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ISMP

Nurse AdviseERR®

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 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). In the April 2015 newsletter, we published **Part 1** of a 2-year analysis of nearly 1,000 reports submitted to the VERP. From that analysis, the vaccines involved in errors most frequently reported included the following, in descending order:

- Influenza (IIV3, IIV4, RIV3, ccIIV3, 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)

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
- 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

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SAFETY wires

Feeding tube connector changeover delayed again. The Global Enteral Device Supplier Association (GEDSA) is the industry group that is overseeing the North American transition to a new connector standard for feeding tubes and associated equipment. GEDSA has announced a delay in implementation of the new system because some manufacturers are not ready to distribute syringes with the new connectors. Syringes with ENFit tips are critical for the introduction of feeding tubes with the ENFit connectors and must be available to provide appropriate therapy for the tube-fed patient.

Since the changeover impacts the entire enteral feeding system across all healthcare settings, a careful and methodical transition to new, safer connectors is recommended over the course of 2015 and 2016. Administration sets with an ENFit connector and transition connector have already begun to arrive in hospitals this

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Final Survey about 2014-2015 Targeted Best Practices

ISMP is repeating, for the final time, a short survey to get a general sense of progress in the implementation of the ***2014-2015 Targeted Medication Safety Best Practices for Hospitals***, before the 2016-2017 Best Practices are identified and released. We would appreciate your participation regardless of whether you have or have not implemented any or all of the practices. You can take the survey by visiting: www.surveymonkey.com/r/TMSBP2015. The survey will be open until **July 8, 2015**. For a description of the Targeted Best Practices, visit: www.ismp.org/sc?id=417. We sincerely appreciate your participation!

Baxter

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- 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—vaccine given to wrong sibling

In **Part 2**, 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 **blue**, 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 birth date (if the patient or parent is available) and referencing the patient's health record, immunization record, and/or medication administration record (MAR). Also, compare the patient's current age with information on the applicable immunization schedule and Vaccine Information Statement (VIS) from the Centers for Disease Control and Prevention (CDC).

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 birth date) 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 the patient's health record and vaccination record to avoid omissions and/or duplicate vaccine doses. If possible, build an alert into the 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.[3] If possible, link the immunization schedule to an 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.[3]*
- 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.[3]*

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quarter. Unfortunately, the scheduled release for enteral-specific syringes with an ENFit tip and enteral feeding tubes with ENFit connectors is delayed until the first quarter of 2016. An article devoted to implementation of ENFit connectors appeared in the April 9, 2015 issue of our acute care newsletter and can be found on our website at: www.ismp.org/sc?id=534. More information on the transition is available at: www.ismp.org/sc?id=530.

No need for line numbering. A hospital pharmacist reported at least three instances in which nurses had administered the wrong dose of insulin when using a supplemental regular insulin coverage scale. A root cause of the error was the numbering system that Meditech, an electronic health record (EHR) and e-prescribing system vendor, had programmed into a "protocol" field. Sometimes nurses have misunderstood the line numbers (1 through 7) of the protocol (**Figure 1**) as the dose of insulin to administer.

Protocol

	Condition	Dose/Route	Instruction
1	Less than 70 mg/dl		Begin Hypoglycemia
2	70-149 mg/dl	0 Units	
3	150-199 mg/dl	2 Units	
4	200-249 mg/dl	4 Units	
5	250-299 mg/dl	7 Units	
6	300-349 mg/dl	10 Units	
7	Greater than 349 mg/dl	12 Units	And Call Provider

Figure 1. No need to number each line. The line numbers have been mistaken as the dose of insulin corresponding to the blood glucose levels.

So, instead of giving 10 units of insulin for a glucose level of 310 mg/dL, as noted on line number 6, the nurse gave 6 units of insulin. The actual dose is listed in the third column under Dose/Route.

Similar confusion with handwritten orders that were numbered has been reported (**Figure 2**). In another case, an order for 2 million units of penicillin G IV was preceded by the number 1 followed by a decimal point, and the dose was misinterpreted as 1.2 mil-

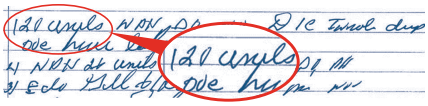

Figure 2. These three orders are numbered. The first numbered order was intended to say, "20 units NPH sq now. D/C insulin drip one hour later." But the numbered order led to misinterpretation as "120 units NPH…"

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- For frequently administered vaccines, establish standard order sets or protocols, which include:[4]*
  - ☐ The full generic name, brand name (if applicable), and standard abbreviation.[5]
  - ☐ 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. When pharmacists work directly in patient care areas, significant reductions in vaccine errors, invalid vaccine doses, and missed opportunities to vaccinate have been documented.[6]*
- Implement a "universal birth dose policy" to ensure that every newborn receives the first dose of HepB vaccine at birth, or no later than at discharge from the hospital.[7] Establish a reliable system of informing pediatricians or primary care physicians about a birth dose of HepB administered (or not) to a newborn.

Wrong route errors caused by unfamiliarity with the vaccine

- Post a quick reference for clinicians to verify the route of administration for all vaccines. An excellent chart is available from the Immunization Action Coalition (IAC).[8]
- Highlight the route of administration on MARs by using boldface type.

