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

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

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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.

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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.

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High-Alert Medications

Specific Medications
Car**BAM**azepine
EPINEPHrine, IM, subcutaneous
Insulin U-500 (special emphasis)*
Lamo**TRI**gine
Methotrexate, oral and parenteral, nononcologic use (special emphasis)*
Phenytoin
Valproic acid

*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.

Classes/Categories of Medications
Antithrombotic agents, oral and parenteral, including: • 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)
Chemotherapeutic agents • Oral and parenteral chemotherapy (e.g., capecitabine, cyclophosphamide) • Oral targeted therapy and immunotherapy (e.g., Palbociclib [**IBRANCE**], imatinib [**GLEEVEC**], bosutinib [**BOSULIF**]) • Excludes hormonal therapy
Immunosuppressant agents, oral and parenteral (e.g., aza**THIO**prine, cyclo**SPORINE**, tacrolimus)
Insulins, all formulations and strengths (e.g., U-100, U-200, U-300, U-500)
Medications contraindicated during pregnancy (e.g., bosentan, **ISO**tretinoin)
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., chlorpro**PAMIDE**, glimepiride, gly**BURIDE**, glipi**ZIDE**, **TOLBUT**amide)

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https://www.ismp.org/recommendations/high-alert-medications-community-ambulatory-list

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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

ISMP Canada. Medications Most Frequently Reported in Harm Incidents over the Past 5 Years (2015–2020). https://www.ismp-canada.org/download/safetyBulletins/2020/ISMPCSB2020-i11-Medications-Reported-Harm.pdf

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Emergency Hospitalization for ADEs

The NEW ENGLAND JOURNAL of MEDICINE

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SPECIAL ARTICLE

Emergency Hospitalizations for Adverse Drug Events in Older Americans

Daniel S. Budnitz, M.D., M.P.H., Maribeth C. Lovegrove, M.P.H., Nadine Shehab, Pharm.D., M.P.H., and Chesley L. Richards, M.D., M.P.H.

N Engl J Med 2011; 365:2002-2012 | November 24, 2011 | DOI: 10.1056/NEJMsa1103053

Abstract | Article | References | Citing Articles (633) | Letters | Metrics

Decreasing the number of preventable rehospitalizations by 20% by the end of 2013 is a goal of the $1 billion federal initiative Partnership for Patients, and the pursuit of this goal represents an opportunity to reduce harm to patients and reduce health care costs.[1,2] Adverse drug events are a direct consequence of clinical care and a key focus of the partnership.

Hospitalizations for adverse drug events are likely to increase as Americans live longer, have greater numbers of chronic conditions, and take more medications. Among adults 65 years of age or older, 40% take 5 to 9 medications and 18% take 10 or more.[3] Age-related physiological changes, a greater degree of frailty, a larger number of coexisting conditions, and polypharmacy have been associated with an increased risk of adverse events,[4,5] and older adults are nearly seven times as likely as younger persons to have adverse drug events that require hospitalization.[6]

Table 4. National Estimates of Medications Commonly Implicated in Emergency Hospitalizations for Adverse Drug Events in Older U.S. Adults, 2007–2009.*

Medication	Annual National Estimate of Hospitalizations (N = 99,628)		Proportion of Emergency Department Visits Resulting in Hospitalization
	no.	*% (95% CI)*	%
Most commonly implicated medications†			
Warfarin	33,171	33.3 (28.0–38.5)	46.2
Insulins	13,854	13.9 (9.8–18.0)	40.6
Oral antiplatelet agents	13,263‡	13.3 (7.5–19.1)	41.5
Oral hypoglycemic agents	10,656	10.7 (8.1–13.3)	51.8
Opioid analgesics	4,778	4.8 (3.5–6.1)	32.4
Antibiotics	4,205	4.2 (2.9–5.5)	18.3
Digoxin	3,465	3.5 (1.9–5.0)	80.5
Antineoplastic agents	3,329‡	3.3 (0.9–5.8)‡	51.5
Antiadrenergic agents	2,899	2.9 (2.1–3.7)	35.7
Renin–angiotensin inhibitors	2,870	2.9 (1.7–4.1)	32.6
Sedative or hypnotic agents	2,469	2.5 (1.6–3.3)	35.2
Anticonvulsants	1,653	1.7 (0.9–2.4)	40.0
Diuretics	1,071‡	1.1 (0.4–1.8)‡	42.4
High-risk or potentially inappropriate medications§			
HEDIS high-risk medications	1,207	1.2 (0.7–1.7)	20.7
Beers-criteria potentially inappropriate medications	6,607	6.6 (4.4–8.9)	42.0
Beers-criteria potentially inappropriate medications, excluding digoxin	3,170	3.2 (2.3–4.1)	27.6

Budnitz et al. Emergency Hospitalizations for Adverse Drug Events in Older Americans. N Engl J Med 2011; 365:2002-2012

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Anticoagulants

Warfarin
Heparin
Enoxaparin
DOACs

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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

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Anticoagulant Problems

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

ISMP. Duplicate oral anticoagulants. ISMP Medication Safety Alert! Community/Ambulatory edition. March 2018 Vol 17, No 3. 1

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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

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Insulin

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Insulin Problems in Pharmacy

- Multitude of insulin products
  - Similar packaging/labeling
  - Storage conditions
- Patient information
  - Blood glucose levels
  - A1C
  - Other medications

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ISMP. Complexity of insulin therapy has risen sharply in the past decade. ISMP Medication Safety Alert! Community/Ambulatory edition. Jan 2004 Vol 3, No 1. 1.

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Lack of Patient Education with Insulin?

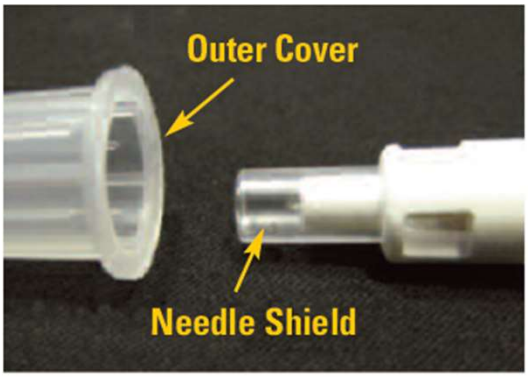
- Differentiating insulin types by touch and separate storage
- Changing concentrations of insulin
  - E.g., from 100 units/mL to 300 units/mL
  - Change in dosing interval in pen
- Sharing insulin pens

ISMP. Differentiating insulin types by touch and separate storage. ISMP Medication Safety Alert! Community/Ambulatory edition. Nov 2017 Vol 16, No 11. 2.
ISMP. Misuse of new insulin strengths . ISMP Medication Safety Alert! Community/Ambulatory edition. Sept 2016 Vol 16, No 9. 3.
ISMP. Insulin pens should not be shared between patients!. ISMP Medication Safety Alert! Community/Ambulatory edition. Jan 2012 Vol 11, No 1. 1.
ISMP. Tresiba U-200 won't allow dosing an odd number of insulin units.. ISMP Medication Safety Alert! Community/Ambulatory edition. Jan 2017 Vol 16, No 1. 1.

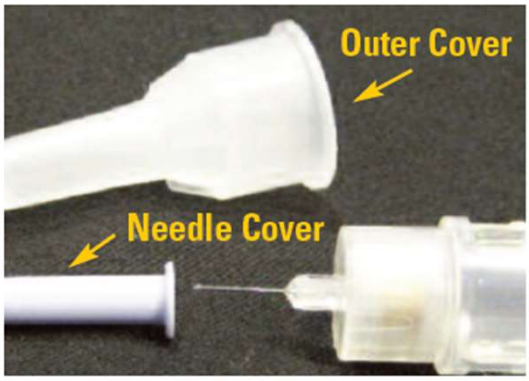
13

Insulin Pen Needles

Safety Pen Needle



Standard Pen Needle



ISMP. Alert! Severe hyperglycemia in patients incorrectly using insulin pens at home. ISMP Medication Safety Alert! Community/Ambulatory edition. Oct 2017 Vol 16, No 10. 1.

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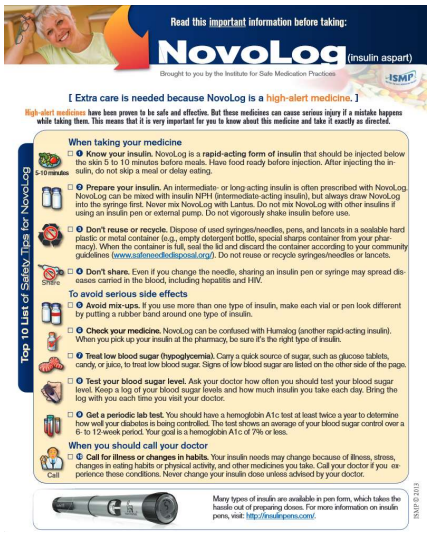
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Patient Education



Read this important information before taking:

NovoLog (insulin aspart)

Brought to you by the Institute for Safe Medication Practices

[Extra care is needed because NovoLog is a high-alert medicine.]

High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is very important for you to know about this medicine and take it exactly as directed.

Top 10 List of Safety Tips for NovoLog

When taking your medicine

- **Know your insulin.** NovoLog is a **rapid-acting form of insulin** that should be injected below the skin 5 to 10 minutes before meals. Have food ready before injection. After injecting the insulin, do not skip a meal or delay eating.
- **Prepare your insulin.** An intermediate- or long-acting insulin is often prescribed with NovoLog. NovoLog can be mixed with insulin NPH (intermediate-acting insulin), but always draw NovoLog into the syringe first. Never mix NovoLog with Lantus. Do not mix NovoLog with other insulins if using an insulin pen or external pump. Do not vigorously shake insulin before use.
- **Don't reuse or recycle.** Dispose of used syringes/needles, pens, and lancets in a sealable hard plastic or metal container (e.g., empty detergent bottle, special sharps container from your pharmacy). When the container is full, seal the lid and discard the container according to your community guidelines (www.safeneedledisposal.org/). Do not reuse or recycle syringes/needles or lancets.
- **Don't share.** Even if you change the needle, sharing an insulin pen or syringe may spread diseases carried in the blood, including hepatitis and HIV.

To avoid serious side effects

- **Avoid mix-ups.** If you use more than one type of insulin, make each vial or pen look different by putting a rubber band around one type of insulin.
- **Check your medicine.** NovoLog can be confused with Humalog (another rapid-acting insulin). When you pick up your insulin at the pharmacy, be sure it's the right type of insulin.
- **Treat low blood sugar (hypoglycemia).** Carry a quick source of sugar, such as glucose tablets, candy, or juice, to treat low blood sugar. Signs of low blood sugar are listed on the other side of the page.
- **Test your blood sugar level.** Ask your doctor how often you should test your blood sugar level. Keep a log of your blood sugar levels and how much insulin you take each day. Bring the log with you each time you visit your doctor.
- **Get a periodic lab test.** You should have a hemoglobin A1c test at least twice a year to determine how well your diabetes is being controlled. The test shows an average of your blood sugar control over a 6- to 12-week period. Your goal is a hemoglobin A1c of 7% or less.

