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ISMP

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

ISMP National Vaccine Errors Reporting Program
Part II: *Preparing for immunization activities and campaigns*

Vaccination ranks high among the greatest public health achievements of the twentieth century. However, analysis of 575 vaccine errors submitted to the ISMP National Vaccine Errors Reporting Program (ISMP VERP) in 2017, which appeared in our June 14, 2018 newsletter (**Part I**, www.ismp.org/node/1090), suggests that vaccine errors continue to occur, potentially undermining the protection immunization provides against serious diseases. Although we have learned important information from the error reports submitted to the ISMP VERP, analysis of the 2017 data differs little from previous years' analyses. Overall, the vaccines involved in the most frequently reported errors have not changed since 2012 and include DTaP, Tdap, DTaP-IPV, DTaP-IPV/Hib, HepA, HepB, influenza virus vaccines, MMRV, and 9vHPV. Furthermore, these errors occurred for many of the same reasons previously noted during analysis of the ISMP VERP data, particularly:

Product-related contributing factors

- Age-dependent formulations of the same vaccine
- Similar brand and generic names, abbreviations, and container labels/packaging
- Conjugate antigen listed on labels mistaken as the target vaccine name

Knowledge and information-related contributing factors

- Unfamiliarity with the indicated ages, dosing, and intervals
- Unfamiliarity with mixing and preparing the vaccines
- Unfamiliarity with vaccine schedules, including individualized catch-up schedules
- Incomplete or confusing vaccination history in a state or local vaccine registry

Practice-related contributing factors

- Failure to verify the patient's age before administration
- Failure to check the chart and vaccine registry for date of prior vaccination
- Failure to document vaccination in the medical record and/or vaccine registry
- Miscommunication of vaccine orders and ambiguous due dates

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Global regulators and safety advocates meet about drug container labeling and packaging

A global summit for regulators on drug container labeling and packaging safety took place on June 19 and 20, 2018, at the US Food and Drug Administration (FDA) White Oak (Silver Spring) campus in MD. The event was co-sponsored by FDA and the International Medication Safety Network (IMSN), an alliance of medication safety organizations and advocates from over 20 countries. The meeting brought together regulators, FDA staff, IMSN members, and invited speakers. The World Health Organization (WHO) was one of the attendees at the meeting, which aligned with the WHO's current Global Patient Safety Challenge: *Medication Without Harm*. The meeting was co-chaired by FDA's Lubna Merchant, Deputy Director of the Office of Medication Error Prevention and Risk Management, and Acting Director of the Division of Medication Error Prevention and Analysis; along with Michael Cohen, chairperson of the IMSN and ISMP president.

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SAFETY briefs

Nucala 100 mg vial has significant overfill. NUCALA (mepolizumab) is a biologic agent used as an add-on maintenance treatment for adult patients with severe eosinophilic asthma. The recommended dose for asthma is 100 mg administered once every 4 weeks by subcutaneous injection into the upper arm, thigh, or abdomen. Some healthcare practitioners have been confused by the vial label, which states "100 mg/vial." Healthcare professionals generally expect that the amount of drug listed on the label is the amount contained in the vial. However, each vial of Nucala contains approximately 144 mg of the drug, which includes overfill to facilitate dose preparation (**Figure 1**). Such confusion could lead to an unintentional overdose of the medication if the entire amount in the vial is drawn into a syringe for a 100 mg dose.

Figure 1. Label on Nucala states "100 mg/vial," even though each vial actually contains 144 mg of the drug.

The Nucala preparation instructions mention that each vial of mepolizumab 100 mg should be reconstituted with 1.2 mL of Sterile Water for Injection, resulting in a final concentration of 100 mg/mL. The recommended 100 mg dose would then be drawn up as 1 mL, with the overfill remaining in the vial. If practitioners believe the total contents of the vial holds just 100 mg, as the vial label prominently states, they might withdraw the full volume (e.g., 1 mL plus overfill).

The drug is only supplied in 100 mg vials; thus, the risk of overdose increases as the dose increases when multiple vials must be

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> Vaccine Part II—continued from page 1

- Preparation of vaccines for multiple patients at the same time
- Immunizing multiple patients in the same treatment room
- Unlabeled syringes

In **Part II** of this newsletter feature, we take all that we have learned about vaccine errors from the ISMP VERP between 2012 and 2017 and provide recommendations to help organizations prepare for immunization activities and vaccine campaigns in hospitals and clinic settings. While not inclusive of all preparations required for immunization activities and campaigns, the recommendations are responsive to the types of errors and contributing factors reported to the ISMP VERP. The recommendations include a list of educational topics and teaching points to cover with staff who will be administering vaccines (**pages 6-8**). The recommendations will also help facilities evaluate their vaccine practices and staff training programs, even if an immunization campaign is not being planned.

