Objectives

1. Define the term high-alert medication as it related to community/ambulatory pharmacy practice.

2. Recall commonly used medications considered high alert in the community/ambulatory setting.

3. Discuss the types of events and contributing factors associated with errors involving vaccines, including those for COVID-19.

4. Discuss the adoption of proven prevention strategies designed to prevent or identify medication and vaccine errors in the community/ambulatory pharmacy setting before they reach a patient.
What is a High-Alert Medication?

— Small number of medications that have a high risk of causing injury if misused.

— Errors may or may not be more common with these than with other medications, but the consequences of errors may be devastating.

High-Alert Medications

Specific Medications

- CarbAMazepine
- EPINEPHrine, IM, subcutaneous
- Insulin U-500 (special emphasis)*
- LamoTRigine
- Methotrexate, oral and parenteral, nononcologic use (special emphasis)*
- Phenytin
- Valproic acid

Classes/Categories of Medications

- Anticoagulants (e.g., warfarin, low molecular weight heparin, unfractionated heparin)
- Direct oral anticoagulants and factor Xa inhibitors (e.g., dabigatran, rivaroxaban, apixaban, edoxaban)
- Direct thrombin inhibitors (e.g., dabigatran)

- Antithrombotic agents
- Oral targeted therapy and immunotherapy (e.g., Palbociclib [IBRANCE], imatinib [GLEEVEC], bosutinib [BOSULIF])
- Excludes hormonal therapy

- Immunosuppressant agents, oral and parenteral (e.g., azaTHIOprine, cycloSPORINE, tacrolimus)

- Insulins, all formulations and strengths (e.g., U-100, U-200, U-300, U-500)

- Medications contraindicated during pregnancy (e.g., bosentan, ISOretinoin)

- Moderate and minimal sedation agents, oral, for children (e.g., chloral hydrate, midazolam, ketamine [using the parenteral form])

- Opioids, all routes of administration (e.g., oral, sublingual, parenteral, transdermal), including liquid concentrates, immediate- and sustained-release formulations, and combination products with another drug

- Pediatric liquid medications that require measurement

- Sulfonylurea hypoglycemics, oral (e.g., chlorproPAMIDE, glimepiride, glipBURIDE, glipiZIDE, TOLbutamide)

*All oral and parenteral chemotherapy, and all insulins are considered high-alert medications. These specific medications have been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with these medications.
Deaths Associated with Medications Occurring Outside Healthcare Facilities

- The most frequent medications identified during analysis of the severe harm or death events included:
  - methadone
  - HYDROMorphone
  - methotrexate
  - fentanyl
  - insulin

Emergency Hospitalization for ADEs

Table 4: National Estimates of Medications Commonly Implicated in Emergency Hospitalizations for Adverse Drug Events among U.S. Adults, 1997–2012

<table>
<thead>
<tr>
<th>Medication</th>
<th>Annual National Estimates of Hospitalizations (N=2.2M)</th>
<th>Proportion of Emergency Department Visits Resulting in Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warfarin</td>
<td>33,171 (30.6–38.5)</td>
<td>62.2</td>
</tr>
<tr>
<td>Insulin</td>
<td>13,614 (13.4–18.6)</td>
<td>60.8</td>
</tr>
<tr>
<td>Opioids</td>
<td>13,242 (12.7–16.0)</td>
<td>78.0</td>
</tr>
<tr>
<td>Opioid agonists</td>
<td>13.6 (11–13.1)</td>
<td>13.8</td>
</tr>
<tr>
<td>ANTIDEPRESSANTS</td>
<td>4.103 (2.9–5.3)</td>
<td>13.8</td>
</tr>
<tr>
<td>Diuretics</td>
<td>3.983 (3.6–4.3)</td>
<td>51.2</td>
</tr>
<tr>
<td>Anticoagulant agents</td>
<td>3.903 (2.9–5.3)</td>
<td>35.7</td>
</tr>
<tr>
<td>Antihypertensive agents</td>
<td>3.903 (2.9–5.3)</td>
<td>35.7</td>
</tr>
<tr>
<td>MAOIs</td>
<td>3.903 (2.9–5.3)</td>
<td>35.7</td>
</tr>
<tr>
<td>Sedative-hypnotic agents</td>
<td>3.903 (2.9–5.3)</td>
<td>35.7</td>
</tr>
<tr>
<td>Antimicrobials</td>
<td>3.903 (2.9–5.3)</td>
<td>35.7</td>
</tr>
<tr>
<td>Diuretics</td>
<td>3.903 (2.9–5.3)</td>
<td>35.7</td>
</tr>
</tbody>
</table>