When you should call your doctor

- **Call for illness or changes in habits.** Your insulin needs may change because of illness, stress, changes in eating habits or physical activity, and other medicines you take. Call your doctor if you experience these conditions. Never change your insulin dose unless advised by your doctor.

Many types of insulin are available in pen form, which takes the hassle out of preparing doses. For more information on insulin pens, visit: http://insulinpens.com/.

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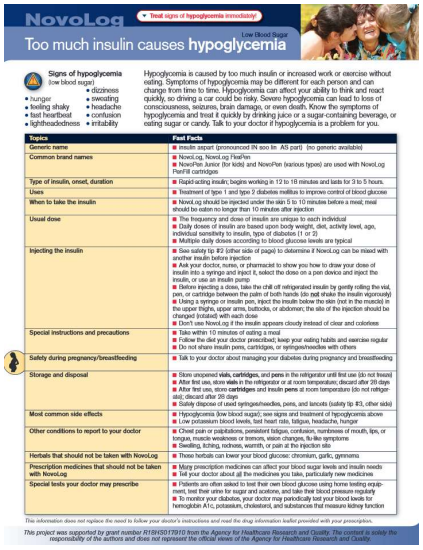

NovoLog — Treat signs of hypoglycemia immediately

Low Blood Sugar

Too much insulin causes hypoglycemia

Signs of hypoglycemia (low blood sugar)

- hunger
- feeling shaky
- fast heartbeat
- lightheadedness
- dizziness
- sweating
- headache
- confusion
- irritability

Hypoglycemia is caused by too much insulin or increased work or exercise without eating. Symptoms of hypoglycemia may be different for each person and can change from time to time. Hypoglycemia can affect your ability to think and react quickly, so driving a car could be risky. Severe hypoglycemia can lead to loss of consciousness, seizures, brain damage, or even death. Know the symptoms of hypoglycemia and treat it quickly by drinking juice or a sugar-containing beverage, or eating sugar or candy. Talk to your doctor if hypoglycemia is a problem for you.

Topics	Fast Facts
Generic name	■ insulin aspart (pronounced IN soo lin AS part) (no generic available)
Common brand names	■ NovoLog, NovoLog FlexPen ■ NovoPen Junior (for kids) and NovoPen (various types) are used with NovoLog PenFill cartridges
Type of insulin, onset, duration	■ Rapid-acting insulin; begins working in 12 to 18 minutes and lasts for 3 to 5 hours.
Uses	■ Treatment of type 1 and type 2 diabetes mellitus to improve control of blood glucose
When to take the insulin	■ NovoLog should be injected under the skin 5 to 10 minutes before a meal; meal should be eaten no longer than 10 minutes after injection
Usual dose	■ The frequency and dose of insulin are unique to each individual ■ Daily doses of insulin are based upon body weight, diet, activity level, age, individual sensitivity to insulin, type of diabetes (1 or 2) ■ Multiple daily doses according to blood glucose levels are typical
Injecting the insulin	■ See safety tip #2 (other side of page) to determine if NovoLog can be mixed with another insulin before injection ■ Ask your doctor, nurse, or pharmacist to show you how to draw your dose of insulin into a syringe and inject it, select the dose on a pen device and inject the insulin, or use an insulin pump ■ Before injecting a dose, take the chill off refrigerated insulin by gently rolling the vial, pen, or cartridge between the palms of both hands (do not shake the insulin vigorously) ■ Using a syringe or insulin pen, inject the insulin below the skin (not in the muscle) in the upper thighs, upper arms, buttocks, or abdomen; the site of the injection should be changed (rotated) with each dose ■ Don't use NovoLog if the insulin appears cloudy instead of clear and colorless
Special instructions and precautions	■ Take within 10 minutes of eating a meal ■ Follow the diet your doctor prescribed; keep your eating habits and exercise regular ■ Do not share insulin pens, cartridges, or syringes/needles with others
Safety during pregnancy/breastfeeding	■ Talk to your doctor about managing your diabetes during pregnancy and breastfeeding
Storage and disposal	■ Store unopened **vials, cartridges,** and **pens** in the refrigerator until first use (do not freeze) ■ After first use, store **vials** in the refrigerator or at room temperature; discard after 28 days ■ After first use, store **cartridges** and insulin **pens** at room temperature (do not refrigerate); discard after 28 days ■ Safely dispose of used syringes/needles, pens, and lancets (safety tip #3, other side)
Most common side effects	■ Hypoglycemia (low blood sugar); see signs and treatment of hypoglycemia above ■ Low potassium blood levels, fast heart rate, fatigue, headache, hunger
Other conditions to report to your doctor	■ Chest pain or palpitations, persistent fatigue, confusion, numbness of mouth, lips, or tongue, muscle weakness or tremors, vision changes, flu-like symptoms ■ Swelling, itching, redness, warmth, or pain at the injection site
Herbals that should not be taken with NovoLog	■ These herbals can lower your blood glucose: chromium, garlic, gymnema
Prescription medicines that should not be taken with NovoLog	■ Many prescription medicines can affect your blood sugar levels and insulin needs ■ Tell your doctor about all the medicines you take, particularly new medicines
Special tests your doctor may prescribe	■ Patients are often asked to test their own blood glucose using home testing equipment, test their urine for sugar and acetone, and take their blood pressure regularly ■ To monitor your diabetes, your doctor may periodically test your blood levels for hemoglobin A1c, potassium, cholesterol, and substances that measure kidney function

This information does not replace the need to follow your doctor's instructions and read the drug information leaflet provided with your prescription.

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https://consumermedsafety.org/medication-safety-articles/item/847-teaching-sheets

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Methotrexate

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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 2.5mg twice daily for a week**
- The patient was hospitalized due to methotrexate toxicity

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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*

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ISMP. 2020-2021 ISMP Targeted Medication Safety Best Practices for Hospitals. https://www.ismp.org/guidelines/best-practices-hospitals

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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

ISMP. Persistent safety hazards that all community and ambulatory care safety programs should address. ISMP Medication Safety Alert! Community/Ambulatory edition. May 2021 Vol 20, No 5. 1.

ISMP. 2020-2021 ISMP Targeted Medication Safety Best Practices for Hospitals. https://www.ismp.org/guidelines/best-practices-hospitals

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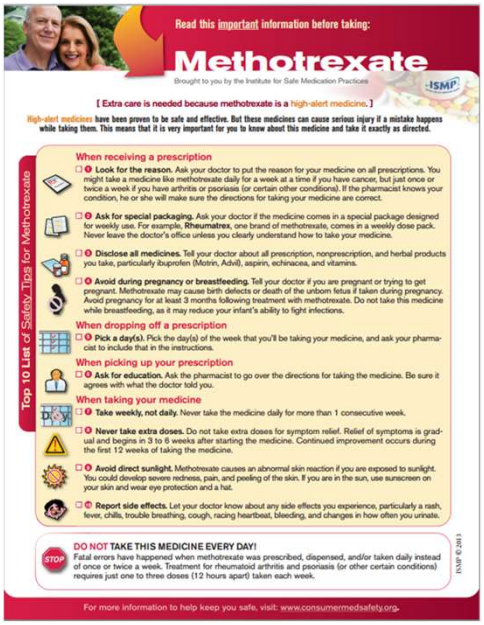
Best Practice 2

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


Read this important information before taking:

Methotrexate

Brought to you by the Institute for Safe Medication Practices

[Extra care is needed because methotrexate is a high-alert medicine.]

High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is very important for you to know about this medicine and take it exactly as directed.

Top 10 List of Safety Tips for Methotrexate

When receiving a prescription

- Look for the reason. Ask your doctor to put the reason for your medicine on all prescriptions. You might take a medicine like methotrexate daily for a week at a time if you have cancer, but just once or twice a week if you have arthritis or psoriasis (or certain other conditions). If the pharmacist knows your condition, he or she will make sure the directions for taking your medicine are correct.
- Ask for special packaging. Ask your doctor if the medicine comes in a special package designed for weekly use. For example, Rheumatrex, one brand of methotrexate, comes in a weekly dose pack. Never leave the doctor's office unless you clearly understand how to take your medicine.
- Disclose all medicines. Tell your doctor about all prescription, nonprescription, and herbal products you take, particularly ibuprofen (Motrin, Advil), aspirin, echinacea, and vitamins.
- Avoid during pregnancy or breastfeeding. Tell your doctor if you are pregnant or trying to get pregnant. Methotrexate may cause birth defects or death of the unborn fetus if taken during pregnancy. Avoid pregnancy for at least 3 months following treatment with methotrexate. Do not take this medicine while breastfeeding, as it may reduce your infant's ability to fight infections.

When dropping off a prescription

- Pick a day(s). Pick the day(s) of the week that you'll be taking your medicine, and ask your pharmacist to include that in the instructions.

When picking up your prescription

- Ask for education. Ask the pharmacist to go over the directions for taking the medicine. Be sure it agrees with what the doctor told you.

When taking your medicine

- Take weekly, not daily. Never take the medicine daily for more than 1 consecutive week.
- Never take extra doses. Do not take extra doses for symptom relief. Relief of symptoms is gradual and begins in 3 to 6 weeks after starting the medicine. Continued improvement occurs during the first 12 weeks of taking the medicine.
- Avoid direct sunlight. Methotrexate causes an abnormal skin reaction if you are exposed to sunlight. You could develop severe redness, pain, and peeling of the skin. If you are in the sun, use sunscreen on your skin and wear eye protection and a hat.
- Report side effects. Let your doctor know about any side effects you experience, particularly a rash, fever, chills, trouble breathing, cough, racing heartbeat, bleeding, and changes in how often you urinate.

STOP

DO NOT TAKE THIS MEDICINE EVERY DAY!

Fatal errors have happened when methotrexate was prescribed, dispensed, and/or taken daily instead of once or twice a week. Treatment for rheumatoid arthritis and psoriasis (or other certain conditions) requires just one to three doses (12 hours apart) taken each week.

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For more information to help keep you safe, visit: www.consumermedsafety.org.

https://consumermedsafety.org/medication-safety-articles/item/847-teaching-sheets

ISMP. 2020-2021 ISMP Targeted Medication Safety Best Practices for Hospitals. https://www.ismp.org/guidelines/best-practices-hospitals

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Opioids

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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**

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Kennedy-Hendricks A, Gielen A, McDonald E, et al. Medication sharing, storage, and disposal practices for opioid medications among US adults. JAMA Intern Med. 2016. doi:10.1001/jamainternmed.2016.2543

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Opioid Naïve vs. Tolerant

- Opioid Naïve
  - **Patients who do not meet the definition of opioid tolerant**
- Opioid Tolerance[1]
  - **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 HYDROmorphone

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

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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**

ISMP Medication Safety Alert! 2005;4(8)

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Problem

- Fenta**NYL** patches (and long-acting opioids) have been inappropriately prescribed:
  - **For opioid-naïve patients to treat acute pain.**
- Fenta**NYL** 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.