Protocols

- Examine the protocols (and/or standing orders) for vaccines that will be used during an immunization activity or campaign to confirm they include:
  - ☐ The full generic name, brand name (if applicable), and current standard abbreviation approved by the Centers for Disease Control and Prevention (CDC)
  - ☐ Indication and vaccine schedule for routine and catch-up vaccination
  - ☐ Criteria for screening patients for contraindications and precautions
  - ☐ A reminder to provide the most current Vaccine Information Statement (VIS) to patients or caregivers prior to immunization
  - ☐ Directions for preparing and administering the vaccine, including the dose, vials/containers to use, route of administration, and any special precautions
  - ☐ Details regarding what (e.g., lot number, expiration date), where (e.g., vaccination record, vaccine registries), and how to document vaccine administration and distribution of the VIS
  - ☐ An emergency protocol to follow if the patient develops an adverse reaction
  - ☐ Information about reporting adverse vaccine events
- The Immunization Action Coalition (IAC) (www.ismp.org/sc?id=310) and Defense Health Agency Immunization Healthcare Branch (www.ismp.org/ext/36) provide sample protocols/standing orders for most vaccines.

Drug Name Listings

- Verify that the brand names of vaccines are listed on computer screens and electronic medication administration records (eMARs).
- Review the way *Haemophilus influenzae* type b, meningococcal, and pneumococcal conjugate vaccines are listed on automated dispensing cabinet (ADC) screens, pharmacy labels, vaccination records, and eMARs, with a goal to reduce the risk of identifying the conjugate antigen (e.g., tetanus toxoid, diphtheria, meningococcal protein) as the targeted vaccine.

Treatment Areas

- If multiple patients (e.g., siblings, parent and child, groups) are likely to be immunized, structure the treatment area to allow separation of the patients into distinct areas so only one patient at a time is available in the immediate treatment area. This allows staff to prepare, administer, and document the vaccination of one patient, without the risk of administering the vaccine to the wrong patient.

Vaccine Storage

- Plan for safe storage of single component vaccines and any associated diluents, and two-component vaccines, during onsite and offsite immunization activities.
- If refrigeration is necessary, temperatures should be set between 36-46°F.
- Vaccine vials and syringes should be separated into bins or other containers according to vaccine type and formulation, and never stored together.

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used to prepare a dose. For example, doses as high as 300 mg every 4 weeks are prescribed for some patients. To prepare a 300 mg dose, withdrawing the full contents of 3 vials, each containing 144 mg, could supply a 432 mg dose if all the medication could be withdrawn from each vial. Although we have not received any reports of mepolizumab toxicity, the medication is known to cause adverse effects including headache, back pain, extremity pain, fatigue, and local site injection reactions in some patients. However, the manufacturer, GlaxoSmithKline, told us that Nucala was studied during clinical trials with single doses as high as 1,500 mg via the IV route of administration, with serious adverse events occurring at a rate similar to lower dose treatment groups and without evidence of dose-related toxicities.

We asked the manufacturer to revise the container labeling to reflect the contents of each vial, and to refer users to the package insert for preparation and dosing instructions. Pharmacies should ensure sterile preparation compounding instructions clearly state that only 1 mL (100 mg) should be withdrawn from the reconstituted vial to ensure the proper dose.

Change in rabies immune globulin concentration. Rabies immune globulin (human) (**HYPERRAB**) is a blood product derivative indicated for emergency rabies prophylaxis in patients who present with animal bites. We learned recently of a change in the concentration of this product, made by the US manufacturer, GRIFOLS. Previously, HyperRAB was provided in a concentration of 150 international units/mL, but this strength is now being phased out and replaced with a higher concentration of 300 international units/mL. Some of the 150 international units/mL product remains on the market and will not be recalled.

We asked the company why the change was made, and the answer provided was twofold: 1) There has been a manufacturing process change in which a solvent/detergent (S/D) process is no longer used; and 2) To enhance delivery, a higher concentration allows for more efficient wound infiltration (i.e., more of the immune globulin can be delivered to the affected area in less

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> Vaccine Part II—continued from page 2

- Adult and pediatric formulations of the same vaccine should be separated.
- Vaccines with similar names or abbreviations, or overlapping components (e.g., DTaP, DT, Tdap, Td) should not be stored in bins or containers next to each other.
- If both varicella-zoster immune globulin and the varicella virus vaccine will be available, store them far away from each other to help prevent a product selection error that might lead to the inadvertent administration of varicella virus vaccine to a pregnant woman instead of the varicella-zoster immune globulin.

