

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Recommendations for practitioners to prevent vaccine errors

Part 2: Analysis of ISMP Vaccine Errors Reporting Program (VERP)

While the risk of adverse reactions to vaccines has been given considerable attention in recent years, the study of preventable adverse events associated with vaccine *errors* has been much less extensive. Despite this, the World Health Organization (WHO) emphasizes that adverse events due to vaccine *errors* are more common than adverse events due to the vaccines themselves.^{1,2} Also, the opportunity for vaccine errors is immense—30 or more vaccines will be administered to fully immunize a child in the US by the age of 6, accounting for a large number of opportunities each year for vaccine-related errors to occur during childhood vaccinations alone.¹

To collect the details needed to understand vaccine errors and their causes, ISMP partnered with the California Department of Public Health in September 2012 to develop the ISMP National Vaccine Errors Reporting Program (VERP) (www.ismp.org/verp). This is the only national vaccine error-reporting program in the US. ISMP sends all reports submitted to VERP to the Vaccine Adverse Event Reporting System (VAERS) used by the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). The primary purpose of the VAERS is to assess adverse events associated with vaccines. Outside of the error reports received from the ISMP VERP, the VAERS contains a very small number of reports that detail vaccine errors.^{3,4}

In the December 2014 newsletter, we published **Part 1** of a 2-year analysis of nearly 1,000 reports submitted to the VERP.⁵ From that analysis, the vaccines most frequently reported to be involved in errors included the following, in descending order:


- Influenza (IIV3, IIV4, RIV3, cclIV3, or LAIV4)
- Diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV)
- Hepatitis A (HepA)
- Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap)
- Human papillomavirus, recombinant (4vHPV, 2vHPV)
- Diphtheria and tetanus toxoids, and acellular pertussis adsorbed (DTaP)
- Measles, mumps, rubella, and varicella (MMRV)
- Hepatitis B (HepB)
- Diphtheria and tetanus toxoids, acellular pertussis adsorbed, inactivated poliovirus, and *Haemophilus influenzae* type b conjugate (DTaP-IPV/Hib)
- *Haemophilus influenzae* type b conjugate (Hib)

Among all vaccine errors in the 2-year VERP data set, the most common contributing factors were as follows:

- Mistakes in choosing age-specific formulations of vaccines intended to prevent the same diseases

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SAFETY briefs

 **Prevpac or “Pred-Pak.”** A nurse from a physician’s office called in a prescription to an outpatient pharmacy for **PREVPAC** (lansoprazole, amoxicillin, clarithromycin) for 14 days and asked the pharmacist if he could “make it” for the patient since it would be less expensive than using a manufacturer’s combination “pack.” However, the pharmacist misheard the nurse and thought the doctor had prescribed a “Pred-Pak,” or a predni**SONE** “dose pack” with tapered dosing. Although the nurse had not specified a starting dose, the pharmacist filled the prescription beginning with a typical 30 mg dose (divided into three 10 mg doses on day 1), with tapering doses so therapy would be complete after 14 days. Since the pharmacist was asked to “make it” rather than dispense the prepackaged drug, he did not question the 14-day therapy instead of the usual 6- or 12-day schedules. The pharmacist had rarely dispensed Prevpac but had been dis-

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ISMP begins 2015 Annual Fund Drive

Medication safety would be very different today without ISMP. The nonprofit organization has worked closely with regulatory authorities, standards organizations, professional and industry groups, and you, to improve safety. As a result, thousands of product and practice changes have occurred since our founding in 1994. We recently launched the **2015 Annual Fund Drive** to ensure that our lifesaving work will continue via an endowment. Please consider donating to this year’s **Annual Fund** to help keep ISMP an important part of the fight against preventable medication errors. To contribute, go to: www.ismp.org/support. Thank you!

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- Unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and a vaccine's components (e.g., combination vaccines; diluent and powder)
- Failure to check or verify the vaccination schedule and the patient's age, health record, or state immunization information system to avoid invalid doses administered too soon, or missed opportunities to vaccinate
- Confusion due to similar vaccine names and abbreviations
- Confusion due to similar and ambiguous vaccine labeling and packaging
- Administering diluents without vaccines, and/or one component of two-component vaccines
- Using the wrong vaccine diluent
- Unsafe storage (e.g., too close to similar-looking vaccines, temperature excursions, expired vaccines)
- Wrong patient errors due to sibling confusion

In **Part 2** of this newsletter feature, we provide recommendations to reduce the risk of vaccine errors based on the contributing factors identified in the 2-year data set. The contributing factors are highlighted in red, and the recommendations are listed under each contributing factor. Some recommendations will reduce the risk of errors associated with several different contributing factors. To avoid duplication, these recommendations appear under a single contributing factor but are highlighted with an asterisk (*) to note their ability to address other causative factors.