ISMP. Inappropriate fentaNYL patch prescriptions for opioid-naïve, elderly patients. ISMP Medication Safety Alert! Community/Ambulatory edition. Aug 2020 Vol 19, No 8. 1.

ISMP. Persistent safety hazards that all community and ambulatory care safety programs should address. ISMP Medication Safety Alert! Community/Ambulatory edition. May 2021 Vol 20, No 5. 1.

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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.*

ISMP. 2020-2021 ISMP Targeted Medication Safety Best Practices for Hospitals. https://www.ismp.org/guidelines/best-practices-hospitals

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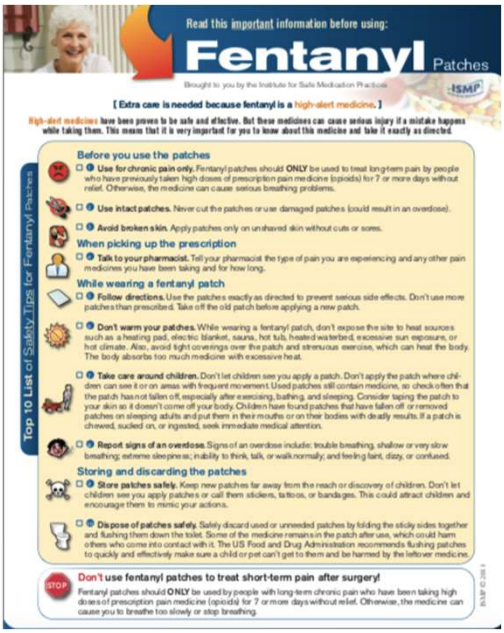
Goals for Best Practice 15

- 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


Read this important information before using:

Fentanyl Patches

Brought to you by the Institute for Safe Medication Practices

[Extra care is needed because fentanyl is a high-alert medicine.]

High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is very important for you to know about this medicine and take it exactly as directed.

Top 10 List of Safety Tips for Fentanyl Patches

Before you use the patches

- **Use for chronic pain only.** Fentanyl patches should **ONLY** be used to treat long-term pain by people who have previously taken high doses of prescription pain medicine (opioids) for 7 or more days without relief. Otherwise, the medicine can cause serious breathing problems.
- **Use intact patches.** Never cut the patches or use damaged patches (could result in an overdose).
- **Avoid broken skin.** Apply patches only on unshaved skin without cuts or sores.

When picking up the prescription

- **Talk to your pharmacist.** Tell your pharmacist the type of pain you are experiencing and any other pain medicines you have been taking and for how long.

While wearing a fentanyl patch

- **Follow directions.** Use the patches exactly as directed to prevent serious side effects. Don't use more patches than prescribed. Take off the old patch before applying a new patch.
- **Don't warm your patches.** While wearing a fentanyl patch, don't expose the site to heat sources such as a heating pad, electric blanket, sauna, hot tub, heated waterbed, excessive sun exposure, or hot climate. Also, avoid tight coverings over the patch and strenuous exercise, which can heat the body. The body absorbs too much medicine with excessive heat.
- **Take care around children.** Don't let children see you apply a patch. Don't apply the patch where children can see it or on areas with frequent movement. Used patches still contain medicine, so check often that the patch has not fallen off, especially after exercising, bathing, and sleeping. Consider taping the patch to your skin so it doesn't come off your body. Children have found patches that have fallen off or removed patches on sleeping adults and put them in their mouths or on their bodies with deadly results. If a patch is chewed, sucked on, or ingested, seek immediate medical attention.
- **Report signs of an overdose.** Signs of an overdose include: trouble breathing, shallow or very slow breathing; extreme sleepiness; inability to think, talk, or walk normally; and feeling faint, dizzy, or confused.

Storing and discarding the patches

- **Store patches safely.** Keep new patches far away from the reach or discovery of children. Don't let children see you apply patches or call them stickers, tattoos, or bandages. This could attract children and encourage them to mimic your actions.
- **Dispose of patches safely.** Safely discard used or unneeded patches by folding the sticky sides together and flushing them down the toilet. Some of the medicine remains in the patch after use, which could harm others who come into contact with it. The US Food and Drug Administration recommends flushing patches to quickly and effectively make sure a child or pet can't get to them and be harmed by the leftover medicine.

STOP **Don't use fentanyl patches to treat short-term pain after surgery!**

Fentanyl patches should **ONLY** be used by people with long-term chronic pain who have been taking high doses of prescription pain medicine (opioids) for 7 or more days without relief. Otherwise, the medicine can cause you to breathe too slowly or stop breathing.

ISMP 47-285-1

https://consumermedsafety.org/medication-safety-articles/item/847-teaching-sheets

ISMP. 2020-2021 ISMP Targeted Medication Safety Best Practices for Hospitals. https://www.ismp.org/guidelines/best-practices-hospitals

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Strategies

- High-Alert Medication List…only effective when combined with risk-reduction strategies MG2
- Implement Risk-Reduction Strategies
  - **Understand the causes of errors**
  - **Layer comprehensive strategies**
- Communicate the List and Strategies
- Assess the Effectiveness of Strategies

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Slide 28

MG2 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.
Michael Gaunt, 10/21/2021

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

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President
Institute for Safe Medication Practices
mcohen@ismp.org

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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

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https://www.ismp.org/report-medication-error

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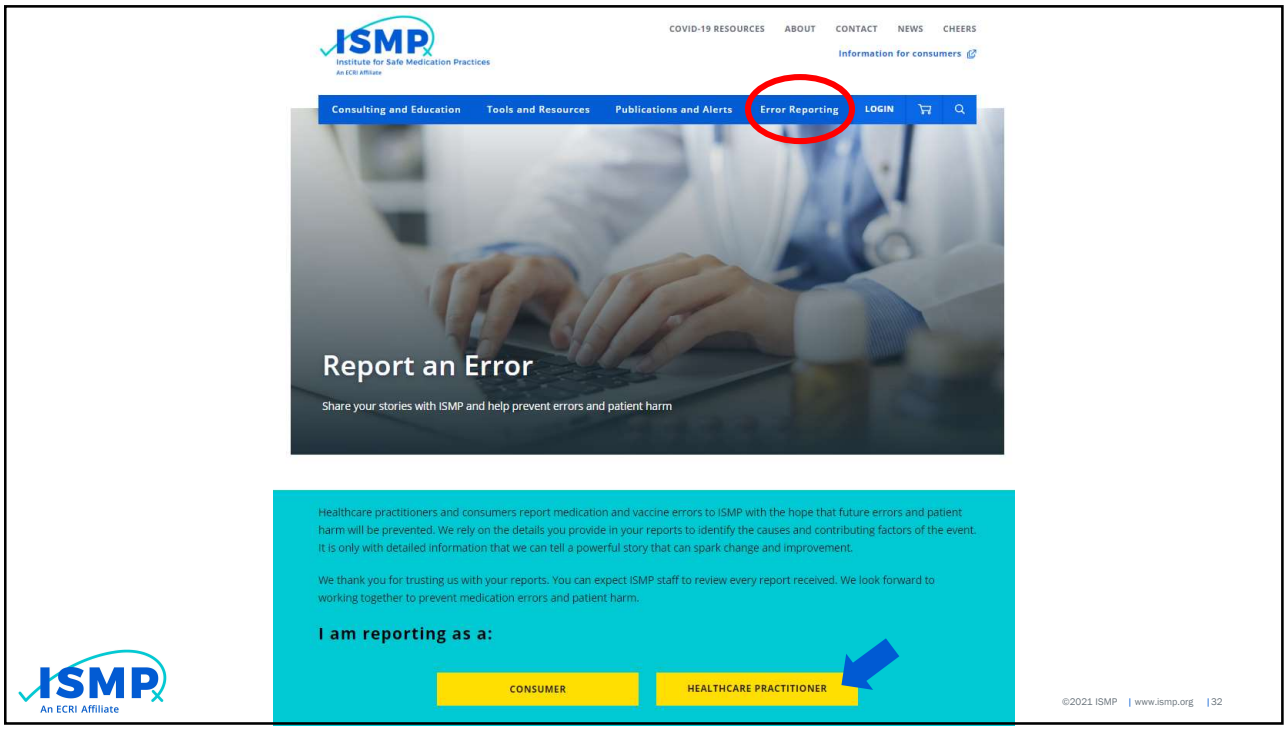

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Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

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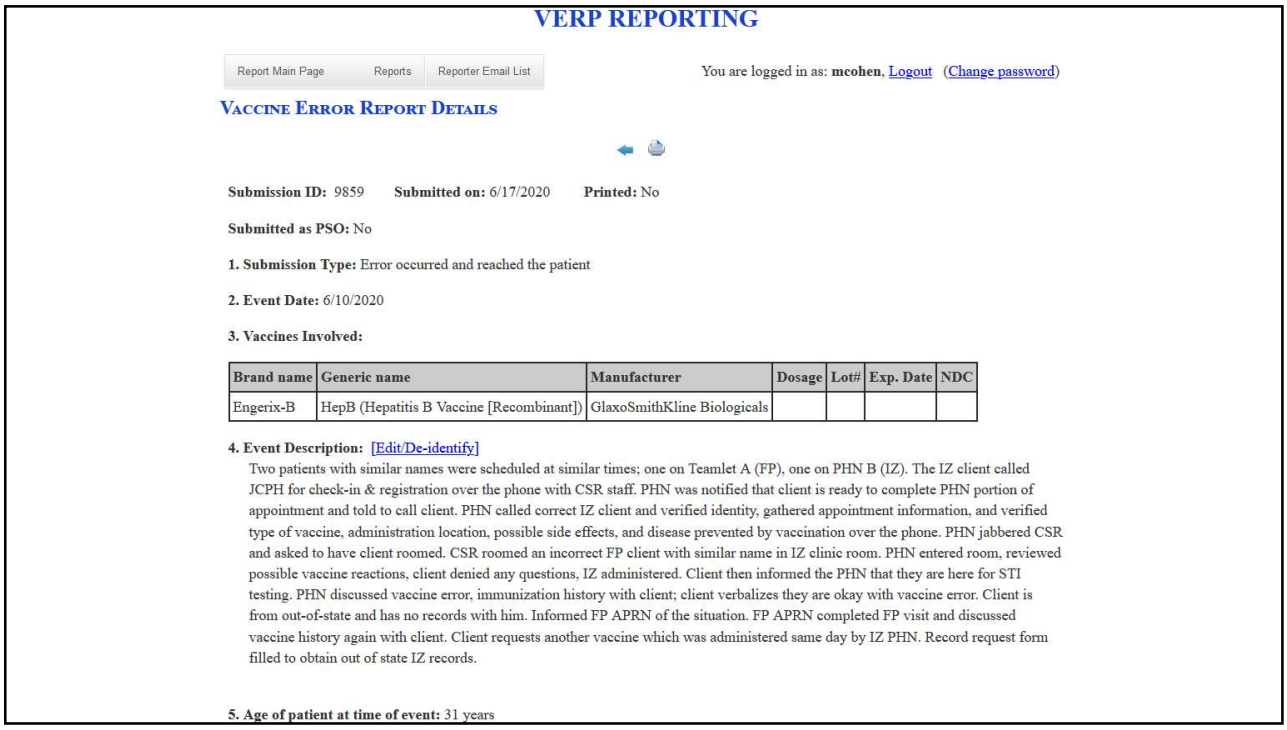