Errors with combination vaccines or vaccines with diluents

- On order sets, MARs, 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.
- Establish a process to keep two-component vaccines together, and to keep diluents and their corresponding vaccines together if storage requirements do not differ.
- 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. Documentation of actual vaccine administration should occur *immediately* as part of the administration process, along with the injection site location.*
- 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

- Differentiate the appearance of similar vaccine names on computer screens and MARs by highlighting dissimilarities and including full product names,

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lion units. Numbering orders adds to the potential for a medication error. As in this case, it's simply not necessary. Chances are, there are other e-prescribing and EHR systems that are set up the same way.

If possible, work with your vendor to remove numbers that may interfere with order clarity. Also avoid listing a numerical dose before a drug name to reduce confusion.

PCA basal infusion overdose. A physician prescribed patient-controlled analgesia (PCA) for a postoperative patient using **HYDRO**morphone demand doses of 0.3 mg, a lockout interval of 10 minutes, and a basal infusion of 1.5 mg per hour. The new order was entered on the medication administration record (MAR), but the basal infusion was misread as 15 mg/hour and, thus, entered incorrectly. The original order was used as a reference when first programming the pump, so the correct basal dose of 1.5 mg was programmed. Then, after the patient ambulated to the bathroom, the pump was not plugged back into the electrical socket. The pump ran out of battery power, and instead of plugging the pump in, a new pump was used. This time, the MAR was used to guide the programming, and the pump was set to deliver 15 mg, not 1.5 mg, of **HYDRO**morphone each hour. An hour later, the patient was found unresponsive. He was given naloxone and transferred to a critical care unit, where he required another dose of naloxone and recovered.

Despite the transcription error that resulted in entering a basal dose of 15 mg/hour instead of 1.5 mg/hour on the MAR, use of a smart pump with dose error-reduction software (DERS) would have alerted the nurse to the error while programming the pump. In fact, a basal dose of 15 mg/hour should result in a hard stop without the ability to override the warning. An independent double check of the PCA settings also may have caught the error. Because the syringe of **HYDRO**morphone was obtained from an automated dispensing cabinet, there was no pharmacy label listing the patient-specific basal dose of 1.5 mg/hour for reference.

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starting with the brand name (if applicable) first, followed by the generic name, especially for multi-component vaccines (e.g., **PENTACEL** [DTap-IPV/Hib]).*

- 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.[8] 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.

Wrong vaccine and dose errors related to labeling and packaging

- In hospitals and birthing centers, separate newborn medications from those typically used for mothers in perinatal areas.
- Whenever possible, administer infant medications in an area that is separate from where medications are administered to the mother.*
- Store vaccines with similar packaging or names on different refrigerator 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.[9] This will help to minimize conditions that could compromise proper handling.
- 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. Examples of vaccine labels for storage areas are provided by the CDC.[10]
- 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 hospitals, 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 in a syringe immediately prior to administration.*

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Basal infusions are not recommended in opioid-naïve patients. (It is uncertain if this patient was opioid-tolerant, but if not, even a 1.5 mg dose per hour would likely be enough to cause serious problems, given its equivalence to more than 10 mg of morphine per hour.) Further, it appears the patient was not being monitored as recommended by the Anesthesia Patient Safety Foundation (APSF) using continuous electronic monitoring of oxygenation (pulse oximetry, monitored from a central location if possible) and intermittent nurse assessments. Other modalities that measure ventilation and airflow adequacy (e.g., capnography) should be employed for patients who need supplemental oxygen to maintain

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Special Announcements

ISMP webinars

Join us on **June 24** for our ***2015 Update on The Joint Commission Medication-Related Standards***. Learn about the most troublesome Medication Management Standards and National Patient Safety Goals along with successful approaches taken by healthcare organizations to accomplish the intent of these Standards. A second presenter will provide personal insight into the Standards, based on a recent Joint Commission survey at a large, nonprofit, teaching hospital. The speaker will share opportunities at both the pharmacy and health-system level.

Join us on **July 30** for ***Missed Safety Opportunities with Subcutaneous Insulin: Addressing the Often Unknown Safety Challenges with Insulin***. A 2014 ISMP survey suggests that pharmacists and nurses believe hospitalized patients are more vulnerable to errors with subcutaneous insulin than errors with any other high-alert medication. Join us as we discuss standardizing basal/bolus insulin doses, managing overlooked risks associated with prescribing, dispensing, and administering subcutaneous insulin, and challenges with patient assessment, education, and adherence.

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

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- Although predrawn syringes are discouraged, a limited amount of vaccines may be drawn into syringes in advance for large immunization clinics if:[9]
  - ☐ 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 vials, and each syringe is individually labeled.
  - ☐ The vaccines are maintained at proper temperatures that are monitored.
  - ☐ 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

- 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 units and 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.[11]

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. In the patient's record, document 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.[12]

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acceptable oxygen saturation levels. Nurses should also be educated regarding safe dose ranges with the opioids used for PCA. Finally, use of a preprinted order set may help guide an appropriate dosing regimen for PCA.

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