Errors with age-specific formulations

- Prior to prescribing, dispensing, or administering a vaccine, verify the patient's age by asking the date of birth (if the patient is available) and referencing the patient's health record, immunization record, medication administration record (MAR), and/or pharmacy profile or label. Also, compare the patient's current age with information on the applicable immunization schedule and Vaccine Information Statement (VIS) from the CDC.
- Affix auxiliary warning labels to vaccines when first received to draw attention to products with different formulations for pediatric, adolescent, and adult patients.
- Investigate purchasing differing age-specific formulations of the same vaccine from different manufacturers to help distinguish them.

Wrong patient errors due to confusion between siblings

- If multiple children, adults, or an adult and child are being seen at the same time for vaccinations in the same immediate vicinity, structure the appointment to vaccinate one patient at a time. Moving siblings to separate treatment rooms when possible is one way to approach the problem.¹ If more than one patient remains together, bring only one patient's vaccines into the treatment area at a time, labeled with the vaccine name and intended patient's name on each container. If more than one vaccine must be administered to a patient, keep them separate (e.g., separate trays; separate vaccine administration stations).*
- Verify the intended patient's identity using two unique identifiers (e.g., name and date of birth) before administering each vaccine.

Invalid doses (given too soon) or missed opportunities to vaccinate

- Prior to vaccination, verify the patient's current immunization status by checking
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dispensing predni**SONE** regularly. This is why he thought he heard "Pred-Pak" rather than "Prevpac." Fortunately, the patient read the leaflet about the newly dispensed medication and then called her doctor to ask why she was receiving a steroid to treat her duodenal ulcer and *Helicobacter pylori* (*H. pylori*) infection. The next day, the prescriber called the pharmacy to clarify the order.

These look- and sound-alike names, Prevpac and "Pred-Pak," demonstrate why telephone orders must be transcribed and read (and spelled) back. This includes the product name, dose, route, and directions for use. Unfortunately, in this case, the names are so close that, even with read-back, the error might not have been detected unless the interpretation of "Pred-Pak" (predni**SONE** dose pack) was included in the readback process. The atypical duration of therapy and the absence of a starting dose should have prompted the pharmacist to verify the order. However, the pharmacist was uncomfortable "bothering" the physician, as he had been difficult to deal with many times in the past. While this can be a powerful disincentive to speak up, it is paramount to ask questions when the safety or quality of drug therapy is uncertain. Providing an indication with the prescription also could have helped to prevent an error, and patient counseling before leaving the pharmacy might have as well.



Health alert! The US Food and Drug Administration (FDA) is warning that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together with **HARVONI** (ledipasvir/sofosbuvir) or with **SOVALDI** (sofosbuvir) taken in combination with another direct-acting antiviral (e.g., ribavirin, simeprevir) for the treatment of hepatitis C infection. Postmarketing adverse event reports include the death of 1 patient due to cardiac arrest and 3 patients requiring placement of a pacemaker to regulate

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the patient's health record, pharmacy profile, and vaccination record to avoid omissions and duplicate vaccine doses. If possible, build an alert into the pharmacy system, electronic MAR, or vaccination record to remind staff to review the patient's immunization record or discuss prior immunizations with the patient or parent.