VERP REPORTING

Report Main Page | Reports | Reporter Email List

You are logged in as: **mcohen**, Logout (Change password)

VACCINE ERROR REPORT DETAILS

Submission ID: 9859 **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:

Brand name	Generic name	Manufacturer	Dosage	Lot#	Exp. Date	NDC
Engerix-B	HepB (Hepatitis B Vaccine [Recombinant])	GlaxoSmithKline Biologicals				

4. Event Description: [Edit/De-identify]

Two patients with similar names were scheduled at similar times; one on Teamlet A (FP), one on PHN B (IZ). The IZ client called JCPH for check-in & registration over the phone with CSR staff. PHN was notified that client is ready to complete PHN portion of appointment and told to call client. PHN 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. PHN jabbered CSR and asked to have client roomed. CSR roomed an incorrect FP client with similar name in IZ clinic room. PHN entered room, reviewed possible vaccine reactions, client denied any questions, IZ administered. Client then informed the PHN that they are here for STI testing. PHN 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 APRN of the situation. FP APRN completed FP visit and discussed vaccine history again with client. Client requests another vaccine which was administered same day by IZ PHN. Record request form filled to obtain out of state IZ records.

5. Age of patient at time of event: 31 years

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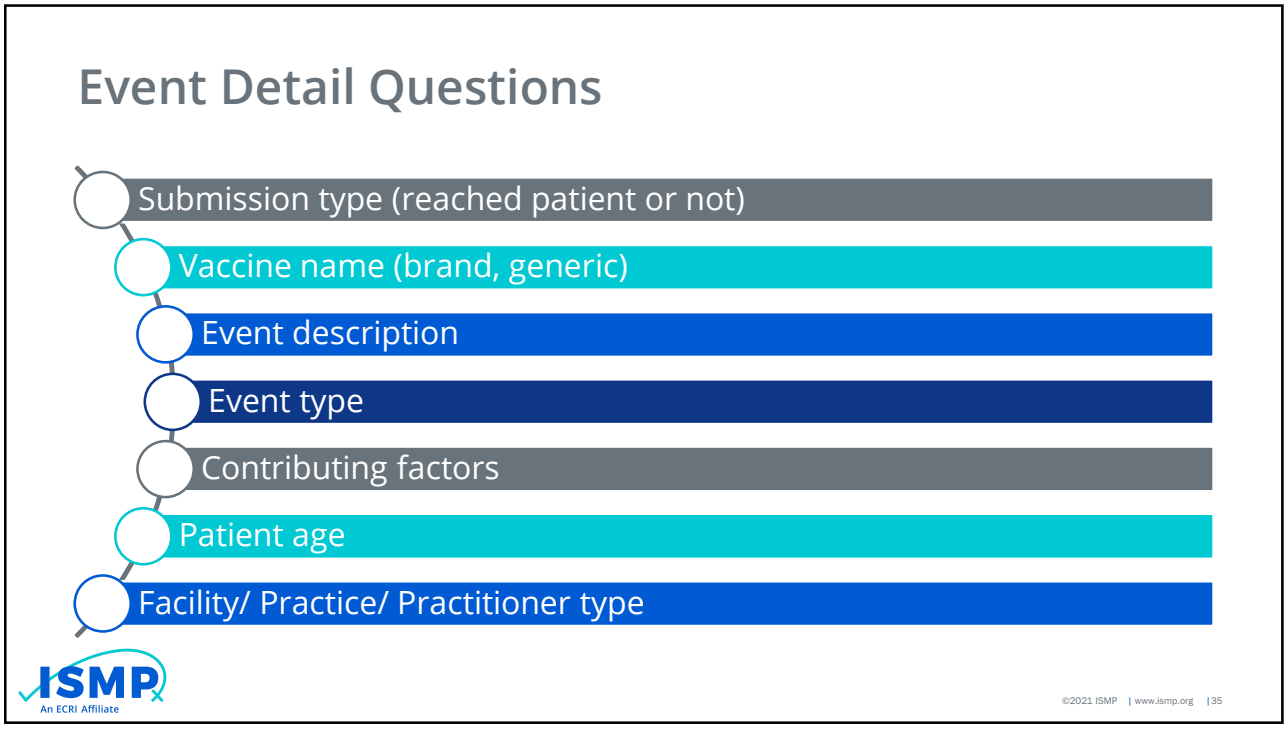

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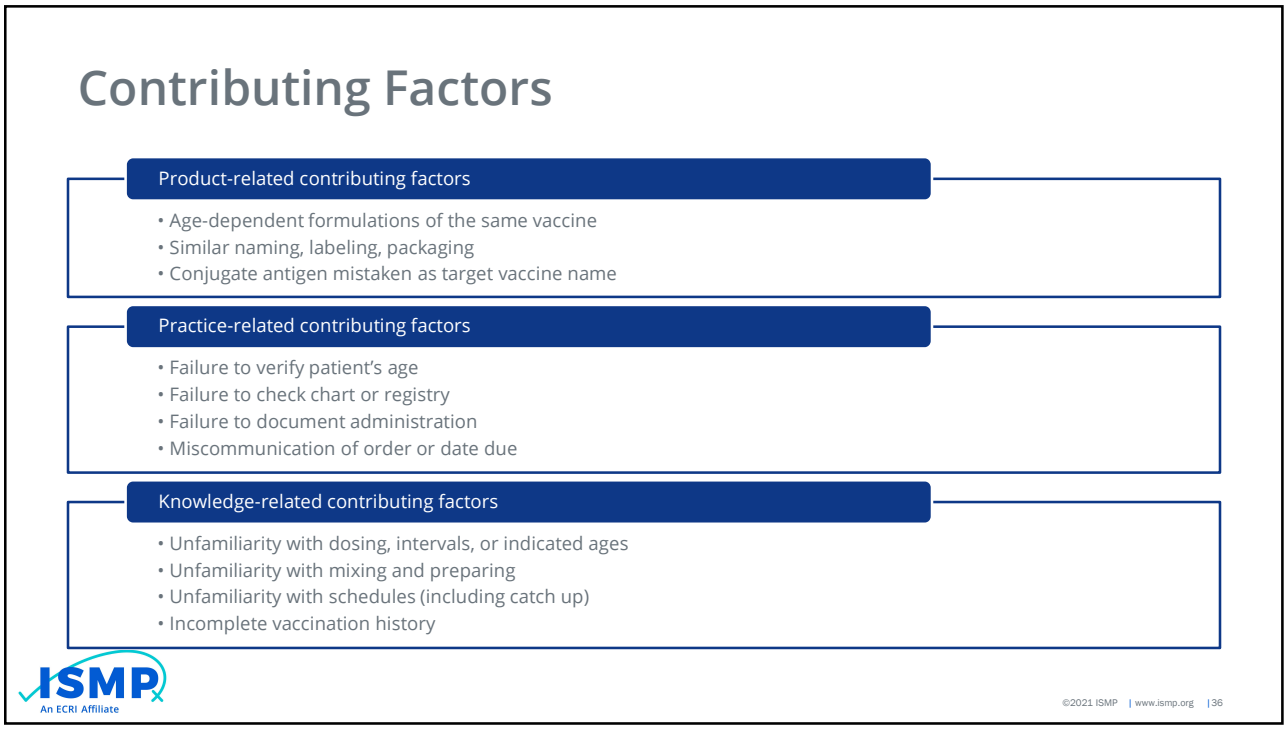

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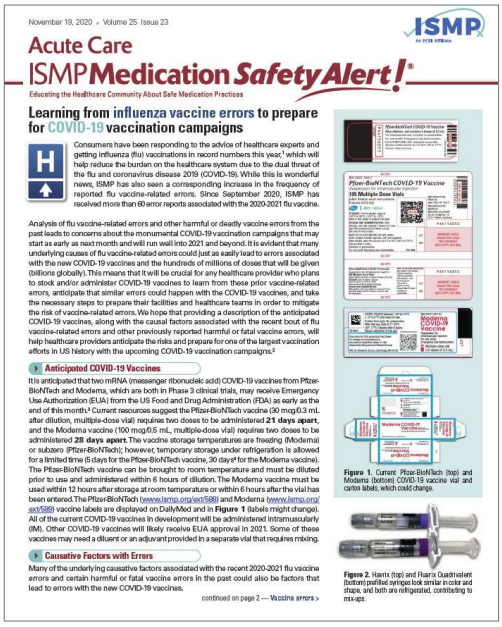
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors



November 19, 2020 • Volume 25 Issue 23

ISMP

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Learning from influenza vaccine errors to prepare for COVID-19 vaccination campaigns

Consumers have been responding to the advice of healthcare experts and getting influenza (flu) vaccinations in record numbers this year,[1] which will help reduce the burden on the healthcare system due to the dual threat of the flu and coronavirus disease 2019 (COVID-19). While this is wonderful news, ISMP has also seen a corresponding increase in the frequency of reported flu vaccine-related errors. Since September 2020, ISMP has received more than 60 error reports associated with the 2020-2021 flu vaccine.

Analysis of flu vaccine-related errors and other harmful or deadly vaccine errors from the past leads to concerns about the monumental COVID-19 vaccination campaigns that may start as early as next month and will run well into 2021 and beyond. It is evident that many underlying causes of flu vaccine-related errors could just as easily lead to errors associated with the new COVID-19 vaccines and the hundreds of millions of doses that will be given (billions globally). This means that it will be crucial for any healthcare provider who plans to stock and/or administer COVID-19 vaccines to learn from these prior vaccine-related errors, anticipate that similar errors could happen with the COVID-19 vaccines, and take the necessary steps to prepare their facilities and healthcare teams in order to mitigate the risk of vaccine-related errors. We hope that providing a description of the anticipated COVID-19 vaccines, along with the causal factors associated with the recent bout of flu vaccine-related errors and other previously reported harmful or fatal vaccine errors, will help healthcare providers anticipate the risks and prepare for one of the largest vaccination efforts in US history with the upcoming COVID-19 vaccination campaigns.[2]

Anticipated COVID-19 Vaccines

It is anticipated that two mRNA (messenger ribonucleic acid) COVID-19 vaccines from Pfizer-BioNTech and Moderna, which are both in Phase 3 clinical trials, may receive Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) as early as the end of this month.[3] Current resources suggest the Pfizer-BioNTech vaccine (30 mcg/0.3 mL after dilution, multiple-dose vial) requires two doses to be administered **21 days apart**, and the Moderna vaccine (100 mcg/0.5 mL, multiple-dose vial) requires two doses to be administered **28 days apart**. The vaccine storage temperatures are freezing (Moderna) or subzero (Pfizer-BioNTech); however, temporary storage under refrigeration is allowed for a limited time (5 days for the Pfizer-BioNTech vaccine, 30 days[4] for the Moderna vaccine). The Pfizer-BioNTech vaccine can be brought to room temperature and must be diluted prior to use and administered within 6 hours of dilution. The Moderna vaccine must be used within 12 hours after storage at room temperature or within 6 hours after the vial has been entered. The Pfizer-BioNTech (www.ismp.org/ext/588) and Moderna (www.ismp.org/ext/589) vaccine labels are displayed on DailyMed and in **Figure 1** (labels might change). All of the current COVID-19 vaccines in development will be administered intramuscularly (IM). Other COVID-19 vaccines will likely receive EUA approval in 2021. Some of these vaccines may need a diluent or an adjuvant provided in a separate vial that requires mixing.