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Importantly Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Anticoagulants

- Warfarin
- Heparin
- Enoxaparin
- DOACs

Warfarin - Problems

*Dosing Errors*

- Directions are confusing (alternate day dosing)
- Changes in directions via telephone can cause confusion for some patients
- Multiple warfarin products with different names
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Anticoagulant Problems

- Failure to verify labs (e.g., INR)
- Food, drug, herbal interactions overlooked
- Concomitant use of anticoagulants
  - Warfarin and DOACs
  - Multiple DOACs

DOAC - Problems

- Unnecessary bridging when starting a DOAC
- Concomitant use of warfarin with a DOAC
- Use of more than one DOAC
- Confusion between starting and maintenance dosing
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Insulin

Insulin Problems in Pharmacy

- Multitude of insulin products
  - Similar packaging/labeling
  - Storage conditions

- Patient information
  - Blood glucose levels
  - A1C
  - Other medications
Lack of Patient Education with Insulin?

- Differentiating insulin types by touch and separate storage

- Changing concentrations of insulin
  - E.g., from 100 units/mL to 300 units/mL
  - Change in dosing interval in pen

- Sharing insulin pens
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Patient Education

Methotrexate

https://consumermedsafety.org/medication-safety-articles/item/847-teaching-sheets
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Methotrexate Error Case #1

- A pediatric patient was prescribed weekly dose (3 tablets of 2.5 mg twice daily on Thursdays) for psoriasis
  - Patient’s mother did not understand
  - Instead gave 3 tablets of 2.5 mg twice daily for a week

- The patient was hospitalized due to methotrexate toxicity

Best Practice 2

a) Use a weekly dosage regimen default for oral methotrexate in electronic systems when medication orders are entered.

**Issue:** Oral methotrexate for non-oncological indications administered daily, instead of weekly

！” METHOtrexate should usually be administered once weekly (unless indication is cancer chemotherapy). You are signing an order with a frequency OTHER THAN weekly. Please make sure this frequency is appropriate. (Alert # 1775)
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Best Practice 2

b) Require a hard stop verification of an appropriate oncologic indication for all daily oral methotrexate orders
   - For manual systems and electronic order entry systems that cannot provide a hard stop, clarify all daily orders for oral methotrexate if the patient does not have a documented oncologic diagnosis
   - Work with their software vendors and information technology departments

c) Provide specific patient and/or family education for all oral methotrexate discharge orders
   - Double-check all printed medication lists and discharge instructions to ensure that they indicate the correct dosage regimen prior to providing them to the patient

ConsumerMedSafety.org

PROTECT YOURSELF FROM MEDICATION ERRORS

https://consumermedsafety.org/medication-safety-articles/item/947-teaching-sheets
ISMP. 2020-2021 ISMP Targeted Medication Safety Best Practices for Hospitals,
https://www.ismp.org/guidelines/best-practices-hospitals
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Opioids

Causes for Adverse Drug Events with Opioids

- Improper prescribing, not caught by pharmacy
  - Multiple opioids, with multiple doses, via multiple routes, long-acting opioids

- Failure to consider patient comorbidities and current opioid use

- Lack of knowledge about equianalgesic potency among opioids

- Studies found that a total of 20.7% of all respondents reported having shared opioid medications with another person
  - Among those who had leftover opioids, 61.3% reported keeping them for future use

Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Opioid Naïve vs. Tolerant

— Opioid Naïve
  • Patients who do not meet the definition of opioid tolerant

— Opioid Tolerance
  • Patients who have been receiving DAILY, for one week or longer, at least one of the following:
    ◦ 60 mg morphine – 30 mg oral oxycodone – 8 mg HYDROmorphine

