was informed that flu vaccines which was received at one of their facilities had been stored at incorrect temperature prior to delivery and therefore deemed ineffective. Notified patients to come in for re-vaccination. Nine prenatal patients were given this ineffective vaccine.*

DISCUSSION

Errors in the vaccination process have not received a great amount of attention.[16,17] In fact, only 7% of reports submitted between 2000-2013 to the Vaccine Adverse Event Reporting System (VAERS) operated by the CDC and the FDA were related to vaccination errors.[18] While vaccination errors usually do not appear to pose a substantial safety risk, they can have epidemiological (lack of immunization which can lead to the propagation of an epidemic), human (adverse events and overvaccination), financial, and other public health consequences.[16] To prevent these consequences, it is paramount to address the common contributing factors to vaccination errors.

Setting and Practitioner type

While there is no acceptable incident rate for errors,[19] under-reporting of vaccination errors can compromise patient safety. Errors reflect numerous problems in the system such as culture not driven toward safety and presence of unfavorable working conditions.[20] An important first step in preventing errors is to understand their scope, prevalence, and magnitude. This can be achieved by reporting vaccine related errors to federally listed patient safety organizations such as ISMP, which allow healthcare professionals to voluntarily and anonymously report errors without legal repercussions.[21]

This study of the ISMP VERP data found that most of the reported vaccine errors where from medical clinics and physician practices. With pharmacists being authorized to administer almost all vaccines in most states,[22] it was surprising to identify only 3.8% of vaccine reports from community pharmacies with none reported from the large national chains. Barriers for reporting errors in most settings include but are not limited to fear of punishment, no clear definition of what constitute an error, and lack of time and resource.[21]

Staff education

As with previous ISMP VERP analysis, 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, physician practices, or hospital ambulatory care centers while RNs were most often involved in events that occurred in public health clinics.[12,23]

The scope of practice of medical assistants is state dependent. A study on state laws and standing orders for immunization services indicated that only 15 of the 50 US states and the District of Columbia addressed medication administration authority for medical assistants.[24] Of these 15 states, 11 states permit medical assistants to administer medication under delegated authority, three states (Georgia, Maryland and Wyoming) have authorized routine administration of injectable medications or vaccines by medical assistants, while one state (Illinois) has prohibited medical assistants from conducting any element of immunization practices.[24] 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 CDC's immunization education and training and Medical Assistants Resources and Training on Immunization (MARTi).

Immunization history

In recent years, more states have implemented various mandatory vaccination policies for healthcare workers and children.[25] With such mandates and the difficulty to keep accurate up-to-date immunization records, most states have developed immunization registries or immunization information systems (IIS) to collect vaccination history information.[26] IIS consolidates the immunization information from all providers within a state to create a more complete and current record. Even though most health professionals endeavor to document immunizations, omissions and subsequent 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 for a mobile society.[27]

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 reported discovering vaccine errors errors 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.[28] For example, most vaccines must be stored in a refrigerator or freezer maintained within a specific temperature range, and many vaccines require protection from light. Excessive heat or cold—even a single exposure in some instances—can reduce vaccine potency.[29]

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.[18] Similarities in manufacturer cartons have also contributed to vaccination errors.

FDA's requirements to list the generic name before the brand name can make it difficult to distinguish some vaccines. Errors also have been associated with the non-prominent differentiation on some product labels between the adult and the pediatric/adolescent formulations.[6]

It should also be noted that storing vaccines too close to non-biologic medications in a refrigerator or freezer also can lead to administration errors. Mix-ups between a vaccine and insulin have been reported. Neuromuscular blocking agents (e.g., pancuronium) have also been inadvertently used to reconstitute vaccines or administered instead of vaccines.[31]

Some of the reported timing-related vaccine errors for series vaccines can be attributed to the complex CDC immunization schedules. In fact, it has been reported that approximately 25% of internists felt age-based vaccination recommendations for adults were difficult to follow. Additionally, 29% reported that vaccine recommendations based on medical condition were difficult to follow.[32]

Another complication with series vaccines is the availability of different brands of some vaccines that are not interchangeable (i.e., the need for the same vaccine brand to be used for all doses in the series). For example, the ACIP meningococcal serogroup B vaccine (**TRUMENBA** and **BEXSERO**) recommendations states that the same vaccine must be used for all doses in the MenB series. If a person has already received one dose of Bexsero and one dose of Trumenba, then the clinician needs to pick a brand and finish the recommended schedule.[33] While data are limited on the safety and immunogenicity effects when **HEPLISAV-B** is interchanged with Engerix-B or Recombivax HB, they can be interchanged provided a total of 3 doses of HepB vaccine is administered (if one of the 3 doses is Heplisav-B).[34] Following is an example of an error involving HepB vaccines:

The client came into immunization clinic for his second Hepatitis B vaccine (Engerix-B) and after the second dose was administered and documented in the clinic's EHR system and state registry, it was discovered that the client's first Hepatitis B vaccine was the new Heplisav-B. Therefore, the second (and final dose when using Heplisav-B) should have been Heplisav-B as it is not interchangeable with Engerix-B or Recombivax. The error was revealed when the client produced a copy of his printed vaccine registry record he obtained after the first Heplisav-B vaccine was administered and, on the paper, copy was hand-written adjustments to the dosing schedule and brand name. The state registry and the clinic's electronic medical record (EMR) have Heplisav-B in their inventory systems but for whatever reason, the state registry has not adjusted its dosing schedule nor indicates the brand name on the general viewing screen as it does for Engerix-B. The client is aware of the error and encouraged to obtain second Heplisav-B vaccine 16 weeks from receiving the first Heplisav-B vaccine to achieve optimal protection, per CDC guidelines.