Staffing and Training

- Staff the immunization activities or campaign with trained providers who have demonstrated competencies related to the vaccine(s) being administered and error-prevention strategies associated with the common error types. See **pages 6-8** for educational topics and teaching points, which are associated with frequently reported vaccine errors, to cover with staff who will be administering vaccines. Three contact hours of free continuing education associated with immunization best practices is also available from the CDC at: www.ismp.org/ext/45.
- When possible, plan to include a pharmacist on the immunization team. Significant reductions in vaccine errors, invalid vaccine doses, and missed opportunities to vaccinate have been documented when including pharmacists on the team.[1]
- Confirm that staff involved in the vaccine activities or campaigns know how to search the vaccine registry (if available), understand the information provided and its level of reliability, and how to document immunizations in the registry.

Reference Materials

- Gather important reference materials and make them easily accessible to staff who will be vaccinating patients. Examples may include:
  - ☐ CDC Advisory Committee on Immunization Practices (ACIP) *General Best Practice Guidelines for Immunization* (www.ismp.org/ext/37), particularly these tables:
    - 3-1: Recommended ages and intervals between vaccine doses (pp. 28-31)
    - 3-2: FDA-licensed combination vaccines (p. 32)
    - 4-1: Contraindications and precautions to commonly used vaccines (pp. 52-58)
    - 5-1: Emergent management of anaphylaxis in infants and children (pp. 79-80)
    - 6-1: Dose and route of administration for selected vaccines (pp. 98-99)
    - 6-2: Needle length and injection site of IM injections (pp. 100-101)
    - 7-1: Vaccine storage temperature recommendations (pp. 115-117)
  - ☐ CDC-approved vaccination abbreviations (www.ismp.org/sc?id=2866)
  - ☐ Immunization schedules (www.ismp.org/ext/38, www.ismp.org/ext/40)
  - ☐ Chart of vaccine doses, routes, sites, and needle sizes (www.ismp.org/sc?id=501)
  - ☐ Injection site maps (www.ismp.org/ext/41 [children], www.ismp.org/ext/42 [adults])
  - ☐ Vaccinations during pregnancy (www.ismp.org/ext/43)
  - ☐ Screening checklist for contraindications to vaccines (www.ismp.org/ext/44)

Dispensing Vaccines

- Plan to use commercially available, prefilled syringes of vaccines whenever possible.
- Investigate purchasing differing age-specific formulations of the same vaccine from different manufacturers to help distinguish them. However, stock and dispense just one brand of the hepatitis A vaccine and the hepatitis B vaccine (adult and pediatric/adolescent formulations from the same manufacturer have the same concentration, while vaccines from different manufacturers may have different concentrations [e.g., **ENGERIX-B** 20 mcg/mL, **RECOMBIVAX HB**, 10 mcg/mL]).
- When space permits, plan to affix auxiliary labels or highlight important label information with a marker for the following vaccine products prone to confusion:
  - ☐ Vaccines with similar names or components, to promote correct selection
  - ☐ Varicella virus vaccines, to avoid use during pregnancy
  - ☐ Vaccines prone to administration by the wrong route (e.g., influenza; rotavirus; measles, mumps, rubella; varicella; zoster; meningococcal vaccines), to draw attention to the correct route

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volume). Rabies immune globulin is used post-exposure by infiltration into the area around the wound(s) if anatomically possible. The recommended one-time dose is 20 international units/kg at the time of the first rabies vaccine dose or up to 7 days later. Any remaining volume after infiltration should be administered intramuscularly, away from the vaccine site.

HIGH-ALERT

Inpatient ketamine overdose with 503B compounded syringe. A patient was supposed to receive ketamine 10 mg as needed for pain. The patient's nurse removed a 503B outsourced prefilled ketamine syringe from an automated dispensing cabinet (ADC) to administer a dose. The ketamine was packaged in a 5 mL syringe prominently labeled as "Ketamine, 10 mg/mL." The total dose and total volume in the syringe can be found only in the smaller print under the highlighted text, outside the yellow background (**Figure 1**). Unfortunately, the nurse did not recognize the total volume in the syringe (5 mL) and the entire 50 mg amount was administered. Because of the 5-fold overdose, the patient became somnolent but, fortunately, recovered.