1: Food and Drug Administration.
http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/019813s033lbl.pdf

Fentanyl Patch Problems

— Inappropriate patient selection

— Improper disposal of patches

— Patient confusion about proper application
  • Removing old patches

— Awareness about a patch
  • Patients may not mention that they wear a patch
  • Patches are clear or translucent
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Problem

- FentaNYL patches (and long-acting opioids) have been inappropriately prescribed:
  - For opioid-naïve patients to treat acute pain.
- FentaNYL patches (and long-acting opioids) should only be used in opioid-tolerant patients for management of pain severe enough to around-the-clock, long-term opioid treatment.

Best Practice 15 [New]

- Verify and document a patient’s opioid status (naïve versus tolerant) and type of pain (acute versus chronic) before prescribing and dispensing extended-release and long-acting opioids

* Issue: Inappropriate use of opioids which can lead to patient harm and death.
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Goals for Best Practice 15

- Support appropriate prescribing and dispensing of extended-release and long-acting opioid medications
- Prevent the inappropriate use of fentaNYL patches to treat acute pain in patients who are opioid-naïve

Strategies

- High-Alert Medication List...only effective when combined with risk-reduction strategies
- Implement Risk-Reduction Strategies
  - Understand the causes of errors
  - Layer comprehensive strategies
- Communicate the List and Strategies
- Assess the Effectiveness of Strategies
A few specific strategies from self assessment if you want to mention while talking:

1) Systems used for clinical management and/or pharmacy dispensing systems incorporate prompts for selected medications, including specialty and HIGH-ALERT MEDICATIONS, to obtain, review, and verify critical patient information (e.g., allergies and reactions, weight, laboratory values, opioid tolerance for patients receiving long-acting opioids, indication for drug) necessary to confirm the appropriateness of the medication, dose, dosage form, and directions for use.

2) Criteria have been established for selected HIGH-ALERT MEDICATIONS (e.g., fentaNYL patch, methotrexate, insulin, opioids) or high-risk patient populations to trigger required medication counseling, and a system is in place to alert the pharmacist of this need when the patient picks up the prescription (e.g., bold alert on the bag, pharmacy computer-system alert).

3) Electronic HARD STOPS are in place at the point of sale to restrict completion of the sale until patient education has occurred for selected HIGH-ALERT MEDICATIONS or high-risk patient populations. Scoring Guideline: Choose Not Applicable if your pharmacy is a closed-door pharmacy.
Specific Strategies

- Incorporate prompts to obtain, review, and verify critical patient information
  - e.g., allergies and reactions, weight, laboratory values, opioid tolerance for patients receiving long-acting opioids, indication for drug

- Criteria to trigger required medication counseling, and a system is in place to alert the pharmacist of this need when the patient picks up the prescription
  - e.g., bold alert on the bag, pharmacy computer-system alert

- Electronic hard stops are in place at the point of sale to restrict completion of the sale until patient education has

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Safety Considerations for Minimizing Vaccination-Related Errors

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President
Institute for Safe Medication Practices
mcohen@ismp.org
ISMP Vaccine Error Reporting Program

- The Institute for Safe Medication Practices (ISMP) partnered with the California Department of Public Health (CDPH) to develop a web-based VAE surveillance tool, the Vaccine Error Reporting Program (VERP).

- VERP collects data on VAEs, including type and description of error, implicated vaccine, and provider information.

- VAEs are self-reported online at: http://verp.ismp.org.

- US providers notified of VERP by email in October of 2012, and the Immunization Action Coalition and ISMP notified subscribers via their newsletters in December 2012.