- Locate missing vaccination records whenever possible by contacting previous healthcare providers and reviewing state or local immunization information systems. If records cannot be located, patients should be started on an age-appropriate vaccination schedule.
- Post up-to-date, easy-to-read immunization schedules for infants, children, teens, and adults that staff can quickly reference in clinical areas where vaccinations may be prescribed and administered.⁶ If possible, link the immunization schedule to the pharmacy system, electronic MAR, and/or vaccination record.*
- 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.^{6*}
- If a child or teen misses a particular vaccination(s), create an individualized *catch-up* schedule of immunization and provide it to the parent or caregiver.^{6*}
- For frequently administered vaccines, establish standard order sets or protocols, which include:^{7*}
 - The full generic name, brand name (if applicable), and standard abbreviation.⁸
 - Criteria for screening patients to determine the need for vaccination, indications, contraindications, and precautions.
 - Directions for administering the vaccine, including the route and any special procedures required to enhance safety.
 - Information regarding any required follow-up doses.
 - Details regarding what (e.g., lot number, expiration date) and where (e.g., vaccination record, immunization registries) to document vaccine administration.
 - An emergency protocol to follow if the patient develops an adverse reaction.
- Integrate an ambulatory clinical pharmacist into the healthcare team in pediatric primary care and public health clinics, and other inpatient and ambulatory settings where vaccines are frequently administered. Pharmacists are uniquely positioned to reduce the barriers to appropriate and safe vaccine use. When pharmacists work directly in patient care areas, significant reductions in vaccine errors, invalid vaccine doses, and missed opportunities to vaccinate have been documented.^{9*}
- Establish a reliable system to obtain information about a birth dose of HepB vaccine administered (or not) to a newborn in the hospital. It is recommended that hospitals implement a "universal birth dose policy" to ensure that every newborn receives the first dose of HepB at birth, or no later than at discharge from the hospital.¹⁰

Wrong route errors caused by unfamiliarity with the vaccine

- Post a quick reference for clinicians to verify the route of administration for all vaccines. A chart is available from the Immunization Action Coalition (IAC).¹¹
- Highlight the route of administration on pharmacy labels and electronic MARs by using boldface type.
- Highlight the route of administration on vaccine carton labels by circling or using color to bring attention to the information as necessary, or by affixing an auxiliary label to vaccines prone to administration by the wrong route—influenza; rotavirus; measles, mumps, rubella; and varicella vaccines.
- When possible, purchase vaccines in packaging or containers that are less likely to mislead clinicians regarding the correct route of administration (e.g., purchase **ROTATEQ** instead of **ROTARIX** to avoid accidental injection of the oral vaccine).

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their heart rhythms. Other patients recovered when either the hepatitis C drug and/or amiodarone were discontinued. The cause of these events has not yet been determined. FDA is recommending that prescribers not order either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone. In cases where alternative treatment options are unavailable, FDA recommends heart monitoring in an inpatient hospital setting for the first 48 hours. Subsequently, monitoring in a doctor's office or self-monitoring of the heart rate should be done every day for at least the first 2 weeks of treatment. Educate patients taking either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone to seek immediate medical attention if they experience signs or symptoms of bradycardia. For more information, visit: www.ismp.org/sc?id=505.



A point about levothyroxine. After reviewing transfer orders from a hospital, a nursing care facility physician ordered **SYNTHROID** (levothyroxine) 0.25 mg for a patient. The long-term care pharmacy confused mg and mcg and dispensed levothyroxine 25 mcg—a 10-fold underdose. This is not the first time we have heard about errors confusing mg and mcg with these products. In our May 2003 newsletter we reported that errors had become so common with levothyroxine that one pharmacist told us that he had set up his computers to signal an alert whenever a 0.25 mg dose was entered. When the warning appeared, the correct dose almost always was 0.025 mg or 25 mcg. Clinicians need to be alerted to the risks associated with dosing this product and have pharmacists or nurses at community, ambulatory, or long-term care sites provide feedback directly to prescribers if a dosing error, especially an overdose, is suspected. In order to avoid decimal points and dose conversions, healthcare practitioners should express the dose of levothyroxine

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Errors with combination vaccines or vaccines with diluents

- On order sets, MARs, pharmacy documentation, and vaccination records, list the brand names and all components of combination vaccines.
- Only use the vaccine diluents supplied and packaged by the manufacturer with vaccines that require reconstitution. Vaccine diluents are not interchangeable, and stock vials of sterile water or normal saline should not be used as a substitute.
- Clearly label or distinguish (e.g., circling or highlighting pertinent label information) diluents if the manufacturer's label could mislead staff into believing the diluent is the vaccine itself.
- 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.
- Document the NDC number, 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.*
- Establish ongoing education of clinical staff who might dispense and administer vaccines,* which includes discussion of safety issues with two-component vaccines and vaccines with specific diluents. Staff should understand the differences between two-component vaccines and vaccines packaged with specific diluents.
- Barcode scanning prior to vaccine administration* could help catch an error if only one vial was being inadvertently used and the system required scanning the barcodes on both vials of two-component vaccines or diluents and corresponding vaccines.