Causative Factors with Errors

Many of the underlying causative factors associated with the recent 2020-2021 flu vaccine errors and certain harmful or fatal vaccine errors in the past could also be factors that lead to errors with the new COVID-19 vaccines.

continued on page 2 — Vaccine errors >

Figure 1. Current Pfizer-BioNTech (top) and Moderna (bottom) COVID-19 vaccine vial and carton labels, which could change.

Figure 2. Havrix (top) and Fluarix Quadrivalent (bottom) prefilled syringes look similar in color and shape, and both are refrigerated, contributing to mix-ups.

January 14, 2021 • Volume 26 Issue 1

ISMP

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Learning from errors with the new COVID-19 vaccines

PROBLEM: In mid-December, the US Food and Drug Administration (FDA) granted emergency use authorization (EUA) to both the Pfizer-BioNTech and Moderna coronavirus disease 2019 (COVID-19) vaccines. Since then, ISMP has received numerous voluntary reports of COVID-19 vaccine errors or hazards through the ISMP National Vaccine Errors Reporting Program (VERP), the ISMP National Consumer Medication Errors Reporting Program (C-MERP), and via email correspondence from professional colleagues. (See the last recommendation on **page 5** regarding a mandatory requirement to report all COVID-19 vaccine errors and adverse reactions to the Vaccine Adverse Event Reporting System (https://vaers.hhs.gov). The following highlights a few of the missteps happening across the nation and internationally, from vaccine dilution errors to look-alike product mix-ups. There is much to be gleaned from these reports, as the same types of errors are likely happening globally, and similar risks exist in most settings. We conclude with safe practice recommendations to help prevent these types of errors in your practice setting.

Dilution Errors

Four dilution errors were reported with the Pfizer-BioNTech COVID-19 vaccine, which was granted EUA for immunization to prevent COVID-19 in individuals 16 years and older. After thawing, each Pfizer-BioNTech multiple-dose vaccine vial contains 0.45 mL, which must be diluted using 1.8 mL of preservative-free (not bacteriostatic) 0.9% sodium chloride injection. Once properly diluted, each vial contains 6, perhaps even 7, doses when using low dead-volume syringes/needles to extract each 0.3 mL (30 mcg) dose. The vaccine is administered intramuscularly (IM) as a series of 2 doses 3 weeks apart.

Dilution errors result in administering too much or too little vaccine. If you add too much diluent, doses may be ineffective; if you add too little diluent, doses may invoke stronger adverse effects (if one happens). In one reported case, mixing the vaccine with too little diluent was suspected when only 0.25 mL remained in the multiple-dose vial when attempting to access the fifth dose. As instructed in the *Fact Sheet*, the 0.25 mL of remaining vaccine was discarded (rather than pooled with excess vaccine from other vials). The previous four doses may represent overdoses.

According to a second report, an inadequate volume of diluent (approximately 1 mL) was added to the vaccine vial. Before the error was discovered, a 60-year-old patient received a nearly 2-fold overdose during his first vaccine dose. The patient had no initial reaction to the overdose and was discharged after an hour, with follow-up calls planned for the next 48 hours. Clinic staff called a Pfizer representative to determine if the patient's second vaccine dose should be altered, but no immediate guidance was offered.

The third dilution error was similar to the previous error in that only 1 mL instead of 1.8 mL of 0.9% sodium chloride injection was used to dilute the vaccine. Again, only one clinic patient received the nearly 2-fold overdose before the error was caught. No details were provided regarding the patient's response to the overdose.

In the last case, which happened internationally, eight healthcare workers in a long-term care (LTC) facility received the entire vial contents (0.45 mL), without dilution, for their first dose of the Pfizer-BioNTech vaccine. Four of the eight workers were hospitalized as a

continued on page 2 — Vaccine errors >

SAFETY briefs

Bamlanivimab confused with belimumab. Four residents at a long-term care (LTC) facility received 700 mg of belimumab (BENLYSTA) instead of the intended bamlanivimab intravenously (IV). Belimumab is indicated for patients with active systemic lupus erythematosus or active lupus nephritis who are also taking other lupus medications. Bamlanivimab was granted emergency use authorization (EUA) for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and children 12 years and older (weighing at least 40 kg) who are at high risk for progressing to severe COVID-19 and/or hospitalization. This event began when a nurse at the LTC facility called the offsite pharmacy with orders but either mispronounced or misread bamlanivimab. The pharmacist heard belimumab, which he prepared and dispensed. The preparations were infused over 90 minutes, but no adverse reactions were reported for any of the residents.

There are several elements in common with belimumab and bamlanivimab. Each drug is added to a 250 mL intravenous (IV) bag of 0.9% sodium chloride injection. Other diluents may also be used with belimumab, but 0.9% sodium chloride injection is one of the recommended base solutions. Also, the dosages can overlap. The pharmacist did not question the dose of 700 mg for belimumab because it aligned with the patients' weights and it fell within a safe dosing range. Both are infused IV over 60 minutes. Bamlanivimab is available in 700 mg vials, while belimumab comes in 120 mg and 400 mg vials for IV use, and in a prefilled syringe or autoinjector for subcutaneous injection. In this case, the pharmacist processing the order was not familiar with either drug. Apparently, the preparations, labeled as belimumab, did not raise a red flag at the LTC facility, either. The incident occurred just as bamlanivimab use was increasing for patients with early

continued on page 3 — SAFETY briefs >

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https://www.ismp.org/newsletters/acute-care

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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

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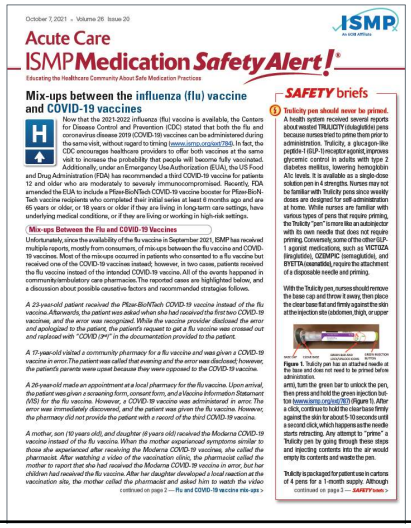
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors

Accidental swap between influenza vaccine and COVID-19 vaccine

ISMP Medication Safety Alert! October 7, 2021, Volume 26, Issue 20



Acute Care

ISMP Medication Safety Alert!

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

SAFETY briefs

1 Trulicity pen should never be primed.

Mix-ups Between the Flu and COVID-19 Vaccines

Unfortunately, since the availability of the flu vaccine in September 2021, ISMP has received multiple reports, mostly from consumers, of mix-ups between the flu vaccine and COVID-19 vaccines. Most of the mix-ups occurred in patients who consented to a flu vaccine but received one of the COVID-19 vaccines instead; however, in two cases, patients received the flu vaccine instead of the intended COVID-19 vaccine. All of the events happened in community/ambulatory care pharmacies. The reported cases are highlighted below, and a discussion about possible causative factors and recommended strategies follows.

A 23-year-old patient received the Pfizer-BioNTech COVID-19 vaccine instead of the flu vaccine. Afterwards, the patient was asked when she had received the first two COVID-19 vaccines, and the error was recognized. While the vaccine provider disclosed the error and apologized to the patient, the patient's request to get a flu vaccine was crossed out and replaced with "COVID (PF)" in the documentation provided to the patient.

A 17-year-old visited a community pharmacy for a flu vaccine and was given a COVID-19 vaccine in error. The patient was called that evening and the error was disclosed; however, the patient's parents were upset because they were opposed to the COVID-19 vaccine.

A 26-year-old made an appointment at a local pharmacy for the flu vaccine. Upon arrival, the patient was given a screening form, consent form, and a Vaccine Information Statement (VIS) for the flu vaccine. However, a COVID-19 vaccine was administered in error. The error was immediately discovered, and the patient was given the flu vaccine. However, the pharmacy did not provide the patient with a record of the third COVID-19 vaccine.

A mother, son (10 years old), and daughter (6 years old) received the Moderna COVID-19 vaccine instead of the flu vaccine. When the mother experienced symptoms similar to those she experienced after receiving the Moderna COVID-19 vaccines, she called the pharmacist. After watching a video of the vaccination clinic, the pharmacist called the mother to report that she had received the Moderna COVID-19 vaccine in error, but her children had received the flu vaccine. After her daughter developed a local reaction at the vaccination site, the mother called the pharmacist and asked him to watch the video

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 | www.ismp.org | 39

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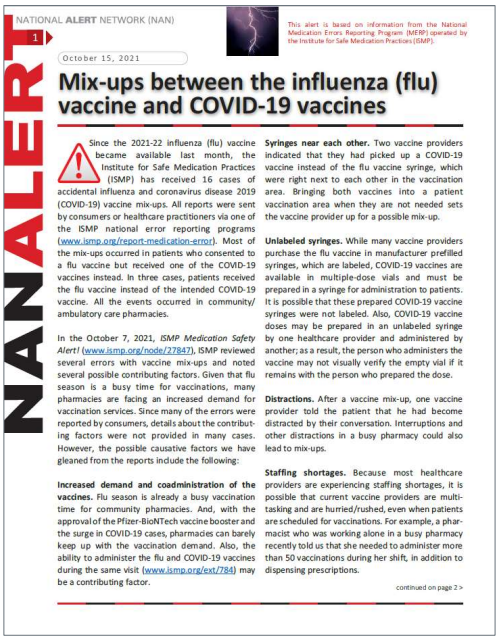

NATIONAL ALERT NETWORK (NAN)

NANALERT

October 15, 2021

This alert is based on information from the National Medication Errors Reporting Program (MERP) operated by the Institute for Safe Medication Practices (ISMP).