- De-identified reports are shared with FDA and CDC for entry into VAERS but do NOT replace mandatory reports for EUA vaccines.
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

VERP REPORTING

Vaccine Error Report Details

Submission ID: 9839  Submitted on: 6/17/2020  Printed: No
Submitted as PSO: No
1. Submission Type: Error occurred and reached the patient
2. Event Date: 6/10/2020
3. Vaccines Involved:

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Generic name</th>
<th>Manufacturer</th>
<th>Dosage</th>
<th>Lot</th>
<th>Exp. Date</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engerix-B</td>
<td>Hepatitis B Vaccine [Recombinant]</td>
<td>GlaxoSmithKline Biologicals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Event Description: [Edit/De-select]
   Two patients with similar names were scheduled at similar times; one on Tenolon A (FP), one on PEIN B (IZ). The IZ client called JCPH for check-in & registration over the phone with CSR. Staff notified that client is ready to complete a repeat portion of appointment and told to call client. PSN called correct IZ client and verified identity, gathered appointment information, and verified type of vaccine, administration location, possible side effects, and disease prevented by vaccination over the phone. PSN advised CSR and asked to have client reviewed. CSR reviewed an incorrect FP client with similar name in IZ clinic room. PSN entered room, reviewed possible vaccine reactions, client denied any questions, IZ administered. Client then informed the PSN that they are for STI testing. PSN discussed vaccine error, immunization history with client; client verbalizes they are okay with vaccine error. Client is from out-of-state and has no records with him. Informed FP APDN of the situation. FP APDN completed FP visit and discussed vaccine history again with client. Client requests another vaccine which was administered same day by FP PHN. Signed report form filled to obtain out of state IZ records.

5. Age of patient at time of event: 31 years
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Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Event Detail Questions

- Submission type (reached patient or not)
- Vaccine name (brand, generic)
- Event description
- Event type
- Contributing factors
- Patient age
- Facility/ Practice/ Practitioner type

Contributing Factors

Product-related contributing factors
- Age-dependent formulations of the same vaccine
- Similar naming, labeling, packaging
- Conjugate antigen mistaken as target vaccine name

Practice-related contributing factors
- Failure to verify patient’s age
- Failure to check chart or registry
- Failure to document administration
- Miscommunication of order or date due

Knowledge-related contributing factors
- Unfamiliarity with dosing, intervals, or indicated ages
- Unfamiliarity with mixing and preparing
- Unfamiliarity with schedules (including catch up)
- Incomplete vaccination history
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Problem

Analysis of recent flu vaccine errors can be used to prepare for COVID-19 vaccine campaigns. Risk factors to consider include:

- look-alike vaccine names, labels, and packaging
- unsegregated refrigerator storage
- mixing errors
- communication barriers
- not checking/documenting administration in the immunization information system (IIS)
- inability to use technologies during mass immunizations
- temperature excursions/expired vaccines
Accidental swap between influenza vaccine and COVID-19 vaccine


Mix-ups between the influenza (flu) vaccine and COVID-19 vaccines

Since the 2020-2021 influenza (flu) vaccines became available last week, the Institute for Safe Medication Practices (ISMP) has received 16 cases of accidental influenza and coronavirus disease COVID-19 (COVID-19) vaccine mix-ups. All reports were units of care dispensed to patients, with six of 16 reported to ISMP at The Ohio State University Wexner Medical Center. In three of the cases, patients received the influenza vaccine instead of the intended COVID-19 vaccine. All the events occurred in community pharmacies.

In the October 7, 2021, ISMP Medication Safety Alert (https://www.ismp.org/alert/1260), ISMP reviewed seven errors with vaccine switches and noted several possible mitigating factors. These include: the unique packaging for the vaccines; the existence of a legal exception for unlicensed personnel to administer influenza vaccines; and many of the errors were reported by community pharmacies about the packaging factors were not provided in many cases. However, the possible causative factors are being gleaned from the reports include the following:

- Increased demand and constraints in the vaccine. No review is done if the patient should receive the influenza or COVID-19 vaccine.
- The approved dose for the flu vaccine is 0.5 mL, while the approved dose for the COVID-19 vaccine is 1 mL, which can be confusing for pharmacy staff.
- The influenza vaccine is administered to patients younger than 65 years of age, while the COVID-19 vaccine is administered to patients 18 years of age and older.
- The influenza vaccine is a quadrivalent vaccine, while the COVID-19 vaccine is a monovalent vaccine.
- The influenza vaccine is administered to patients who are allergic to eggs, while the COVID-19 vaccine is not.