Wrong vaccine errors related to vaccine nomenclature

- When feasible, circle or highlight with a marker the brand names on carton labels of vaccine products that have long generic names, to promote correct product recognition.
- Differentiate the appearance of similar vaccine names on computer screens and MARs by highlighting dissimilarities and including full product names, starting with the brand name (if applicable) first, followed by the generic name, especially for multi-component vaccines (e.g., **PENTACEL**).*
- Prescribe vaccines with look-alike generic names using brand names, not by the CDC-approved abbreviation alone.*
- If vaccine abbreviations are permitted, allow only current, standard, CDC-approved abbreviations to be used.¹¹ Follow the CDC recommendations to list both the full generic name (and brand name) along with the approved abbreviation on all electronic and preprinted forms to reinforce the product identity and the correct use of abbreviations.
- Use patient vaccination records with enough space to list full vaccine names.
- Avoid listing the conjugate with polysaccharide vaccines on order entry and automated dispensing cabinet (ADC) computer screens, pharmacy labels, MARs, vaccination records, and shelf/storage area labels. For example, do not include tetanus toxoid when listing the generic name of ActHIB, which appears on the label as *Haemophilus b* conjugate vaccine (tetanus toxoid conjugate).
- Prohibit the use of coined or informal names for vaccines.
- Read back verbal orders to the prescriber for clarification.

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in the same way most manufacturers express the dose—in mcg, not mg.



Clotrimazole topical solution. We received a report that clotrimazole 1% topical solution was administered into a patient's eye in error. Clotrimazole is available as a cream and topical solution for the topical treatment of candidiasis due to *Candida Albicans* and tinea versicolor due to *Malassezia furfur*. The topical solution is available in what looks like a typical ophthalmic dropper squeeze bottle (Figure 1). The outer carton and immediate container labels contain warnings that the product is for topical use only. However, in this case, it appears that these warnings were missed, or “topical” may have been misunderstood as including the eye. We have communicated with the US Food and Drug Administration (FDA) about the packaging.



Figure 1. Bottle of clotrimazole 1% topical solution mistaken as eye drops bottle.



Homeopathic public hearing. The US Food and Drug Administration (FDA) has announced that it will hold a public meeting April 20-21 in Silver Spring, MD to obtain information and comments from stakeholders about the current use of human products labeled as homeopathic, as well as the Agency's regulatory framework for such products. These products include prescription drugs, biological products, and over-the-counter (OTC) drugs labeled as homeopathic. FDA is seeking participants for the public hearing and written comments from all interested parties, including, but not limited to, consumers, patients, caregivers, healthcare professionals, patient groups, and industry. For additional information and specific questions FDA is seeking input on, visit: <https://federalregister.gov/a/2015-07018>.

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Wrong vaccine and dose errors related to labeling and packaging

- Reduce the risk of look-alike vaccine mix-ups by purchasing vaccine products from different manufacturers so they do not look as similar.*
- Store vaccines with similar packaging or names on different refrigerator or freezer shelves to lessen the risk of errors.*
- Unless the vaccine is prepared in front of the patient and administered immediately, vaccines prepared in syringes must be labeled. *Peel-off* labels to use for this purpose may be available on some, but not all, manufacturer's vaccine vials. So it is difficult to standardize a process that includes them. The *peel-off* labels can also be used to document administration of a vaccine on vaccination records.*

Errors related to unsafe vaccine storage

- Consult the CDC Vaccine Storage and Handling Toolkit to ensure the use of proper vaccine storage units and equipment, temperature ranges, temperature monitoring, placement of vaccines in storage units, and recommended actions. This will help to minimize conditions that could compromise proper handling.¹²
- Purchase refrigeration and freezer units large enough to store and organize labeled stock.
- 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.
- Do not store vaccines with similar labels, names, abbreviations, or overlapping components (e.g., DTaP, DT, Tdap, Td) immediately next to each other or on the same shelf.*
- Separate the storage areas of pediatric and adult formulations of vaccines, and affix auxiliary labels to the vaccines and/or storage areas to draw attention to the specific ages for these vaccines.*
- Label the specific locations where vaccines are stored to facilitate correct, age-specific selection and to remind staff to combine the contents of vials as indicated. Examples of vaccine labels for storage areas are provided by the CDC.¹³
- Do **not** draw a single vaccine or batches of vaccines into syringes in advance of immunization clinics. Draw up vaccines only at the time of administration. As a safer alternative, use commercially available, prefilled and labeled syringes of vaccines from manufacturers whenever possible.
- If not using manufacturer's prefilled syringes in settings with pharmacy services, the pharmacy should prepare each vaccine in a clearly labeled syringe and dispense it for immediate administration when possible. If vaccines are prepared outside of the pharmacy, each dose should be prepared immediately prior to administration.*
- Although predrawn syringes are discouraged, a limited amount of vaccine may be drawn into syringes in advance for large immunization clinics if:¹²
 - Only one type of vaccine is being administered (or separate vaccine administration stations have been set up for each vaccine).
 - The vaccines are transported at the proper temperatures in the original packaging.
 - The vaccines are drawn up onsite, not offsite hours ahead of time.
 - Each clinician draws up only 10 doses or fewer from the multiple-dose vial, and each syringe is individually labeled.
 - The vaccines are maintained at proper temperatures that are monitored.