Multi-vial vaccines

ISMP continues to receive errors related to the use of the wrong "diluent" to prepare vaccines. Currently, there are 10 vaccines with specific diluents[35] and three vaccines (Menveo [MenA], Pentacel [DTaP-IPV/Hib], and Shingrix [RZV] [**Figure 11**]) have an active lyophilized vaccine powder that needs to be reconstituted with an "active" liquid component. Errors related to these vaccines include the administration of just the manufacturer-supplied diluent or liquid component. For example, despite the changes to the label of Menveo, we received reports in which practitioners inadvertently administered the liquid component alone instead of first using it to reconstitute the powder. The use of an inappropriate diluent, ones from a different vaccine, to reconstitute the lyophilized vaccine powder have also been reported.[36] This is particularly dangerous since diluents are designed for the specific needs of each vaccine with respect to volume, pH, and chemical properties of the final solution containing the immunizing agent.[37] Using the wrong diluent may result in incorrect doses and possible contamination.

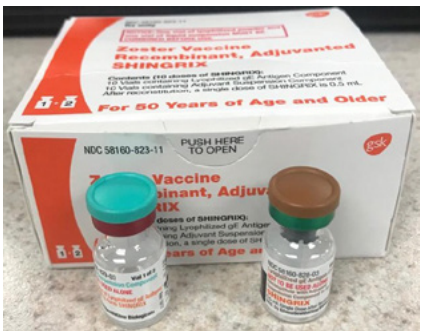


Figure 11. Shingrix vaccine carton contains one vial of lyophilized varicella zoster virus glycoprotein E (gE) antigen component and one vial of $AS01_B$ adjuvant suspension component.

Administration of an expired vaccine

Vaccine and diluent expiration dates printed on vials, prefilled syringes, and packages indicate when the product must be discarded. However, the expiration date expression is not always clear and easily deciphered (**Figure 12**). Also, some expiration dates specify a specific day of expiry while others only provide month and year information. When the expiration date has a day included with the month and year, the product may only be used through the end of that day. If only a month and year is present, the product may be used up to and including the last day of that month. Reconstituted vaccines, multidose vials, and manufacturer-shortened expiration dates (when vaccine is exposed to inappropriate storage conditions) may require an earlier expiration date.[38] After the expiration date, the product might lose its stability and potency and should not be administered.[39] Following is a reported example of an ambiguous expression of expiration date:

Expired Haemophilus b conjugate vaccine (Tetanus toxoid conjugate) was administered to a pediatric patient. Expiration date is written on manufacturers box and vial as 20Dec18 and medical assistant mistakenly assumed that the vaccine expired Dec 18, 2020.

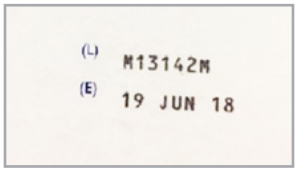


Figure 12. Confusing expiration date on **IMOVAX** (rabies vaccine). Does the vaccine expire on June 19, 2018 or June 18, 2019?

RISK REDUCTION STRATEGIES

Organizations and healthcare facilities can strive to identify system-based causes of errors involving vaccines, keeping in mind that these errors do not occur only during vaccine administration. Errors originate in all stages of the vaccination process, including prescribing and dispensing, and 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.[40,41]

Several reports described implementation of lower-leverage risk-reduction strategies, such as double checking by the same person, concentrating on a task at hand, or educating staff. Educating staff, students, and patients is a necessary component of a safety plan but relies on human vigilance to prevent errors. Layering multiple high- and low-leverage strategies (**Figure 13**) is important to reduce the risk of error.