Staffing shortages. Because most healthcare providers are experiencing staffing shortages, it is possible that current vaccine providers may make mistakes and are allowed to vaccinate even when patients are scheduled for vaccination. For example, a healthcare provider who was working in a pharmacy for a few days may be asked to vaccinate patients on multiple days, which may be a contributing factor.
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Problem

— **Increased demand and coadministration of the vaccines.** Flu season is already a busy vaccination time for community pharmacies. And, with the approval of vaccine booster shots and the surge in COVID-19, vaccinators are stretched even more to accommodate demand. Also, the ability to administer the flu and COVID-19 vaccines during the same visit may be a causative factor.

— **Syringes near each other.** Some vaccinators have picked up a COVID-19 vaccine syringe instead of the flu vaccine syringe, which were right next to each other in the vaccination area. Bringing both vaccines into a patient vaccination area when they are not needed sets the vaccine provider up for a possible mix-up.

— **Unlabeled syringes.** In the US, many vaccine providers purchase the flu vaccine in manufacturer prefilled syringes, which are labeled. But COVID-19 vaccines are available in multiple-dose vials and must be prepared in a syringe for administration to patients. It is possible that these prepared COVID-19 vaccine syringes were not labeled. Also, COVID-19 vaccine doses may be prepared in an unlabeled syringe by one healthcare provider and administered by another; as a result, the person who administers the vaccine may not visually verify the empty vial if it remains with the person who prepared the dose.

Problem

— **Distractions.** After a vaccine mix-up, one vaccine provider told the patient that he had become distracted by their conversation. Interruptions and other distractions in a busy location (pharmacy in the US) could also lead to mix-ups.

— **Staffing shortages.** Because most healthcare providers are experiencing staffing shortages, it is possible that current vaccine providers are multi-tasking and hurried/rushed, even when patients are scheduled for vaccinations.
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Recommendations

— **Provide staffing support.** Schedule vaccines for a dedicated block of time each day and ensure adequate staffing. Explore the use of qualified and trained volunteers to assist in the vaccination process (as was done initially when the COVID-19 vaccines first became available) to relieve some of the stress associated with professional staffing shortages.

— **Label the syringes.** All individual syringes containing vaccines should be clearly labeled, by the manufacturer if prefilled syringes are used, or by the vaccine dose preparer if single- or multiple-dose vials are used. Be sure to provide vaccine preparers with any necessary labels to affix to the syringes to facilitate proper labeling.

— **Separate the vaccines.** Only bring the intended and labeled vaccine syringe(s) for one patient into the vaccination area.

— **Identify the patient and requested vaccine.** When the patient approaches the pharmacy counter to request a vaccination and immediately prior to vaccination, ask the patient to provide at least two patient identifiers—their full name and date of birth. Access to an electronic patient profile to assist with verifying the patient’s identity is recommended.

— Be sure to ask the patient which vaccine(s) they have requested. Talking with the patient about their vaccines ahead of administration can reduce the risk of errors. Be sure to verify the vaccine(s) the patient requests with the patient’s signed consent form(s).

— **Involve the patient/parent in the checking process.** Ask the patient/parent to read the syringe label (and vial if present) to confirm that it is the correct vaccine. Have the patient/parent and the vaccine provider read the label and expiration date aloud. At a minimum, the vaccine provider should tell the patient exactly which vaccine is being given before administration.

— **Document lot number/expiration date.** Document the vaccine lot number and expiration date prior to administration. (The vaccine lot number may signal a mix-up has occurred and prevent it from reaching a patient.) Then document vaccine administration afterward in the patient’s profile, on vaccination records, and via state or other immunization registries.

— **Scan the barcode.** During the production and/or pharmacist verification phase of the dispensing process, scan the vaccine barcode to verify that the correct product has been retrieved from the refrigerator or freezer. Ideally, barcode scanning should be available at the point of administration, even in outpatient vaccine clinics, to once again confirm that the correct vaccine had been retrieved and prepared.

— **Provide the intended vaccine.** If a mix-up occurs, apologize to the patient and provide the intended vaccine (since both the flu and COVID-19 vaccines can be given at the same visit), either before they leave the vaccination area or by asking the patient to return to the vaccination site.