It was later identified that the way the 10 mg/mL concentration was highlighted in yellow on both the manufacturer's outer packaging and the syringe itself, led the nurse to believe that the total amount in the syringe was just 10 mg, which was the dose ordered for the patient. Currently, 503B outsourcers are not required to follow USP <7> labeling requirements to list the concentration as the total amount of drug per the total volume in the syringe, as is required by all commercial manufacturers. However, most practitioners have come to expect labeling that prominently displays the total amount of drug per total volume in the container. The ketamine error was discussed during a hospital-wide safety huddle, and a decision was made to alert all nursing staff about

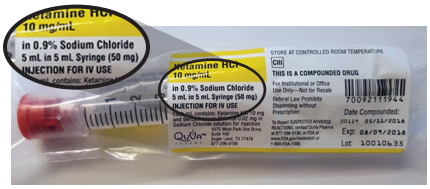

Figure 1. This syringe contains 50 mg of ketamine but was thought to hold just 10 mg given the prominent expression of the concentration as 10 mg/mL.

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- ☐ Vaccines with different age formulations, to help identify targeted ages
- ☐ Polysaccharide conjugate vaccines, to draw attention to the target vaccine's name
- ☐ Diluents supplied with vaccines, to ensure staff do not believe the diluent alone is the vaccine (see next main bullet)
- ☐ Two-component vaccines, to ensure that they are mixed together prior to administration (see next main bullet)

- Establish a process to keep two-component vaccines together, and to keep diluents and their corresponding vaccines together if storage requirements do not differ.
- If barcode technology is used prior to drug administration, plan to affix a barcode to dispensed vaccines or ensure that a manufacturer's barcode is easily scannable.
- Check for expired vaccines prior to the immunization activity or campaign. Implement measures to avoid dispensing an expired vaccine.

Verification of Immunization Status

- Confirm that policies and procedures require staff to verify the patient's current immunization status *prior* to vaccination by checking the patient's health record, vaccination record, and/or vaccine registry. Policies and procedures should direct staff to locate missing vaccination records whenever possible by contacting previous healthcare providers and reviewing vaccine registries. If records cannot be located, patients should be started on an age-appropriate vaccination schedule.

Patient Education

- Be prepared to provide a current VIS (if available) to patients, parents, or legal guardians prior to vaccination, in the primary languages of the target population. VISs are available on the CDC (www.ismp.org/ext/46) and IAC websites (www.immunize.org/vis/) and have been translated into more than 40 languages. The VISs can be printed or viewed on smart phones, tablets, or other mobile devices, and can be linked to the vaccination record or eMAR so they are readily available.
- Check your VIS stock to be sure you have the most current versions (e.g., recent updates in 2018 include anthrax, MMR, MMRV, rotavirus, varicella, and zoster).

Documentation of Vaccine Administration

- Examine the vaccine administration records that will be used during an immunization activity or campaign to confirm they:
  - ☐ Prompt for all information required to be documented (e.g., vaccine generic and brand name, date of vaccination, funding source [federal, state, private], route, site [if injection], lot number/expiration date of vials/diluents, manufacturer, publication date of the VIS and date provided to the patient/caregiver, vaccinator name)
  - ☐ Provide enough space to list full brand and generic vaccine names
- Determine who will document vaccine administration in available local or state vaccine registries, and establish a plan to ensure said documentation occurs.

Other

In response to prior VERP analyses, ISMP has provided recommendations to improve vaccine safety in the following *ISMP Medication Safety Alert!* newsletters:

- March 13, 2014: Recommendations for practitioners and manufacturers to address system-based causes of vaccine errors (www.ismp.org/node/592)
- May 22, 2014: Administering just the diluent or one of two vaccine components leaves patients unprotected (www.ismp.org/node/584)
- March 26, 2015: Recommendations for practitioners to prevent vaccine errors. Part 2: Analysis of ISMP Vaccine Errors Reporting Program (www.ismp.org/node/268)
- July 28, 2016: ISMP National Vaccine Errors Reporting Program. One in three vaccine errors associated with age-related factors (www.ismp.org/node/208)
- February 23, 2017: DTaP, LAIV, MCV4, PPSV23, HZV, 9vHPV… Alphabet soup vaccine abbreviations and acronyms lead to errors (www.ismp.org/node/226)

Reference: 1) Haas-Gehres A, Sebastian S, Lamberjack K. Impact of pharmacist integration in a pediatric primary care clinic on vaccination errors: a retrospective review. *J Am Pharm Assoc.* 2014;54(4):415-8.

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the labeling issue. An auxiliary label indicating the total dose is now also attached to the product.