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

Since the 2021-22 influenza (flu) vaccine became available last month, the Institute for Safe Medication Practices (ISMP) has received 16 cases of accidental influenza and coronavirus disease 2019 (COVID-19) vaccine mix-ups. All reports were sent by consumers or healthcare practitioners via one of the ISMP national error reporting programs (www.ismp.org/report-medication-error). Most of the mix-ups occurred in patients who consented to a flu vaccine but received one of the COVID-19 vaccines instead. In three cases, patients received the flu vaccine instead of the intended COVID-19 vaccine. All the events occurred in community/ambulatory care pharmacies.

In the October 7, 2021, *ISMP Medication Safety Alert!* (www.ismp.org/node/27847), ISMP reviewed several errors with vaccine mix-ups and noted several possible contributing factors. Given that flu season is a busy time for vaccinations, many pharmacies are facing an increased demand for vaccination services. Since many of the errors were reported by consumers, details about the contributing factors were not provided in many cases. However, the possible causative factors we have gleaned from the reports include the following:

Increased demand and coadministration of the vaccines. Flu season is already a busy vaccination time for community pharmacies. And, with the approval of the Pfizer-BioNTech vaccine booster and the surge in COVID-19 cases, pharmacies can barely keep up with the vaccination demand. Also, the ability to administer the flu and COVID-19 vaccines during the same visit (www.ismp.org/ext/784) may be a contributing factor.

Syringes near each other. Two vaccine providers indicated that they had picked up a COVID-19 vaccine 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. While many vaccine providers purchase the flu vaccine in manufacturer prefilled syringes, which are labeled, 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.

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 pharmacy could also lead to mix-ups.

Staffing shortages. Because most healthcare providers are experiencing staffing shortages, it is possible that current vaccine providers are multitasking and are hurried/rushed, even when patients are scheduled for vaccinations. For example, a pharmacist who was working alone in a busy pharmacy recently told us that she needed to administer more than 50 vaccinations during her shift, in addition to dispensing prescriptions.

continued on page 2 >

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 | www.ismp.org | 40

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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.

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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.

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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).

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Recommendations

- **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

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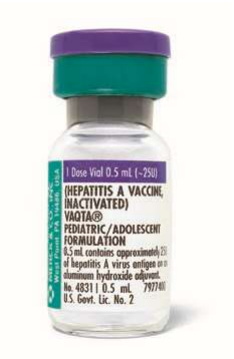
Wrong Age Errors



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Age-dependent Formulations of the Same Vaccine

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https://www.vaccineshoppe.com

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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)

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

Correspondence

Avoiding shoulder injury from intramuscular vaccines

With the roll-out of COVID-19 vaccination programmes to tens of millions of people, some individuals might receive vaccines, which have received rigorous safety checks and approval from regulatory bodies, via intramuscular injection. However, the safety around the technique used and the site of injection, in particular, has received little attention. As recommended by the Joint Committee on Vaccination and Immunisation (JCVI), adults aged 16 years or older will be the main population receiving the intramuscular vaccine. The JCVI recommends the deltoid muscle as the optimal injection site, shown graphically as a triangle with the base starting around 1–3 cm below the acromion (appendix).[1] However, this site is not universally accepted as the most appropriate; other organisations advocate alternative sites, such as a triangular region with the base around 5 cm below the acromion and the apex at the level of the axilla apex (approximating the middle third of the deltoid muscle),[2] or midway between the acromion and the deltoid tubercle.[3]

The site closest to the acromion and origin of the deltoid has several anatomical structures within its vicinity, including the posterior circumflex humeral artery, the anterior branch of the axillary nerve (located 5 cm below the acromion lateral border), and the subacromial-subdeltoid bursa.[2] The subdeltoid bursa can extend to 4·0 cm below the acromion and 1·3 cm below the skin.

A range of injuries have been reported to the Vaccine Adverse Event Reporting System database in the USA following vaccination (mostly for influenza). Injuries were predominantly shoulder pain and dysfunction (due to pain, joint-range restriction, bursitis, and stiff shoulder), and patients reported that the vaccines were administered "too high" on the arm.[2] Spanish pharmacovigilance organisations have similarly reported bursitis and other shoulder injuries following intramuscular vaccination administered in the deltoid.

Anthropometric studies of the optimal site of vaccination have identified that the safest anatomical site in adults of both sexes would be approximately (varying by size and sex) 7–13 cm below the mid-acromion, anatomically midway between the acromion and the deltoid tuberosity (appendix). This region avoids the anterior branch of the axillary nerve or the subacromial-subdeltoid bursa.[2,4] The risk of injury can be further reduced by the recipient placing their hand on the ipsilateral hip (ie, abducting the shoulder to 60°) when receiving the injection. This manoeuvre reduces exposure of the subacromial-subdeltoid bursa to injury. An injection administered at 90° to the skin's surface with a 25 mm needle routinely penetrates at least 5 mm of muscle in men and women.

Updating policy and training vaccinators to safely administer the vaccine in the appropriate intramuscular site will be essential for ensuring efficacy of the vaccine, as placement in a bursa or joint will prevent immune system exposure, and for increasing comfort and reducing pain in vaccine recipients.

We declare no competing interests.

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1 Public Health England. Immunisation procedures: the green book. March 20, 2013. In: Immunisation against infectious disease. https://www.gov.uk/government/publications/immunisation-procedures-the-green-book-chapter-4 (accessed Dec 21, 2020).

2 New Zealand Ministry of Health. Vaccine administration. In: Immunisation handbook 2020. Wellington: Ministry of Health, 2020: 48–60.

3 Cook IF. An evidence-based protocol for the prevention of upper arm injury related to vaccine administration (UAIRVA). Hum Vaccin 2011; 7: 845–48.

4 Nakajima Y, Mukai K, Takaoka K, et al. Establishing a new appropriate intramuscular injection site in the deltoid muscle. Hum Vaccin Immunother 2017; 13: 2123–29.

5 Hibbs BF, Ng CS, Moro PL, et al. Reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010–2012. Vaccine 2020; 38: 1422–43.

Time to revise the strategy for Gavi funding of rabies vaccine?

The Global Burden of Disease cause and risk summary on rabies shows the 12 700 deaths worldwide in 2019, close to the estimated 12 700 furious rabies cases in India alone.[1] Figure 4 of this summary is misleading, especially the key. As there is no surveillance in many of the poorest countries, the global annual deaths quoted by WHO[2] of 59 000 is derived from extensive extrapolation. Rabies encephalomyelitis is always fatal in Asia and Africa. Although prevention of infection by correct vaccination after dog bites is extremely effective, vaccines are often inaccessible in most African countries.

Gavi, the Vaccine Alliance, has committed to conditional funding of post-exposure rabies vaccine in Asia and Africa starting in 2021.[3] Preparatory surveys in several African countries show a widespread lack of infrastructure and public health provision. For example, in Chad, only 42% of health clinics surveyed had cold facilities for vaccine storage.[4] Effective distribution and use of vaccines would be difficult and take many years to achieve. The realistic costs of implementation in rural areas were not considered in recent evaluations of possible approaches.[5]

The COVID-19 pandemic has dramatically changed the situation. Innovative concepts, plans, and

For the Global Burden of Disease cause and risk summary on rabies see https://www.thelancet.com/pb-assets/Lancet/gbd/summaries/diseases/rabies.pdf

See Online for appendix

For more on the Vaccine Adverse Event Reporting System database see https://wonder.cdc.gov/vaers.html

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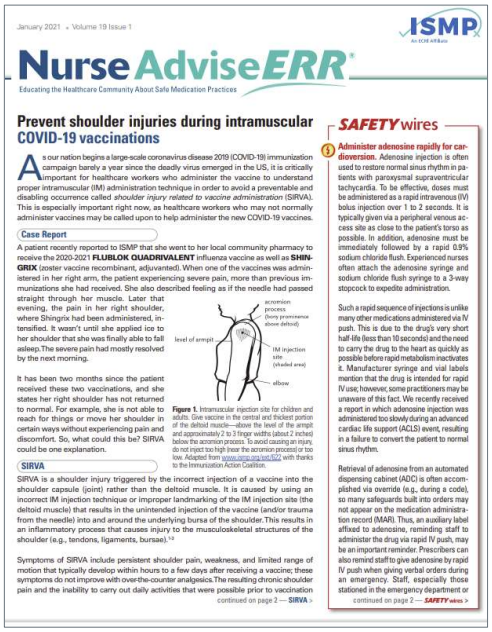

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Nurse AdviseERR

Educating the Healthcare Community About Safe Medication Practices

Prevent shoulder injuries during intramuscular COVID-19 vaccinations

As our nation begins a large-scale coronavirus disease 2019 (COVID-19) immunization campaign barely a year since the deadly virus emerged in the US, it is critically important for healthcare workers who administer the vaccine to understand proper intramuscular (IM) administration technique in order to avoid a preventable and disabling occurrence called *shoulder injury related to vaccine administration* (SIRVA). This is especially important right now, as healthcare workers who may not normally administer vaccines may be called upon to help administer the new COVID-19 vaccines.

Case Report

A patient recently reported to ISMP that she went to her local community pharmacy to receive the 2020-2021 **FLUBLOK QUADRIVALENT** influenza vaccine as well as **SHINGRIX** (zoster vaccine recombinant, adjuvanted). When one of the vaccines was administered in her right arm, the patient experiencing severe pain, more than previous immunizations she had received. She also described feeling as if the needle had passed straight through her muscle. Later that evening, the pain in her right shoulder, where Shingrix had been administered, intensified. It wasn't until she applied ice to her shoulder that she was finally able to fall asleep. The severe pain had mostly resolved by the next morning.

It has been two months since the patient received these two vaccinations, and she states her right shoulder has not returned to normal. For example, she is not able to reach for things or move her shoulder in certain ways without experiencing pain and discomfort. So, what could this be? SIRVA could be one explanation.

Figure 1. Intramuscular injection site for children and adults. Give vaccine in the central and thickest portion of the deltoid muscle—above the level of the armpit and approximately 2 to 3 finger widths (about 2 inches) below the acromion process. To avoid causing an injury, do not inject too high (near the acromion process) or too low. Adapted from www.ismp.org/sirva with thanks to the Immunization Action Coalition.

SIRVA

SIRVA is a shoulder injury triggered by the incorrect injection of a vaccine into the shoulder capsule (joint) rather than the deltoid muscle. It is caused by using an incorrect IM injection technique or improper landmarking of the IM injection site (the deltoid muscle) that results in the unintended injection of the vaccine (and/or trauma from the needle) into and around the underlying bursa of the shoulder. This results in an inflammatory process that causes injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae).[1,2]

Symptoms of SIRVA include persistent shoulder pain, weakness, and limited range of motion that typically develop within hours to a few days after receiving a vaccine; these symptoms do not improve with over-the-counter analgesics. The resulting chronic shoulder pain and the inability to carry out daily activities that were possible prior to vaccination

continued on page 2 — SIRVA >

SAFETY wires

Administer adenosine rapidly for cardioversion. Adenosine injection is often used to restore normal sinus rhythm in patients with paroxysmal supraventricular tachycardia. To be effective, doses must be administered as a rapid intravenous (IV) bolus injection over 1 to 2 seconds. It is typically given via a peripheral venous access site as close to the patient's torso as possible. In addition, adenosine must be immediately followed by a rapid 0.9% sodium chloride flush. Experienced nurses often attach the adenosine syringe and sodium chloride flush syringe to a 3-way stopcock to expedite administration.