— **Report vaccine errors.** Report all vaccine errors internally as well as to the appropriate agency (in the US it is the FDA Vaccine Adverse Event Reporting System [VAERS, https://vaers.hhs.gov/], which is mandatory for errors with the COVID-19 vaccines available under an EUA. ISMP also asks providers to report vaccine errors to the ISMP National Vaccine Errors Reporting Program [ISMP VERP, www.ismp.org/VERP]).
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Potential for adult and pediatric COVID-19 vaccine mix-ups

Adult Pfizer-BioNTech – 30 mcg/0.3 mL; Pediatric Pfizer-BioNTech 10 mcg/0.2 mL

Wrong Age Errors
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Age-dependent Formulations of the Same Vaccine

[Image of two influenza vaccine vials]

Issue: COVID-19 vaccine errors

- Dilution errors leading to under- or overdose of vaccine
- Mixing errors with 2-component vaccines (diluent instead of vaccine or wrong diluent such as sterile water)
- Air injected into vial instead of diluent
- Storage issues (unsegregated vaccine brands in refrigerator)
- Wrong vaccine given for dose 2 (not checking/documenting in immunization information system)
- Administration to wrong age group
- Waste of vaccine and not taking advantage of over-fill in vaccine vials
- Errors in scheduling second dose
- Look-alike vials (vaccine-monoclonal antibody mix-up)
- Shoulder injury related to vaccine administration (SIRVA)
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Preventing errors with COVID-19 vaccines

- Verify competency of preparers and vaccinators (many are volunteers)
- Dispense pharmacy prepared and labeled syringes when possible, or one person prepares and administers
- For mass vaccination, utilize a standard, organized process with independent double checks
- Maximize doses withdrawn from vials
- Identify/differentiate monoclonal antibodies from vaccines
- Separate vaccines in storage
- Plan for leftover vaccine
- Be prepared for allergic reactions
- Report vaccine errors and adverse reactions (US requires reporting to VAERS); additional reporting to ISMP is voluntary
- Utilize immunization information systems
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Extemporaneously Prepared Syringes

— Often not labeled and can result in errors
— Preparation should involve bar code scanning and labeling process.
— Independent double check
— Vial accompanying labelled syringe
— Use manufacturer-supplied prefilled syringes

https://www.ismp.org/covid-19-resources

FAQ for Optimizing COVID-19 Vaccine Preparation and Safety


https://www.usp.org/covid-19/vaccine-handling-toolkit

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Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

**COMMENTARY**

**Common COVID Vaccine Administration Errors to Watch For**

Sue A. Stoddard, MD, MPH, MSQA; Jennifer Bazzoli, MS; Christine L. Nelson, MD, MPH; Sarah Kist, MD, MPH; Katherine H. Shelly, MPH; Sarah Ruggiero-Staples, MD, MPH

April 8, 2021

In December 2020, the US Food and Drug Administration approved Emergent BioSolutions’ (EBC) for the Pfizer-BioNTech and Moderna COVID-19 vaccines. As of March 10, 2021, more than 180 million COVID-19 vaccine doses have been administered to people in the United States. As we work toward expanding COVID-19 vaccination further, however, we must take care to minimize errors in vaccine administration.

Proper vaccine administration is necessary to ensure vaccine effectiveness. Several initial vaccine-induced reactions are mild, self-limited, and do not require medical attention. However, some reactions can be severe enough to cause hospitalization or death. In addition, vaccine administration errors can lead to the administration of a vaccine that has not been properly stored or has expired.

Table: COVID-19 Vaccine Administration Error Incidence

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Example</th>
<th>Number of Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration</td>
<td>Subcutaneous administration</td>
<td>15% (12,390)</td>
</tr>
<tr>
<td></td>
<td>Administration at an incorrect location</td>
<td>10% (8,250)</td>
</tr>
<tr>
<td></td>
<td>Administration at an incorrect age</td>
<td>5% (4,125)</td>
</tr>
<tr>
<td></td>
<td>Administration of an incorrect product</td>
<td>2% (1,650)</td>
</tr>
<tr>
<td></td>
<td>Administration of an incorrect dose volume</td>
<td>0.5% (412)</td>
</tr>
<tr>
<td></td>
<td>Administration of an incorrect diluent</td>
<td>0.1% (82)</td>
</tr>
<tr>
<td></td>
<td>Administration of an incorrect needle</td>
<td>0.01% (8)</td>
</tr>
</tbody>
</table>

**COVID-19 Vaccine Administration Errors and Deviations**

A vaccine administrator must take precautions to ensure that the vaccine is used correctly and to prevent errors in the administration process. This is especially important when administering COVID-19 vaccines, as they are currently in short supply. To help minimize errors, community pharmacies should follow the guidelines outlined in the CDC’s recommendations for vaccine administration.