This error is similar to previously reported errors described in our March 22, 2018 newsletter article, *FDA guidance needed to assure safe labeling practices by 503A and 503B compounders* (www.ismp.org/node/998). As noted in that article, the total quantity per total volume (above 1 mL) should be the primary and prominent expression on the principal display panel of the label, followed by quantity per mL in parentheses; for example, 50 mg per 5 mL (10 mg/mL). For safety reasons, we highly recommend purchasing and using only outsourced syringes that are labeled following USP <7> requirements. Unfortunately, the 503B pharmacies tell us that many hospitals have specifically requested the per mL expression, which is why they label the medications in this manner. They are concerned that, if they stopped labeling medications using a per mL designation, they would lose business to other outsourcers that continue to label this way. The US Food and Drug Administration (FDA) must step in and require the USP <7> standard so every outsourcer is safely labeling syringes the same way. ISMP has had ongoing communication with FDA in support of this position. For organizations that desire the per mL designation, this expression of strength is already on the label when USP <7> is followed although it is not the most prominent expression.

Assessment data workbook available to participants

The **Preliminary Comparative Data from the ISMP Medication Safety Self Assessment® for High-Alert Medications** workbook is now available to participants who submitted their findings to ISMP. The workbook contains aggregate data that can be used by participants to compare their results to the aggregate results of demographically similar facilities. To access the workbook and associated worksheets, log in to your account at: https://ismpassessments.org/high_alert/ and click on the links titled "Results Workbook" and "Results Worksheets" in the top right corner of the page.

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Participating regulators included:

- Brazilian Health Regulatory Agency (ANVISA)
- Mexico Federal Commission for the Protection against Sanitary Risks (COFEPRIS)
- European Medicines Agency (EMA – European Union)
- Health Canada
- Portugal National Authority of Medicines and Health Products (INFARMED)
- Netherlands Medicines Evaluation Board (MEB)
- United Kingdom Medicines & Healthcare products Regulatory Agency (MHRA)
- Saudi Food and Drug Authority (SFDA)
- US Food and Drug Administration (FDA)

To reduce overall harm related to medication errors, harmonization at the global level is necessary. Many product containers exhibit labeling and packaging issues that contribute to errors in various countries. Also, domestic drug manufacturing does not exist in many countries, so drugs are commonly imported, often with features that can result in safety issues. In the US, we have experienced drug shortages that have also led to temporary importation of products, some of which exhibit unfamiliar characteristics (e.g., absence of a barcode) that increase the risk of errors. Some international regulators have undertaken successful packaging and labeling changes that have reduced the risk of errors. The meeting provided an opportunity to share these experiences.

One of the goals of the meeting was to create a minimum set of best practices for labeling and packaging aimed at reducing medication errors. Another goal was to promote the use of technologies to reduce medication errors, which led to discussions regarding the need for an international barcode standard. Representatives from GS1, a global standards organization for barcodes, were among the invited speakers.

Participants agreed that guidelines are needed regarding the presentation of critical label information to deal with look-alike labels, noting that logos and highly stylized graphics detract from readability of the label. They also suggested review of existing guidelines and consideration of the following best practices related to drug labeling and packaging:

1) Include both the *per mL* and the *per container* quantity, not the *per mL* quantity alone, when presenting the concentration for injectables
2) Use metric units for products, and eliminate ratio expressions
3) Eliminate potentially error-prone abbreviations and dose designations on labels, such as U for units, IU for international units, or trailing zeros (e.g., 1.0) to express strength
4) Prominently display cautionary statements on carton and immediate container labels of neuromuscular blockers, potassium chloride concentrate injection, methotrexate, and other selected error-prone medications
5) Use contrasting label backgrounds for the printing on glass ampules, and recommend font size and label orientation, to improve readability
6) Physically link or integrate diluents with drugs that are powders
7) Increase the adoption of ready-to-use/ready-to-administer syringes, premixed IV solutions, unit-dose packaging, and other more efficient, safer packaging, while considering the overall cost of implementation
8) Develop product-specific world safety standards; for example, standard packaging for non-oncologic methotrexate to prevent accidental daily use and overdoses
9) Include barcodes on packages so they can be scanned at the bedside or other locations where medications are dispensed or administered by healthcare providers

A discussion was also held on the processing and sharing of medication error information by global pharmacovigilance (PV) centers. A recommendation was made for the PV centers to seek input from healthcare practitioners and medication/patient safety organizations such as those already established in many of the IMSN member countries. Finally, participants agreed to create a white paper to promulgate these best practices. Further meetings and discussions are planned, including a follow-up meeting this fall in Cascais, Portugal, during which industry participation will be sought.

Special Announcements

ISMP joins two national safety efforts

ISMP is taking part in two new cooperative efforts. First, ISMP is a member of the National Steering Committee for Patient Safety, which is charged with creating an action plan to guide patient safety efforts across the country in a cohesive, coordinated fashion. It is being led by the Institute for Healthcare Improvement (IHI) and co-chaired by the Agency for Healthcare Research and Quality (AHRQ). Next, the National Patient Safety Collaborative, organized by The Joint Commission (TJC), has been created to help prominent patient safety organizations join forces to collectively work on mutually identified safety concerns. TJC recently hosted the inaugural meeting of the group, whose other member organizations are the Association for the Advancement of Medical Instrumentation (AAMI), ECRI Institute, ISMP, and IHI.