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

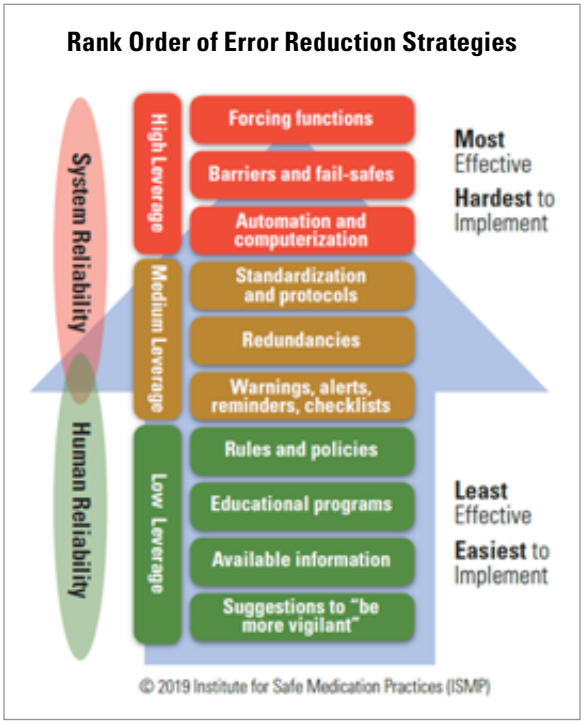


Figure 13: Items at the top of the list, such as forcing functions and automation, are more powerful strategies because they focus on systems. The tools in the middle attempt to fix the system yet rely in some part on human vigilance and memory. Items at the bottom, such as education, are tools that are important but focus on individual performance and therefore are weaker and ineffective when used alone.

Staff education

- Require all healthcare professionals and medical assistants 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.[29] Training should include content on proper administration technique and vaccine timing/spacing, especially for vaccines with complex schedules.[18]
- 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.[17]
- Implement and enforce procedures to properly screen patients for contraindications before vaccine administrations (e.g., live vaccines in pregnant women).[11]
- Where possible, encourage staff to use point-of-care barcode scanning to verify that the correct vaccine and age-specific formulation has been selected and prepared for administration to a patient.[17,42]
- 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.[43,44]

Patient education

- Require staff to provide all patients, parents, or legal guardians with a VIS in their preferred language prior to vaccination. VISs are available on the CDC and the Immunization Action Coalition (IAC) websites and have been translated into more than 40 languages.[29,42,44]
- 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.[17]
- 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.[17,42]
- Always submit complete information to the vaccination registry including vaccine administration date.[44]
- Document the national drug code (NDC), lot number, and expiration date of each vial in the vaccination record or log before administration to confirm selection or preparation of both components of two-component vaccines. Documenting actual administration of the vaccine should always occur after it is given.[17,23,44]
- 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.[6,44]
- 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[38] 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. Never store different vaccines in the same containers.[17]
- 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 ACIP, the CDC has published vaccine storage labels that can help staff quickly locate and choose the correct vaccine.[45] These labels could be placed on 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 determine the targeted ages for these vaccines.[17]
- 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 freezer shelves.[17]
- Improve monitoring of vaccine storage temperatures[11] and take immediate actions in response to temperature excursions.[17] Specify the storage requirements for each vaccine and diluent in your inventory. If feasible, 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.[38]
- List Haemophilus influenzae type b, meningococcal, and pneumococcal conjugate vaccines on automated dispensing cabinet (ADC) screens, pharmacy labels, vaccination records, and electronic medication administration records (eMARs), in a way that reduces the risk of identifying the conjugate antigen (e.g., tetanus toxoid, diphtheria, meningococcal protein) as the targeted vaccine.[46]

Multi-vial 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. Dispense the products together in a bag with an auxiliary label to remind staff to use both vials.[17,23]
- Be sure staff understand the differences between two-component vaccines (vaccines with active liquid and lyophilized powder components) and vaccines packaged with specific diluents.[23]
- 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.[29]
- Where technology is utilized, require barcode scanning of both components of two-component vaccines prior to mixing and administration.[14,30]

Administering an expired vaccine

- Check for expired vaccines weekly and immediately remove any expired vaccines or diluent.[17]
- Check expiration dates while counting stock and remove expired doses immediately.[25]
- Rotate the stock based on the expiration date to prevent unnecessary waste by placing vaccines first to expire in the front.[17]
- 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.[17]

» Contact CDC or the vaccine manufacturer for further guidance if an expired vaccine was administered in error.[17]

» Always check the expiration date on both the diluent/liquid component and lyophilized vaccine powder. Never use an expired diluent or vaccine.[35]

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.[23]

» Package two-component vaccines in redesigned vials that accommodate larger labels to reduce label crowding and increase the font size of important text.[23]

» 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.[23]

» Continue to improve labeling and packaging to differentiate age-dependent formulations of the same vaccine[23] and vaccines with similar names or acronyms.[18]

» 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.[27] This can help prevent missed opportunities while reducing vaccine administration errors.

» Seek to reduce the complexity of the vaccination schedules especially the catch-up vaccine schedule.

» For two-component vaccine containers (including those with associated diluents) provide clear directions for use and warnings to administer the contents of both vials together on the front label of the carton, each vial, and on the vial cap).[23]

» Follow established standardized and easily understood human-readable expiration date formats.

LIMITATIONS

The comprehensiveness of the pre-defined categories and 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 effective 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 near misses to the ISMP VERP.