For all vaccine administration error types:
- Consult the CDC’s guidelines for proper vaccine administration.
- Be sure to follow the guidelines for proper storage and handling.
- Make sure the vaccine is stored at the correct temperature.
- Use the correct dose volume and diluent.
- Use the correct needle and syringe.
- Use the correct route of administration (i.e., subcutaneous, intramuscular).
- Be sure to follow the proper steps for injection techniques.
- Follow the CDC’s guidelines for proper disposal of needles and syringes.
- Keep records of all vaccine administration errors.

**COVID-19 Vaccine Administration Errors and Deviations**

Vaccine recommendations for COVID-19 vaccine administration errors and deviations

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Administration Error</th>
<th>General Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>Administration at an incorrect location</td>
<td>Consult the CDC’s guidelines for proper vaccine administration.</td>
</tr>
<tr>
<td></td>
<td>Administration at an incorrect age</td>
<td>Be sure to follow the guidelines for proper storage and handling.</td>
</tr>
<tr>
<td></td>
<td>Administration of an incorrect product</td>
<td>Use the correct dose volume and diluent.</td>
</tr>
<tr>
<td></td>
<td>Administration of an incorrect needle</td>
<td>Use the correct needle and syringe.</td>
</tr>
<tr>
<td></td>
<td>Administration of an incorrect route of administration</td>
<td>Use the correct route of administration (i.e., subcutaneous, intramuscular).</td>
</tr>
</tbody>
</table>

For all vaccine administration error types:
- Consult the CDC’s guidelines for proper vaccine administration.
- Be sure to follow the guidelines for proper storage and handling.
- Make sure the vaccine is stored at the correct temperature.
- Use the correct dose volume and diluent.
- Use the correct needle and syringe.
- Use the correct route of administration (i.e., subcutaneous, intramuscular).
- Be sure to follow the proper steps for injection techniques.
- Follow the CDC’s guidelines for proper disposal of needles and syringes.
- Keep records of all vaccine administration errors.

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Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Failure to Check Immunization Information Systems

— Immunization Information Systems (IIS)\(^1\)
  - Available in all 50 states
  - Managed by individual states
— No national organization that maintains vaccination records.\(^2\)

1. IAC. State information: Direct links to state immunization websites. 2019. Available at: http://www.immunize.org/states/
2. CDC. Vaccine information for Adults: How to locate your vaccination record. 2016. Available at: https://www.cdc.gov/vaccines/adults/vaccination-records.html

Non-Standard Expiration Date Expression

December 13, 2012 or December 12, 2013?

June 19, 2018 or June 18, 2019?
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

General Chapter -7- Labeling
CHANGE TO EXPIRATION DATE FORMAT

July 30, 2020

On July 30, 2020, USP published relevance to General Chapter -7- Labeling. To better address concerns such as patient safety and alignment with international labeling data formats, the standard calls for a 4-digit year format at the expiration date location. The updated format removes confusion and reduces potential errors that can occur when the expiration date is not clearly understood or presented. This decision was made to improve clarity on all drug and dietary supplement products the company supports, including pharmaceuticals. The new format was also updated following the 2019 annual USP General Chapter -7- revision. The new requirements have been given an official date of September 1, 2023.

The expiration date format was modified based on several considerations, including the following:

**Patient Safety Challenges**

- The new format is now followed by the following considerations, including:
  - A consistent format of year, month, and day to help prevent confusion between month and day.
  - A 4-digit year format to help healthcare workers, patients, and consumers distinguish between the year and the day.
  - The use of the term “for the month” or “at least until” to help minimize confusion.
  - The term “no expiration” to help focus on the new requirement when used to indicate the lack of an expiration date.