Free Baxter-sponsored webinar

Join us on **July 19** for a **free** webinar, ***Choosing Safe Practices for IV Push Medication Use in Adults: Addressing Risk in Challenging Times***. Presenters will describe the current challenges with IV push medications that threaten safety and discuss best practices and error-reduction strategies identified in *ISMP's Safe Practice Guidelines for Adult IV Push Medications*. For details and to register, visit: www.ismp.org/ext/50.

To subscribe: www.ismp.org/node/10

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Staff Educational Topics and Teaching Points to Prevent Errors During Vaccine Administration

Topic or Teaching Points (Additional Resources)	Rationale	Details from the ISMP VERP
General Vaccine Knowledge		
CDC approved vaccine abbreviations (www.ismp.org/sc?id=2866; www.ismp.org/node/226)	There are dozens of similar vaccine abbreviations prone to confusion. Some abbreviations include specifiers (e.g., the numerals in IIV3 and IIV4 for inactivated influenza vaccine, trivalent and quadrivalent) to distinguish vaccines, which may be left off when prescribing and documenting administration.	The most frequent abbreviation mix-ups are between Tdap and DTaP; DT and Td; MMR and MMRV; PCV13 and PPSV23; Hib and HepB; HepA and HepB; and DTaP-HepB-IPV, DTaP-IPV/Hib, and DTaP-IPV.
Vaccines for the same targeted disease available in different age-specific formulations (www.ismp.org/node/208)	Choosing among age-specific formulations of vaccines intended to prevent the same diseases has led to errors, particularly if the vaccine label is not prominently marked with the targeted age groups.	Most frequent mix-ups are between pediatric and adult formulations of HepA and HepB, age-specific formulations of the influenza virus vaccine, and combination vaccines that target diphtheria, tetanus, and/or pertussis.
Differences between the various diphtheria, tetanus, and/or pertussis vaccines (www.ismp.org/ext/47)	Mix-ups are often caused by different age-dependent formulations, similar vaccine abbreviations, and confusion regarding vaccine components.	Most frequent mix-ups are between Tdap and DTaP, and DT and Td.
Combination vaccines (www.ismp.org/ext/37, p. 32)	Unfamiliarity with the components of combination vaccines has led to administration of a combination vaccine when only one component was needed, administration of a single vaccine already contained in a combination vaccine, or administration of an unintended component.	Examples of errors include administration of: Kinrix (DTaP-IPV) by staff who thought it contained HepB; Pediarix (DTaP-HepB-IPV) by staff who thought it contained Hib; Pentacel (DTaP-IPV/Hib) along with separate DTaP and IPV vaccinations; MMR and MMRV; and MMRV and Varivax.
Vaccines with a conjugate polysaccharide antigen (www.ismp.org/node/1090)	The conjugate antigen (i.e., tetanus toxoid, diphtheria, meningococcal) listed on some vaccine labels has been mistaken as the target vaccine name.	Wrong vaccine errors have occurred with the conjugate vaccines that protect against *Haemophilus* b (PedvaxHIB, Hiberix, ActHIB), meningococcal (Menveo), and pneumococcal (Prevnar 13) infections.
Two-component vaccines, and vaccines that require a special diluent (www.ismp.org/sc?id=364; www.ismp.org/node/584)	Diluents have been administered without the active vaccine, often due to similar cartons or vial labels. Or, the wrong diluent has been used, often due to the mistaken belief that vaccine diluents are interchangeable or substitutable. Only one of two-component vaccines has been administered, due to unfamiliarity with preparing these vaccines or the mistaken belief that the liquid vaccine component is a standard diluent.	Administering diluents alone has occurred most frequently with ActHIB, Varivax, and Zostavax. Administering one component of two-component vaccines has most frequently involved Pentacel and Menveo (and more recently, Shingrix). The wrong diluent (including a neuromuscular blocking agent) has been used to reconstitute MMR and MMRV vaccines.
Patient Screening Before Vaccination		
Verify the patient's immunization status and/or date of the prior vaccine dose by checking the health record, vaccination record, and vaccine registry, and/or contacting previous healthcare providers. If records cannot be located, start the patient on an age-appropriate vaccination schedule. (www.ismp.org/ext/48)	Failure to check the patient's record and/or vaccine registry has led to duplicate vaccines, omissions, wrong patient, and wrong interval errors. Except for the influenza virus vaccine, only electronic or written, dated records should be accepted as evidence of vaccination and prior doses, not self-reported doses. Uncertainty has been reported regarding whether to immunize patients who are unsure about prior vaccination.	Duplicate vaccines, omissions, and wrong patient errors are most frequent with vaccines that target diphtheria, tetanus, and/or pertussis; influenza virus vaccines; HepA; HepB; and MMRV. Wrong vaccine interval errors are most common with vaccines that target diphtheria, tetanus, and/or pertussis; HepB; HepA; and 9vHPV.