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
Haemophilus influenzae type b conjugate vaccine	PedvaxHIB	Hib
	Hiberix	
	ActHIB	
Haemophilus influenzae type b conjugate and hepatitis B vaccine	Comvax*	Hib-HepB
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
Influenza virus vaccine, Live, Intranasal	Flumist Quadrivalent	LIAV
Influenza virus vaccine, Quadrivalent	Several brand names	IIV4
Influenza virus vaccine, Trivalent	Several brand names	IIV3
Measles, mumps, and rubella vaccine	M-M-R II	MMR
Measles, mumps, rubella, and varicella vaccine	ProQuad	MMRV
Pneumococcal conjugate vaccine (13-valent)	Prevnar 13	PCV13
Pneumococcal polysaccharide vaccine (23-valent)	Pneumovax 23	PPSV23
Quadrivalent meningococcal conjugate vaccine	Menactra	MenACWY-D
	Menveo	MenACWY-CRM
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

*No longer available in the US market. List adapted from the Center for Disease Control and Prevention (CDC). ACIP: Acronyms for Vaccines. https://www.cdc.gov/vaccines/hcp/acip-recs/vac-abbrev.html Accessed February 21, 2019

APPENDIX B

Vaccines cited in reported errors and contributing factors

Vaccine (% all vaccine reports, N = 1,143)	Contributing factors	% (per specific vaccine)
HepA (10.5%, n = 120)	Age dependent formulations of same vaccine	**30.0**
	Vaccine stored at temperature greater than recommended	**9.2**
	Not familiar with indicated patient ages for product	**6.7**
	Patient chart not checked before administration	**5.8**
	Not familiar with dosing of product	**5.8**
	Similar generic names	**5.0**
	Miscommunication of drug order	**5.0**
	State vaccine registry not checked	**4.2**
	Routine check for expired products not conducted	**3.3**
	Products stored near one another	**3.3**
	Similar brand names	**3.3**
	Patient age not verified before administration	**2.5**
	Similar vaccine abbreviations	**2.5**
	Not familiar with vaccination interval for product	**2.5**
	Patient did not recall previous vaccine administration	**1.7**
	Vaccine drawn up into syringe and confused with vaccine in another syringe	**0.8**
	Ambiguous/confusing expression of expiration date	**0.8**
	Similar vaccine container labels/packaging	**0.8**
	Prior vaccination not documented	**0.8**
	Confusion regarding components of vaccine	**0.8**
DTaP-IPV (8.3%, n = 95)	Not familiar with indicated patient ages for product	**37.9**
	Age dependent formulations of same vaccine	**14.7**
	Miscommunication of drug order	**6.3**
	Vaccine stored at temperature greater than recommended	**5.3**
	Patient age not verified before administration	**5.3**
	Patient chart not checked before administration	**4.2**
	Confusion regarding components of vaccine	**4.2**
	Similar brand names	**3.2**
	Similar generic names	**3.2**
	Routine check for expired products not conducted	**2.1**
	Products stored near one another	**2.1**
	Similar vaccine abbreviations	**2.1**
	Similar vaccine container labels/packaging	**1.1**
	Not familiar with route of administration for product	**1.1**
	Patient did not recall previous vaccine administration	**1.1**
	State vaccine registry not checked	**1.1**
	Not familiar with product(s)	**1.1**
	Not familiar with vaccination interval for product	**1.1**

IIV4 (6.9%, n = 79)	Age dependent formulations of same vaccine	**29.1**
	Patient age not verified before administration	**7.6**
	Not familiar with indicated patient ages for product	**7.6**
	Not familiar with dosing of product	**5.1**
	State vaccine registry not checked	**5.1**
	Patient chart not checked before administration	**3.8**
	Products stored near one another	**3.8**
	Similar vaccine container labels/packaging	**3.8**
	Similar brand names	**2.5**
	Miscommunication of drug order	**2.5**
	Routine check for expired products not conducted	**2.5**
	Patient did not recall previous vaccine administration	**2.5**
	Two patient identifiers not used	**1.3**
	Vaccine stored at temperature greater than recommended	**1.3**
	Similar patient names	**1.3**
IIV3 (6.9%, n = 79)	Age dependent formulations of same vaccine	**26.6**
	Similar brand names	**7.6**
	State vaccine registry not checked	**7.6**
	Patient chart not checked before administration	**6.3**
	Miscommunication of drug order	**5.1**
	Patient age not verified before administration	**5.1**
	Not familiar with dosing of product	**3.8**
	Patient did not recall previous vaccine administration	**3.8**
	Products stored near one another	**2.5**
	Not familiar with indicated patient ages for product	**2.5**
	Similar generic names	**2.5**
	Similar vaccine container labels/packaging	**2.5**
	Not familiar with product(s)	**1.3**
	Not familiar with correct administration site for product	**1.3**
	Routine check for expired products not conducted	**1.3**
	Similar vaccine abbreviations	**1.3**
Tdap (6.9%, n = 79)	Similar vaccine abbreviations	**13.9**
	Similar generic names	**11.4**
	Age dependent formulations of same vaccine	**10.1**
	Miscommunication of drug order	**8.9**
	Similar vaccine container labels/packaging	**6.3**
	Similar brand names	**5.1**
	Not familiar with product(s)	**3.8**
	Products stored near one another	**3.8**
	Patient age not verified before administration	**2.5**
	Patient chart not checked before administration	**2.5**
	State vaccine registry not checked	**2.5**
	Routine check for expired products not conducted	**1.3**
	Patient information missing/wrong (e.g., age, pregnancy status)	**1.3**
	Not familiar with indicated patient ages for product	**1.3**
	Not familiar with route of administration for product	**1.3**