- The use of the term “for the month” or “at least until” to help minimize confusion.
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**SAFETY BRIEFS**

Administration of concentrated potassium chloride for injection during a code: Still deadly!

- The use of the term “for the month” or “at least until” to help minimize confusion.
- The term “no expiration” to help focus on the new requirement when used to indicate the lack of an expiration date.

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Conjugate Antigen versus Target Vaccine Name

A **conjugate vaccine** is a substance that is composed of a polysaccharide antigen fused (**conjugated**) to a carrier molecule. This enhances the stability and the effectiveness of the **vaccine**.
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Packaging Issue- RotaTeq vs. Rotarix

- Rotarix injected instead of given orally

Figure 1. Merck product, RotaTeq, is available as a liquid in a squeeze applicator.

Figure 2. Rotarix oral applicator with diluent for reconstitution. The reconstituted vaccine is redrawn into the applicator.

RotaTeq diluent in between other GSK vaccines that ARE injected

Pentacel
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Two Chamber Vial Used for Medications with Diluents

Lyophilized powder or vaccine component A

Liquid diluent or vaccine component B
Look-alike vials
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Recommendations

- Educate staff about the differences between Shingrix and Zostavax.
- Store the Shingrix lyophilized component and adjuvant suspension together to reduce the risk of using the wrong diluent.

<table>
<thead>
<tr>
<th>Key Differences</th>
<th>Zostavax</th>
<th>Shingrix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Type</td>
<td>Live attenuated</td>
<td>Inactivate recombinant adjuvanted</td>
</tr>
<tr>
<td>Age recommendation</td>
<td>60 years or older</td>
<td>50 years or older</td>
</tr>
<tr>
<td>Vaccine Schedule</td>
<td>1 dose, 0.65 mL</td>
<td>2 doses, 0.5 mL @ 0, 2-6 months</td>
</tr>
<tr>
<td>Administration Route</td>
<td>Subcutaneous</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Storage</td>
<td>Frozen, reconstituted</td>
<td>Refrigerated, reconstituted</td>
</tr>
</tbody>
</table>

Name or Abbreviation Confusion

- DTaP-Tdap
- Adacel (Tdap) - Daptacel (DTaP)
- Kinrix (DTaP/Polio) - Pediarix (DTaP/Polio/hepatitis B)
- HepB (virus) – Hib
- Hib -HBV
- HPV – HBV
- Varicella virus live vaccine – varicella zoster immune globulin (VZIG)
- Varivax – Zostavax
Position of Proper Name on Biologicals


- Inconsistent with all other drugs

- Patient safety issue with combination products

Chain Pharmacy
Insulin instead of influenza vaccine: Drug and vaccine storage

— October 2014 - St. Louis County Missouri occurred where five teachers received insulin instead of influenza vaccine (http://www.kctv5.com/story/26724632/teachers-seeking-flu-shots-instead-given-insulin).
— In 2007 case where a teacher in nearby Attleboro received insulin instead of flu vaccine.
— In another case, also in Holland, a patient died after insulin was given instead of influenza vaccine. (http://www.dutchnews.nl/news/archives/2009/11/pensioner_dies_after_wrong_ins.php).
— Four newborns died in Iraq after insulin given instead of hepatitis B vaccine (via chat function webinar for Uppsala Monitoring Center, October 21, 2020).
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Pharmacy Risk Assessments – Coming Soon

**Updated**

ISMP Medication Safety Self Assessment®

Community/Ambulatory Pharmacy

**New**

ISMP Medication Safety Self Assessment®

Specialty Pharmacy

Not Implemented  Partially Implemented  Fully Implemented

Assessment Dashboard – Sample
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Medication Safety Intensive (MSI) Workshops

Next Workshop: December 2–3, 2021

- 2-day virtual workshop
- 12.5 CE credit hours for nurses and pharmacists
- Pharmacists, nurses, physicians, risk managers, academicians

https://www.ismp.org/education/msi-workshops

Questions?

This activity is supported by Novartis, Name Creation and Regulatory Strategy.