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Topic or Teaching Points (Additional Resources)	Rationale	Details from the ISMP VERP
Check the vaccination schedule and VIS for the recommended ages, and then verify the patient's age by asking the patient/caregiver for a full date of birth and comparing it to the health record, vaccine record, and/or eMAR. (www.ismp.org/ext/38, www.ismp.org/ext/39, www.ismp.org/ext/40)	Failure to check or verify the vaccination schedule and the patient's age has led to invalid or early doses, or missed opportunities to vaccinate.	Not verifying the patient's age contributes to about 1 in 5 errors in which a patient has been vaccinated with a vaccine, formulation, or dose not indicated at that time interval or age. While this type of error can happen with any vaccine, the most frequent reports involve administration of 9vHPV to children younger than 9 or older than 26.
Screen patients for contraindications (including pregnancy) and precautions, and to confirm the need and indication for vaccination. (www.ismp.org/ext/44; www.ismp.org/ext/43; www.ismp.org/ext/37, pp. 52-58)	Criteria and/or a checklist to follow help staff determine whether it is safe to administer a vaccine to a patient and to verify that vaccination is appropriate at that time. Staff must also know the next steps to take if a contraindication, precaution, or inconsistency with the indication is encountered during the screening process.	The most frequent problem has been forgetting to screen patients, particularly if a screening protocol or checklist is not provided and integrated into the vaccination process. Administration of a pregnancy-contraindicated vaccine (e.g., live, attenuated or live bacterial vaccine) to women who are pregnant or did not know to avoid pregnancy within 3 months of vaccination has also been reported.
Patient Education		
Provide all patients and/or caregivers with a VIS (paper or electronic media) in their primary language, with enough time to read it prior to vaccination (required by federal law for most vaccines). (www.immunize.org/vis/)	The VIS provides details regarding the vaccine indication, contraindications, age specifications, interval, risk and benefits, and what to do if a serious reaction occurs. The VIS can help inform patients and involve them in the verification process. Patients/caregivers who read the VIS can help prevent wrong age and wrong interval errors, and even wrong vaccine errors if staff state the vaccine name and show the patient the label on the syringe.	Frequent errors associated with the wrong vaccine, wrong age, and wrong interval have been reported. These errors might have been prevented if patients and/or caregivers had been given a VIS and time to read it prior to vaccination.
Vaccine Preparation (See General Vaccine Knowledge for teaching points associated with preparing vaccines with diluents and two-component vaccines)		
Check the expiration date on each prefilled syringe or vial prior to vaccine preparation or administration.	The potency of vaccines is not guaranteed after the expiration date. If an expired vaccine is administered in error, it must be repeated (e.g., at least 4 weeks later if a live virus vaccine; immediately if not a live virus vaccine). Expiration dates are prone to misinterpretation given their lack of format uniformity and difficult-to-read small font sizes. Diluents may have a different expiration date than the vaccine.	Failing to conduct a routine check for expired vaccines is a common contributing factor associated with administration of an expired vaccine. While this type of error occurred with many vaccine types, it was most frequent with Hib; DTaP; and the live, attenuated influenza virus vaccine, which has a short shelf life of about 18 weeks. Confusion regarding how the expiration date is expressed on the label has been reported.
Per CDC, do not draw a single vaccine or batches of vaccines into syringes well in advance of administration. As a safer alternative, use commercially available, prefilled and labeled syringes of vaccines from manufacturers whenever possible.	Filling a syringe before it is needed increases the risk of an error. Predrawn syringes may be unlabeled and difficult to tell apart from other syringes. Also, there is no data on the stability of vaccines stored in syringes filled by providers. Bacterial contamination and growth can occur in syringes that do not contain a bacteriostatic agent.	Several errors associated with possible loss of potency and/or contamination have been reported when vaccines were drawn into syringes up to 24 hours prior to administration. The predrawn syringes were also unlabeled. Some cases led to revaccination of clinic patients.
If prefilled syringes are not available, prepare each vaccine dose immediately prior to administration for one patient at a time, and label the container unless the vaccine is prepared in front of the patient and administered immediately.	Unlabeled syringes can lead to misidentification of the vaccine and administration to the wrong patient at the wrong age or by the wrong route. Preparing more than one vaccine at a time for multiple patients can lead to wrong patient errors. Patients should be taught to never accept immunizations from unlabeled syringes.	Dozens of wrong vaccine, wrong age, wrong patient, and wrong route errors have involved unlabeled syringes. In some cases, staff used colored stickers or markings to identify the syringes, or they banded the vial to the unlabeled syringe; however, errors still occurred.