HepB (6.4%, n = 73)	Age dependent formulations of same vaccine	**21.9**
	Not familiar with dosing of product	**13.7**
	Patient chart not checked before administration	**11.0**
	Miscommunication of drug order	**8.2**
	Similar vaccine abbreviations	**8.2**
	Similar generic names	**6.8**
	Routine check for expired products not conducted	**4.1**
	Prior vaccination not documented	**2.7**
	Confusion regarding components of vaccine	**2.7**
	Products stored near one another	**2.7**
	Patient information missing/wrong (e.g., age, pregnancy status)	**1.4**
	State vaccine registry not checked	**1.4**
	Similar vaccine container labels/packaging	**1.4**
	Patient age not verified before administration	**1.4**
	Not familiar with correct administration site for product	**1.4**
	Vaccine stored at temperature greater than recommended	**1.4**
	Similar brand names	**1.4**
	Incorrect or crowded storage shelf/refrigerator	**1.4**
	Patient did not recall previous vaccine administration	**1.4**
MMRV (6.2%, n = 71)	Similar vaccine container labels/packaging	**18.3**
	Similar vaccine abbreviations	**11.3**
	Products stored near one another	**9.9**
	Not familiar with indicated patient ages for product	**9.9**
	Miscommunication of drug order	**8.5**
	Similar generic names	**8.5**
	Routine check for expired products not conducted	**7.0**
	Age dependent formulations of same vaccine	**4.2**
	Confusion regarding components of vaccine	**2.8**
	Not familiar with product(s)	**2.8**
	Similar brand names	**2.8**
	Not familiar with route of administration for product	**2.8**
	Vaccine drawn up into syringe and mislabeled	**1.4**
	Patient age not verified before administration	**1.4**
	Patient chart not checked before administration	**1.4**
DTaP (5.2%, n = 60)	Routine check for expired products not conducted	**13.3**
	Age dependent formulations of same vaccine	**15.0**
	Similar vaccine abbreviations	**10.0**
	Miscommunication of drug order	**8.3**
	Similar generic names	**6.7**
	Not familiar with indicated patient ages for product	**6.7**
	Patient chart not checked before administration	**5.0**
	Not familiar with product(s)	**3.3**
	Similar brand names	**3.3**
	Ambiguous/confusing expression of expiration date	**1.7**
	Vaccine stored at temperature greater than recommended	**1.7**
	Similar vaccine container labels/packaging	**1.7**

9vHPV (4.6%, n = 53)	Vaccine stored at temperature greater than recommended	**24.5**
	Patient chart not checked before administration	**11.3**
	Miscommunication of drug order	**5.7**
	Not familiar with vaccination interval for product	**5.7**
	Similar patient names	**3.8**
	Similar vaccine abbreviations	**3.8**
	Patient age not verified before administration	**3.8**
	Not familiar with product(s)	**3.8**
	Patient did not recall previous vaccine administration	**3.8**
	Vaccine drawn up into syringe and confused with vaccine in another syringe	**1.9**
	Confusion regarding components of vaccine	**1.9**
	Vaccine stored at temperature lower than recommended	**1.9**
	Not familiar with indicated patient ages for product	**1.9**
	Not familiar with correct administration site for product	**1.9**
	Prior vaccination not documented	**1.9**
	Incorrect or crowded storage shelf/refrigerator	**1.9**
	Products stored near one another	**1.9**
	Not familiar with dosing of product	**1.9**
	Routine check for expired products not conducted	**1.9**
DTaP-IPV/Hib (4.5%, n = 51)	Not familiar with how to mix or prepare product	**11.8**
	Not familiar with indicated patient ages for product	**7.8**
	Miscommunication of drug order	**5.9**
	Age dependent formulations of same vaccine	**3.9**
	Products stored near one another	**3.9**
	Routine check for expired products not conducted	**3.9**
	Patient information missing/wrong (e.g., age, pregnancy status)	**2.0**
	Patient chart not checked before administration	**2.0**
	Similar vaccine abbreviations	**2.0**
	Similar brand names	**2.0**
	Carton/container label misleading or difficult to read	**2.0**
	Similar packaging	**2.0**
	Prior vaccination not documented	**2.0**
	Ambiguous/confusing expression of expiration date	**2.0**
PCV13 (4.0%, n = 46)	Routine check for expired products not conducted	**15.2**
	Vaccine stored at temperature greater than recommended	**10.9**
	Miscommunication of drug order	**10.9**
	State vaccine registry not checked	**13.0**
	Similar generic names	**6.5**
	Similar brand names	**6.5**
	Patient chart not checked before administration	**6.5**
	Similar vaccine abbreviations	**4.3**
	Not familiar with product(s)	**4.3**
	Not familiar with vaccination interval for product	**4.3**
	Products stored near one another	**4.3**
	Not familiar with indicated patient ages for product	**2.2**
	Not familiar with route of administration for product	**2.2**
	Patient did not recall previous vaccine administration	**2.2**