Such a rapid sequence of injections is unlike many other medications administered via IV push. This is due to the drug's very short half-life (less than 10 seconds) and the need to carry the drug to the heart as quickly as possible before rapid metabolism inactivates it. Manufacturer syringe and vial labels mention that the drug is intended for rapid IV use; however, some practitioners may be unaware of this fact. We recently received a report in which adenosine injection was administered too slowly during an advanced cardiac life support (ACLS) event, resulting in a failure to convert the patient to normal sinus rhythm.

Retrieval of adenosine from an automated dispensing cabinet (ADC) is often accomplished via override (e.g., during a code), so many safeguards built into orders may not appear on the medication administration record (MAR). Thus, an auxiliary label affixed to adenosine, reminding staff to administer the drug via rapid IV push, may be an important reminder. Prescribers can also remind staff to give adenosine by rapid IV push when giving verbal orders during an emergency. Staff, especially those stationed in the emergency department or

continued on page 2 — SAFETY wires >

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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

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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

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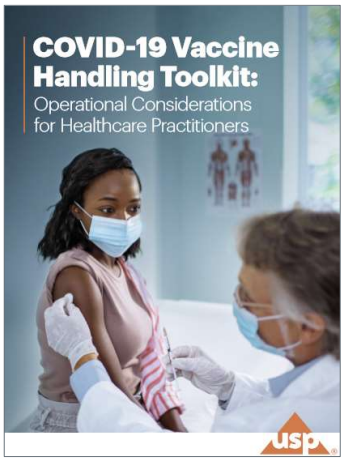
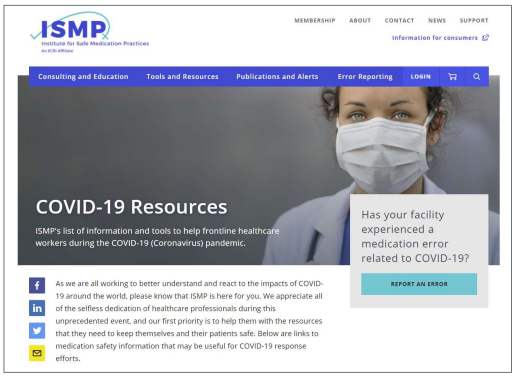


https://www.usp.org/covid-19/vaccine-handling-toolkit



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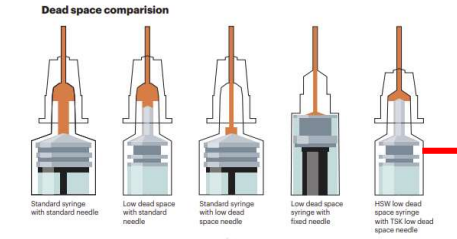

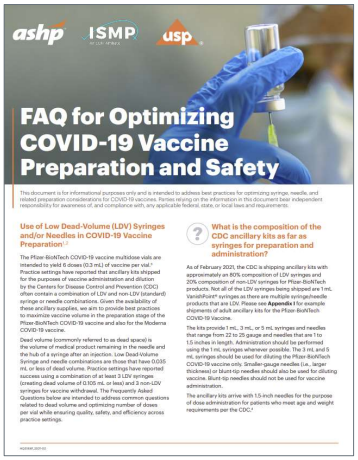

https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/FAQ-optimizing-covid-vaccine-prep-safety.ashx

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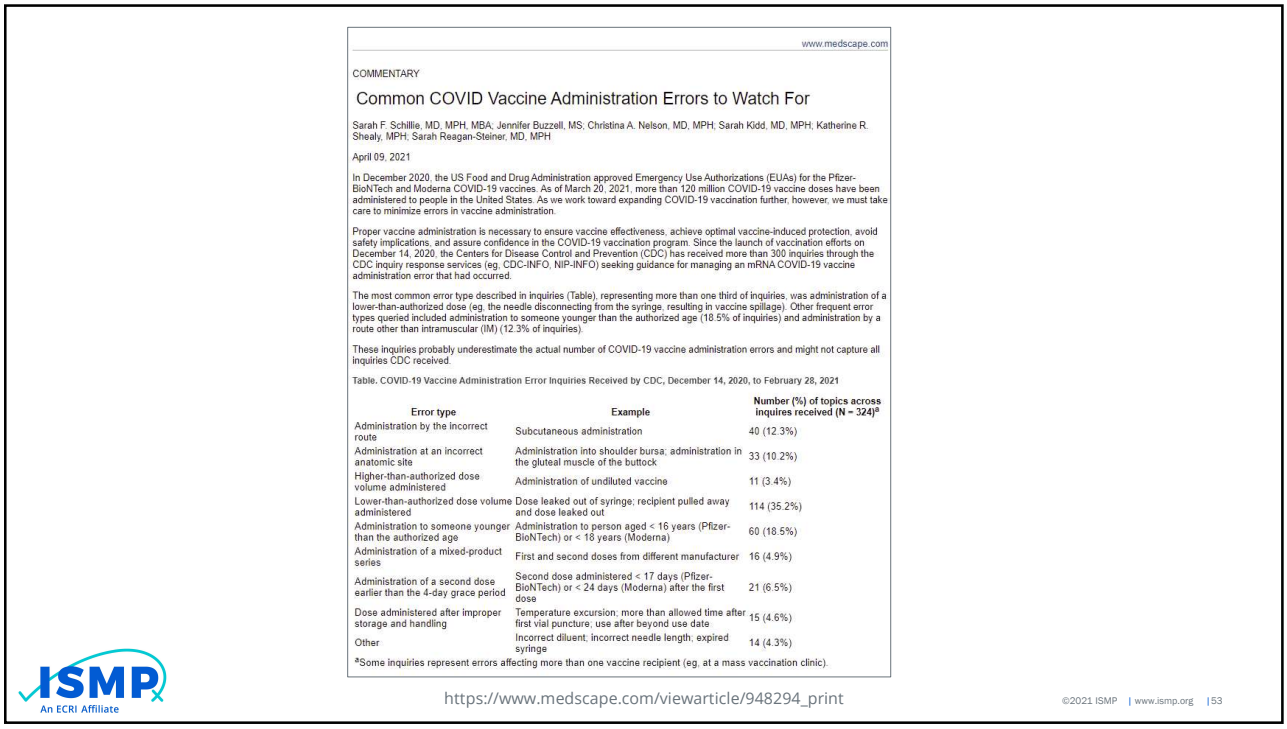
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors



www.medscape.com

COMMENTARY

Common COVID Vaccine Administration Errors to Watch For

Sarah F. Schillie, MD, MPH, MBA; Jennifer Buzzell, MS; Christina A. Nelson, MD, MPH; Sarah Kidd, MD, MPH; Katherine R. Shealy, MPH; Sarah Reagan-Steiner, MD, MPH

April 09, 2021

In December 2020, the US Food and Drug Administration approved Emergency Use Authorizations (EUAs) for the Pfizer-BioNTech and Moderna COVID-19 vaccines. As of March 20, 2021, more than 120 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, achieve optimal vaccine-induced protection, avoid safety implications, and assure confidence in the COVID-19 vaccination program. Since the launch of vaccination efforts on December 14, 2020, the Centers for Disease Control and Prevention (CDC) has received more than 300 inquiries through the CDC inquiry response services (eg, CDC-INFO, NIP-INFO) seeking guidance for managing an mRNA COVID-19 vaccine administration error that had occurred.

The most common error type described in inquiries (Table), representing more than one third of inquiries, was administration of a lower-than-authorized dose (eg, the needle disconnecting from the syringe, resulting in vaccine spillage). Other frequent error types queried included administration to someone younger than the authorized age (18.5% of inquiries) and administration by a route other than intramuscular (IM) (12.3% of inquiries).

These inquiries probably underestimate the actual number of COVID-19 vaccine administration errors and might not capture all inquiries CDC received.

Table. COVID-19 Vaccine Administration Error Inquiries Received by CDC, December 14, 2020, to February 28, 2021

Error type	Example	Number (%) of topics across inquires received (N = 324)[a]
Administration by the incorrect route	Subcutaneous administration	40 (12.3%)
Administration at an incorrect anatomic site	Administration into shoulder bursa; administration in the gluteal muscle of the buttock	33 (10.2%)
Higher-than-authorized dose volume administered	Administration of undiluted vaccine	11 (3.4%)
Lower-than-authorized dose volume administered	Dose leaked out of syringe; recipient pulled away and dose leaked out	114 (35.2%)
Administration to someone younger than the authorized age	Administration to person aged < 16 years (Pfizer-BioNTech) or < 18 years (Moderna)	60 (18.5%)
Administration of a mixed-product series	First and second doses from different manufacturer	16 (4.9%)
Administration of a second dose earlier than the 4-day grace period	Second dose administered < 17 days (Pfizer-BioNTech) or < 24 days (Moderna) after the first dose	21 (6.5%)
Dose administered after improper storage and handling	Temperature excursion; more than allowed time after first vial puncture; use after beyond use date	15 (4.6%)
Other	Incorrect diluent; incorrect needle length; expired syringe	14 (4.3%)

[a]Some inquiries represent errors affecting more than one vaccine recipient (eg, at a mass vaccination clinic).