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> Vaccine training—continued from page 7

Topic or Teaching Points (Additional Resources)	Rationale	Details from the ISMP VERP
Vaccine Administration		
If multiple adults and children are being vaccinated at the same time, separate them into distinct treatment areas when possible. Bring only one patient's vaccines into the treatment area at a time, each labeled with the vaccine name and patient's name.	Preparation of different vaccines or different age-formulations of the same vaccine for more than one patient has led to wrong patient errors, particularly when treating multiple patients in the same treatment area, and when vaccine syringes are unlabeled.	Examples of errors include administration of an adult influenza vaccine to children while their parents received the pediatric influenza vaccine, or sibling confusion in which one child received a vaccine intended for another child in the treatment area.
Verify the patient's identity using two unique identifiers (e.g., full name and full date of birth) before administering each vaccine.	Failure to verify the patient's identity has led to wrong patient errors, particularly when preparing vaccines in unlabeled syringes and administering vaccines to more than one patient in the same treatment area.	Preparation of different vaccines or different age-formulations of the same vaccine in unlabeled syringes for multiple siblings in the same treatment area was the most frequent contributing factor with wrong patient errors. Some of these errors involved administration of an unused vaccine intended for a previous patient.
Verify the vaccine's route of administration and recommended needle size prior to administration. (www.ismp.org/sc?id=501; www.ismp.org/ext/37, pp. 98-99)	Most vaccines are administered IM or subcutaneously, but a few are administered orally (rotavirus), intranasally (FluMist), intradermally (Fluzone Intradermal), or percutaneously (BCG). Except for the hepatitis B and rabies vaccines, vaccines given by the wrong route are often counted as valid.	Because many vaccines are administered IM, most of the wrong route errors involved administration of a subcutaneous (e.g., ZVL, IPV, MMR, VAR, MMRV) or oral (rotavirus) vaccine by the more common IM route. Tetanus vaccines have been administered intradermally after being mistaken as a tuberculin test (PPD).
When available, utilize barcode scanning technology.	Barcode scanning technology is an automated redundancy used to verify that the correct vaccine and dose are being administered to the correct patient.	Wrong vaccine errors have occurred when the barcode on a prefilled syringe was not scanned. Many reports involve complaints about the quality of the barcode and inability to scan it.
Documentation		
Prior to vaccine administration, document the vaccine's National Drug Code (NDC) number, lot number, and expiration date of each vial (e.g., both vials of two-component vaccines; both diluent vials and lyophilized powder vaccine vials) or syringe in the vaccination record, along with the publication date of the VIS and date it was given to the patient/caregiver. Documenting actual administration of the vaccine should always occur *after* it is given.	Documenting the NDC number, lot number, and expiration date of each vial or syringe on the patient's record immediately before administration allows for redundant reading of the label, which may help detect an expired vaccine or an error, particularly vaccines that require two components to be mixed together prior to administration. Requiring documentation of the VIS dates prior to administration can remind staff to distribute these statements before administration, which allows the patient to be involved in the verification process. Actual documentation of vaccine administration should only occur after the vaccine has been given.	Approximately 1 in 10 reports of vaccine errors are related to documentation errors in which accurate and all necessary information has not been documented in the patient's health record. These reports frequently reference missing documentation of prior vaccine administration. Examples of detecting errors when documenting NDC numbers, lot numbers, and expiration dates have been reported, most often associated with expired drugs, wrong vaccines, and wrong doses.
Document all vaccine administration in the local or state vaccine registry (if available). (www.ismp.org/ext/51)	Vaccine registries (immunization information systems) are confidential, community-wide, computerized databases that record vaccines administered by participating healthcare professionals. The registry helps consolidate vaccination records for patients and allows staff to assess patients' immunization status prior to vaccination. This reduces the risk of unnecessary vaccine doses or missed opportunities to vaccinate. Uncertainty has been reported regarding how to access the registry, and missing information has been a concern since documentation is not always mandatory.	Most reports were associated with incomplete information in the vaccine registry when it was queried prior to administration, resulting in duplicate doses and wrong interval errors. Some errors involved not checking the registry prior to administration, although lack of confidence in the registry was often cited. Some reports also involved entering the wrong search criteria or name into a registry, or misinterpreting the registry information. However, many reports noted how checking and documenting in the registry helped prevent or detect errors.