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Special Announcements

ISMP webinars

Join us on **April 30** for *The Human Dimension: When Being Human Gets in the Way of Medication Safety*. While the importance of designing reliable systems in healthcare should not be understated, viewing a mishap from the sharp end, at the human contribution to error, is critical—and interesting! During this webinar, a model of the brain's information processing system will be presented, along with the perceptual and cognitive tendencies that influence behavior, including change bias, inattentional blindness, normalcy bias, and others. The focus of the program will be on the conditions, both human and system, that degrade human performance, and strategies to reduce their impact on medication safety.

Join us on **May 27** for *Expanding Barcode Medication Administration: Making a Difference in the Emergency Department (ED) and Other Outpatient Settings*. Despite widespread adoption of barcode medication administration in hospitals, the safety benefits of this technology have not been as quickly adopted in many associated outpatient clinical locations, such as the ED, oncology clinics, and dialysis locations, where a large number of high-alert medications are administered. Our faculty will provide an inside look at the implementation of bedside barcode scanning in clinical areas once thought to be "off limits" for this type of technology.

For details, visit: www.ismp.org/sc?id=349.

Unique 2-day program

Attend one of the ISMP Medication Safety **INTENSIVE** workshops being held in 2015: **Indianapolis** on April 16-17; **Bellevue (near Seattle)** on September 17-18; and **New Orleans** on December 4-5. This workshop provides hands-on experiences with risk assessment, event investigation, error analysis, error-reduction strategies, measuring effectiveness, and more! For details, visit: www.ismp.org/educational/MSI.

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- ☐ Patient flow is monitored to avoid preparation of unneeded doses.
- ☐ Unused doses are discarded at the end of the workday.

Administration of an expired drug

- Check for expired vaccines weekly and when vaccines are removed from stock. Rotate the stock based on the expiration date to prevent unnecessary waste by placing vaccines first to expire in the front.
- Be aware of the short shelf life of live, attenuated influenza vaccine and implement measures to avoid administering an expired vaccine.
- 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.
- If an expired vaccine has been administered in error, revaccination with a valid dose is advised.¹⁴

Involve the patient in the verification process

- Provide all patients, parents, or legal guardians with a VIS in their native language prior to vaccination. Time to read the VIS *before* vaccination should be provided. Document in the patient's record or profile the publication date of the VIS and the date it was given to the patient, parent, or guardian.*
- Link the VIS (in the most predominant languages of the population served) to the electronic MAR or vaccination record so they are readily accessible.
- Hold discussions with patients, parents, or legal guardians about the vaccines being administered and answer any questions. The VISs are not a substitute for direct conversation between the provider and patient regarding the risks and benefits of vaccination.
- Ask patients or parents to participate in the verification process prior to vaccine administration by reading the VIS and verifying that the patient is within the specific ages for the intended vaccine, and by simultaneously comparing the name of the vaccine on the VIS to the vaccine name stated by the clinician and listed on the vaccine label. Immunization records and/or vaccine logs in which the vaccine name, dose, lot number, and expiration date have been recorded immediately before vaccination can also be verified by the patient or parent as the information on the vaccine label is read aloud by the clinician.*
- Remind parents that a fever in young children may occur after vaccination, but the CDC Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics do **not** recommend the *prophylactic* use of an analgesic/antipyretic medication such as acetaminophen before or at the time of vaccination.¹⁵
- Provide all patients, parents, or legal guardians with an up-to-date, completed vaccine record or log after the vaccination.*

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