MMR (3.3%, n = 38)	Similar vaccine abbreviations	**15.8**
	Routine check for expired products not conducted	**10.5**
	Similar vaccine container labels/packaging	**10.5**
	Patient chart not checked before administration	**7.9**
	Not familiar with route of administration for product	**5.3**
	Ambiguous/confusing expression of expiration date	**5.3**
	Products stored near one another	**5.3**
	Similar generic names	**5.3**
	Miscommunication of drug order	**5.3**
	Similar brand names	**5.3**
	Not familiar with product(s)	**2.6**
	Not familiar with how to mix or prepare product	**2.6**
	Not familiar with indicated patient ages for product	**2.6**
MenB (2.6%, n = 30)	Vaccine stored at temperature greater than recommended	**26.7**
	Similar generic names	**16.7**
	Miscommunication of drug order	**13.3**
	Similar brand names	**10.0**
	Routine check for expired products not conducted	**6.7**
	Confusion regarding components of vaccine	**6.7**
	Products stored near one another	**3.3**
	Similar vaccine container labels/packaging	**3.3**
	Not familiar with product(s)	**3.3**
	Not familiar with vaccination interval for product	**3.3**
	Similar vaccine abbreviations	**3.3**
	Vaccine drawn up into syringe and confused with vaccine in another syringe	**3.3**
MenACWY-D (2.6%, n = 30)	Vaccine stored at temperature greater than recommended	**13.3**
	Similar generic names	**10.0**
	Patient chart not checked before administration	**10.0**
	Routine check for expired products not conducted	**10.0**
	Not familiar with product(s)	**6.7**
	Patient did not recall previous vaccine administration	**3.3**
	Similar vaccine abbreviations	**3.3**
	Miscommunication of drug order	**3.3**
	Not familiar with route of administration for product	**3.3**
	Age dependent formulations of same vaccine	**3.3**
VAR (2.5%, n = 29)	Miscommunication of drug order	**17.2**
	Products stored near one another	**10.3**
	Not familiar with product(s)	**6.9**
	Not familiar with route of administration for product	**6.9**
	Ambiguous/confusing expression of expiration date	**3.4**
	Vaccine stored at temperature greater than recommended	**3.4**
	State vaccine registry not checked	**3.4**

DTaP-HepB-IPV (2.5%, n = 29)	Vaccine stored at temperature greater than recommended	**17.2**
	Miscommunication of drug order	**17.2**
	Not familiar with product(s)	**13.8**
	Patient chart not checked before administration	**10.3**
	Confusion regarding components of vaccine	**6.9**
	Age dependent formulations of same vaccine	**3.4**
	Similar vaccine abbreviations	**3.4**
	Patient age not verified before administration	**3.4**
	Similar brand names	**3.4**
	Prior vaccination not documented	**3.4**
PPSV23 (2.1%, n = 24)	Similar generic names	**37.5**
	Similar brand names	**29.2**
	State vaccine registry not checked	**12.5**
	Similar vaccine abbreviations	**12.5**
	Patient did not recall previous vaccine administration	**8.3**
	Vaccine drawn up into syringe and confused with vaccine in another syringe	**4.2**
	Patient chart not checked before administration	**4.2**
	Not familiar with vaccination interval for product	**4.2**
	Confusion regarding components of vaccine	**4.2**
	Routine check for expired products not conducted	**4.2**
	Miscommunication of drug order	**4.2**
RZV (1.6%, n = 18)	Not familiar with route of administration for product	**44.4**
	Not familiar with how to mix or prepare product	**11.1**
	Similar packaging	**5.6**
	Miscommunication of drug order	**5.6**
Hib (Tetanus Toxoid Conjugate) (1.5%, n = 17)	Routine check for expired products not conducted	**17.6**
	Ambiguous/confusing expression of expiration date	**5.9**
	Similar packaging	**5.9**
	Not familiar with dosing of product	**5.9**
	Patient information missing/wrong (e.g., age, pregnancy status)	**5.9**
	Not familiar with indicated patient ages for product	**5.9**
	Miscommunication of drug order	**5.9**
	Similar vaccine container labels/packaging	**5.9**
	Patient chart not checked before administration	**5.9**
	State vaccine registry not checked	**5.9**
	Not familiar with how to mix or prepare product	**5.9**
	Products stored near one another	**5.9**
RV5 (1.5%, n = 17)	Routine check for expired products not conducted	**11.8**
	Not familiar with indicated patient ages for product	**11.8**
	Not familiar with vaccination interval for product	**11.8**
	Age dependent formulations of same vaccine	**5.9**
	Patient chart not checked before administration	**5.9**
	Patient age not verified before administration	**5.9**
	Not familiar with route of administration for product	**5.9**

MenACWY-CRM (1.5%, n = 17)	Not familiar with how to mix or prepare product	**52.9**
	Similar packaging	**11.8**
	Similar vaccine container labels/packaging	**5.9**
	Not familiar with dosing of product	**5.9**
	Carton/container label misleading or difficult to read	**5.9**
	Ambiguous/confusing expression of expiration date	**5.9**
	Patient chart not checked before administration	**5.9**
RV1 (1.1%, n = 13)	Routine check for expired products not conducted	**7.7**
	Age dependent formulations of same vaccine	**7.7**
	Confusion regarding components of vaccine	**7.7**
	Not familiar with route of administration for product	**7.7**
Hib (Meningococcal Protein Conjugate) (1.0%, n = 11)	Miscommunication of drug order	**27.3**
	Not familiar with product(s)	**18.2**
	Similar vaccine container labels/packaging	**9.1**
	Similar generic names	**9.1**
IPV (0.9%, n = 10)	State vaccine registry not checked	**10.0**
	Similar vaccine container labels/packaging	**10.0**
	Vaccine stored at temperature greater than recommended	**10.0**
	Patient chart not checked before administration	**10.0**
	Miscommunication of drug order	**10.0**
	Routine check for expired products not conducted	**10.0**
	Products stored near one another	**10.0**
ZVL (0.9%, n = 10)	Routine check for expired products not conducted	**20.0**
	Miscommunication of drug order	**20.0**
	State vaccine registry not checked	**10.0**
	Confusion regarding components of vaccine	**10.0**
	Similar brand names	**10.0**
	Not familiar with route of administration for product	**10.0**
	Products stored near one another	**10.0**
	Not familiar with product(s)	**10.0**
	Similar vaccine abbreviations	**10.0**
	Similar vaccine container labels/packaging	**10.0**
HepA-HepB (0.9%, n = 10)	Age dependent formulations of same vaccine	**20**
	Miscommunication of drug order	**10**
	Similar generic names	**10**
	Similar vaccine abbreviations	**10**
	Patient chart not checked before administration	**10**
IIV3, adjuvanted (0.7%, n = 8)	Patient age not verified before administration	**50.0**
	Age dependent formulations of same vaccine	**25.0**
	Not familiar with indicated patient ages for product	**25.0**
	Products stored near one another	**12.5**
Td (0.6%, n = 7)	Similar generic names	**28.6**
	Similar vaccine abbreviations	**28.6**
	Vaccine stored at temperature greater than recommended	**14.3**

Typhoid Vi Polysaccharide Vaccine (0.3%, n = 4)	Routine check for expired products not conducted	**25.0**
4vHPV (0.3%, n = 3)	Patient chart not checked before administration	**33.3**
	Similar vaccine abbreviations	**33.3**
	Routine check for expired products not conducted	**33.3**
LIAV (0.2%, n = 2)	No contributing factors selected	
Smallpox (Vaccinia) Vaccine, Live (0.2%, n = 2)	Two patient identifiers not used	**50.0**
MPSV4 (0.2%, n = 2)	Not familiar with route of administration for product	**50.0**
Typhoid Vaccine Live Oral Ty21a (0.1%, n = 1)	No contributing factor selected	
DT (0.1%, n = 1)	Similar vaccine abbreviation	**100.0**
Rabies Vaccine (0.1%, n = 1)	Vaccine stored at temperature lower than recommended	**100.0**
Hib-HepB (0.1%, n = 1)	Patient chart not checked before administration	**50.0**

APPENDIX C

Top contributing factors and associated vaccines for each event type

Event type (% of all reports, N = 1,143)	Top reported contributing factors (% within event type)	Top reported vaccines (% per contributing factor)
Wrong vaccine (24.2%, n = 277)	Similar generic names (22.0%, n = 61)	Tdap (14.8%, n = 9)
		PPSV23 (14.8%, n = 9)
	Similar vaccine abbreviations (21.7%, n = 60)	Tdap (18.3%, n = 11)
		MMRV (13.3%, n = 8)
	Similar brand names (15.2%, n = 42)	PPSV23 (16.7%, n = 7)
		IIV3 (14.3%, n = 6)
Wrong age (17.4%, n = 199)	Not familiar with indicated patient ages for product (38.2%, n = 76)	DTaP-IPV (47.4%, n = 36)
		HepA (10.5%, n = 8)
	Age dependent formulations of same vaccine (37.2%, n = 74)	HepA (18.9%, n = 14)
		IIV4 (18.9%, n = 14)
	Patient age not verified before administration (15.1%, n = 30)	IIV3 (26.7%, n = 8)
		IIV4 (20.0%, n = 6)
Extra dose (10.5%, n = 120)	Patient chart not checked before administration (31.7%, n = 38)	IIV4 (18.4%, n = 7)
		9vHPV (13.2%, n = 5)
	State vaccine registry not checked (19.2%, n = 23)	PCV13 (26.1%, n = 6)
		HepA, IIV3 and PPSV23 each (13.0%, n = 3)
	Miscommunication of drug order (15.8%, n = 19)	IIV3 (15.8%, n = 3)
		HepB (15.8%, n = 3)
Expired vaccine (8.4%, n = 96)	Routine check for expired products not conducted (59.4%, n = 57)	DTaP (14.0%, n = 8)
		PCV13 (12.3%, n = 7)
	Ambiguous/confusing expression of expiration date (8.3%, n = 8)	MMR (25.0%, n = 2)
		Hib, HepA, VAR, MenACWY-CRM, DTaP-IPV/Hib and DTaP each (12.5%, n = 1)

Wrong timing/interval (7.8%, n = 89)	Patient chart not checked before administration (31.5%, n = 28)	HepB (21.4%, n = 6)
		HepA (14.3%, n = 4)
	Miscommunication of drug order (14.6%, n = 13)	HepA (30.8%, n = 4)
		DTaP and DTaP-IPV each (15.4%, n = 2)
	Not familiar with vaccination interval for product (11.2%, n = 10)	9vHPV (30.0%, n = 3)
		HepA (30.0%, n = 3)
Wrong dose - over dosage (5.5%, n = 63)	Age dependent formulations of same vaccine (47.6%, n = 30)	HepA (40.0%, n = 12)
		IIV3 (30.0%, n = 9)
	Not familiar with dosing of product (22.2%, n = 14)	HepA (50.0%, n = 7)
		HepB and IIV3 each (21.4%, n = 3)
	Miscommunication of drug order (9.5%, n = 6)	MMRV (33.3%, n = 2)
		Hep A, Hib, IIV3, and MenB-4C each (16.7%, n = 1)
Contaminated or deteriorated vaccine (5.4%, n = 62)	Vaccine stored at temperature greater than recommended (91.9%, n = 57)	9vHPV (22.8%, n = 13)
		HepA (19.3%, n = 11)
	Vaccine stored at temperature lower than recommended (3.2%, n = 2)	9vHPV and Rabies each (50.0%, n = 1)
Wrong dose – under dosage (3.6%, n = 41)	Age dependent formulations of same vaccine (46.3%, n = 19)	HepA (47.4%, n = 9)
		HepB (36.8%, n = 7)
	Not familiar with dosing of product (26.8%, n = 11)	HepB (45.5%, n = 5)
		IIV4 (36.4%, n = 4)
Wrong route of administration (e.g., IM vs. subcutaneous) (3.3%, n = 38)	Not familiar with route of administration for product (57.9%, n = 22)	RZV (36.4%, n = 8)
		MMR, MMRV and VAR each (9.1%, n = 2)
	Miscommunication of drug order (7.9%, n = 3)	MMR, Tdap and RZV each (33.3%, n = 1)
Vaccine/component omission – Only one component of multi-component vaccine administered (2.7%, n = 31)	Not familiar with how to mix or prepare product (32.3%, n = 10)	DTaP-IPV/Hib (50.0%, n = 5)
		MenACWY-CRM (30.0%, n = 3)
	Similar packaging (9.7%, n = 3)	DTaP-IPV/Hib, MenACWY-CRM and Hib each (33.3%, n = 1)
	Carton/container label misleading or difficult to read (6.5%, n = 2)	MenACWY-CRM and DTaP-IPV/Hib each (50.0%, n = 1)

Vaccine/component omission - Diluent given without the vaccine (1.6%, n = 19)	Not familiar with how to mix or prepare product (47.4%, n = 9)	MenACWY-CRM (66.7%, n = 6)
		MMRV, RZV and DTaP-IPV/Hib each (11.1%, n = 1)
	Similar packaging (10.5%, n = 2)	RZV and MenACWY-CRM each (50.0%, n = 1)
Wrong patient (1.0%, n = 11)	Similar patient names (27.3%, n =3)	9vHPV (66.7%, n = 2)
		IIV4 (33.3%, n = 1)
	Two patient identifiers not used (18.2%, n = 2)	IIV4 and smallpox each (50.0%, n = 1)
Wrong administration site (e.g., gluteus maximus rather than the deltoid) (0.6%, n = 7)	Not familiar with correct administration site for product (42.9%, n = 3)	9vHPV, HepB and IIV3 each (33.3%, n = 1)

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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. ISMP is known and respected as the gold standard for medication safety information. It also has served as a vital force for progress. ISMP's advocacy work alone has resulted in numerous necessary changes in clinical practice, public policy, and drug labeling and packaging.

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. As an independent watchdog organization, ISMP receives no advertising revenue and depends entirely on charitable donations, educational grants, newsletter subscriptions, and volunteer efforts to pursue its life-saving work.

Visit **www.ismp.org** for more information.

Institute for Safe Medication Practices (ISMP)
200 Lakeside Drive, Suite 200, Horsham, PA 19044
Phone: (215) 947-7797 Fax: (215) 914-1492
www.ismp.org

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