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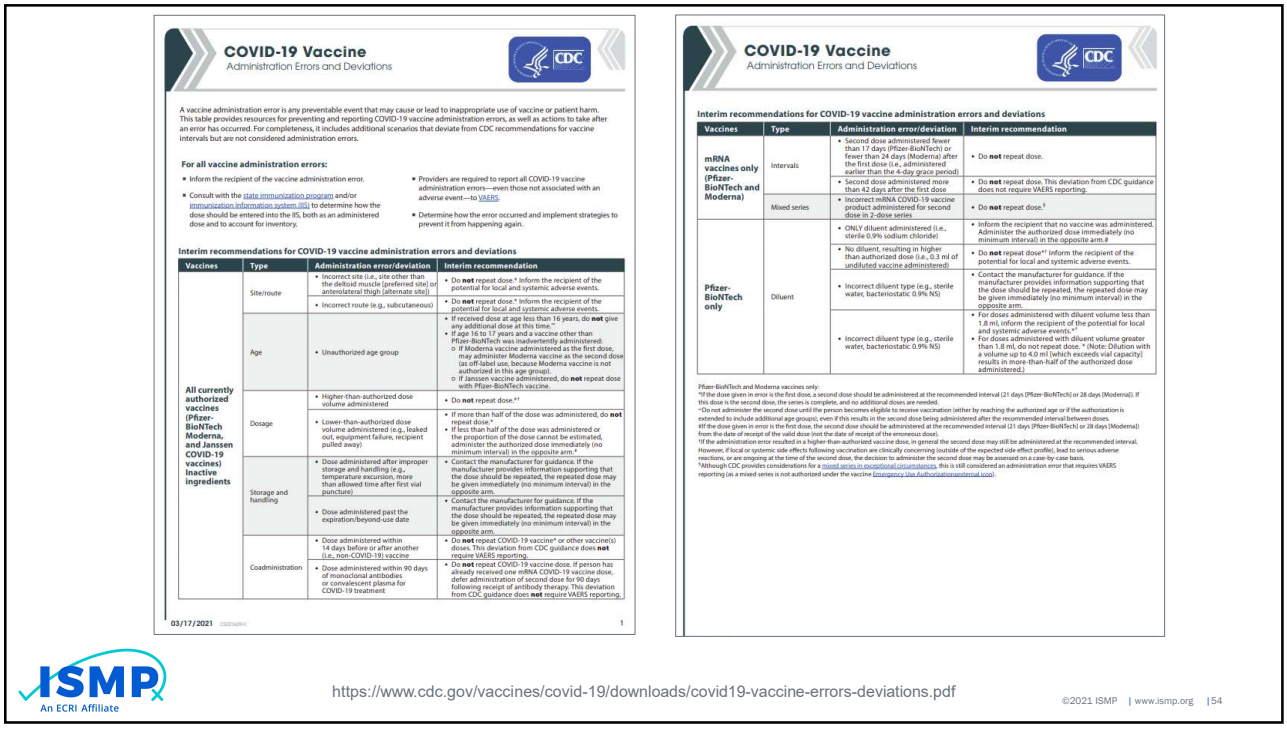

COVID-19 Vaccine
Administration Errors and Deviations

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. This table provides resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, it includes additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again.

Interim recommendations for COVID-19 vaccine administration errors and deviations

Vaccines	Type	Administration error/deviation	Interim recommendation
All currently authorized vaccines (Pfizer-BioNTech Moderna, and Janssen COVID-19 vaccines) Inactive ingredients	Site/route	• Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	• Do **not** repeat dose.* Inform the recipient of the potential for local and systemic adverse events.
		• Incorrect route (e.g., subcutaneous)	• Do **not** repeat dose.* Inform the recipient of the potential for local and systemic adverse events.
	Age	• Unauthorized age group	• If received dose at age less than 16 years, do **not** give any additional dose at this time.* • If age 16 to 17 years and a vaccine other than Pfizer-BioNTech was inadvertently administered: ○ If Moderna vaccine administered as the first dose, may administer Moderna vaccine as the second dose (as off-label use, because Moderna vaccine is not authorized in this age group). ○ If Janssen vaccine administered, do **not** repeat dose with Pfizer-BioNTech vaccine.
	Dosage	• Higher-than-authorized dose volume administered	• Do **not** repeat dose.*†
		• Lower-than-authorized dose volume administered (e.g., leaked out, equipment failure, recipient pulled away)	• If more than half of the dose was administered, do **not** repeat dose.* • If less than half of the dose was administered or the proportion of the dose cannot be estimated, administer the authorized dose immediately (no minimum interval) in the opposite arm.*
	Storage and handling	• Dose administered after improper storage and handling (e.g., temperature excursion, more than allowed time after first vial puncture)	• Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.
		• Dose administered past the expiration/beyond-use date	• Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.
	Coadministration	• Dose administered within 14 days before or after another (i.e., non-COVID-19) vaccine	• Do **not** repeat COVID-19 vaccine* or other vaccine(s) doses. This deviation from CDC guidance does **not** require VAERS reporting.
		• Dose administered within 90 days of monoclonal antibodies or convalescent plasma for COVID-19 treatment	• Do **not** repeat COVID-19 vaccine dose. If person has already received one mRNA COVID-19 vaccine dose, defer administration of second dose for 90 days following receipt of antibody therapy. This deviation from CDC guidance does **not** require VAERS reporting.

03/17/2021

COVID-19 Vaccine
Administration Errors and Deviations

Interim recommendations for COVID-19 vaccine administration errors and deviations

Vaccines	Type	Administration error/deviation	Interim recommendation
mRNA vaccines only (Pfizer-BioNTech and Moderna)	Intervals	• Second dose administered fewer than 17 days (Pfizer-BioNTech) or fewer than 24 days (Moderna) after the first dose (i.e., administered earlier than the 4-day grace period)	• Do **not** repeat dose.
		• Second dose administered more than 42 days after the first dose	• Do **not** repeat dose. This deviation from CDC guidance does not require VAERS reporting.
	Mixed series	• Incorrect mRNA COVID-19 vaccine product administered for second dose in 2-dose series	• Do **not** repeat dose.§
Pfizer-BioNTech only	Diluent	• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Inform the recipient that no vaccine was administered. Administer the authorized dose immediately (no minimum interval) in the opposite arm.#
		• No diluent, resulting in higher than authorized dose (i.e., 0.3 ml of undiluted vaccine administered)	• Do **not** repeat dose*† Inform the recipient of the potential for local and systemic adverse events.
		• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	• Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.
		• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	• For doses administered with diluent volume less than 1.8 ml, inform the recipient of the potential for local and systemic adverse events.*† • For doses administered with diluent volume greater than 1.8 ml, do not repeat dose. * (Note: Dilution with a volume up to 4.0 ml [which exceeds vial capacity] results in more-than-half of the authorized dose administered.)

Pfizer-BioNTech and Moderna vaccines only:
*If the dose given in error is the first dose, a second dose should be administered at the recommended interval (21 days [Pfizer-BioNTech] or 28 days [Moderna]). If this dose is the second dose, the series is complete, and no additional doses are needed.
†Do not administer the second dose until the person becomes eligible to receive vaccination (either by reaching the authorized age or if the authorization is extended to include additional age groups), even if this results in the second dose being administered after the recommended interval between doses.
‡If the dose given in error is the first dose, the second dose should be administered at the recommended interval (21 days [Pfizer-BioNTech] or 28 days [Moderna]) from the date of receipt of the valid dose (not the date of receipt of the erroneous dose).
§If the administration error resulted in a higher-than-authorized vaccine dose, in general the second dose may still be administered at the recommended interval. However, if local or systemic side-effects following vaccination are clinically concerning (outside of the expected side-effect profile), lead to serious adverse reactions, or are ongoing at the time of the second dose, the decision to administer the second dose may be assessed on a case-by-case basis.
¶Although CDC provides considerations for a mixed series in exceptional circumstances, this is still considered an administration error that requires VAERS reporting (as a mixed series is not authorized under the vaccine Emergency Use Authorization/experimental IND).

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https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-errors-deviations.pdf

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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]

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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

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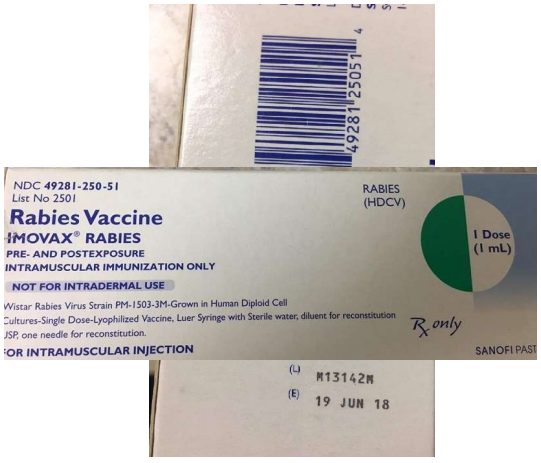
Non-Standard Expiration Date Expression

December 13, 2012
or
December 12, 2013?

June 19, 2018
or
June 18, 2019?



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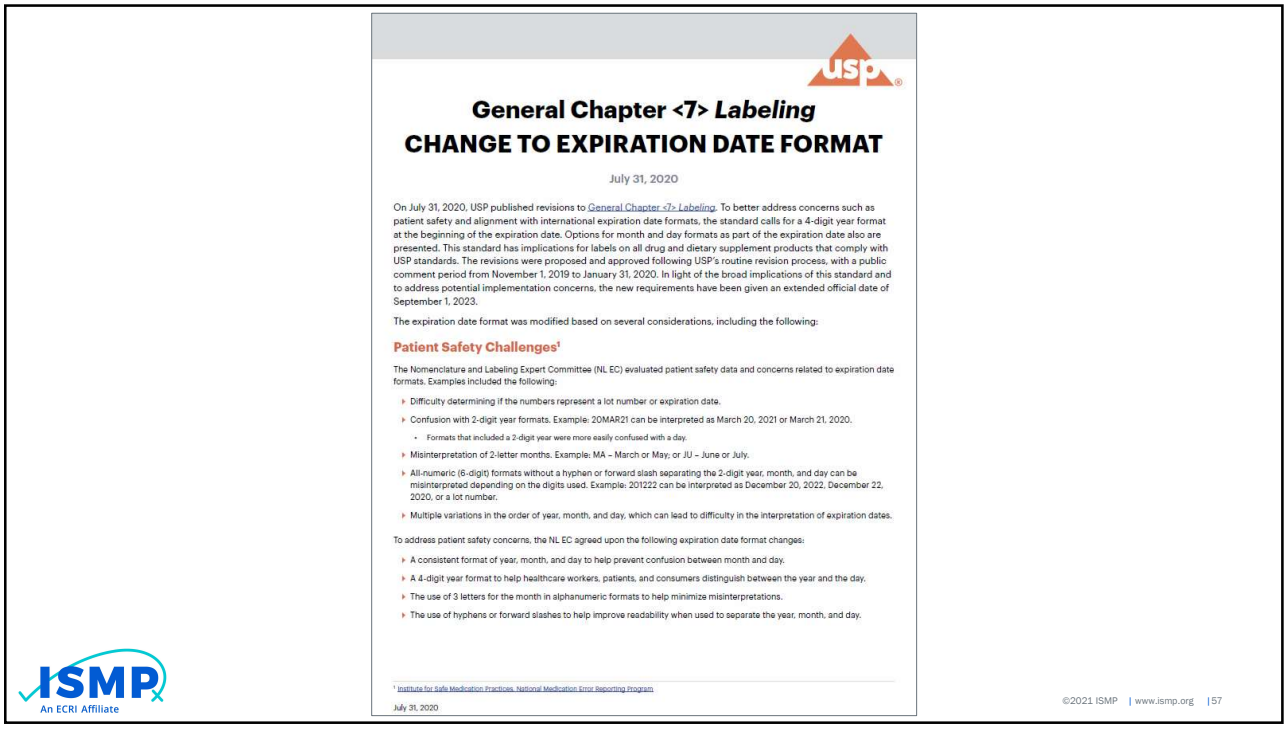
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors



USP

General Chapter <7> *Labeling*
CHANGE TO EXPIRATION DATE FORMAT

July 31, 2020

On July 31, 2020, USP published revisions to General Chapter <7> *Labeling*. To better address concerns such as patient safety and alignment with international expiration date formats, the standard calls for a 4-digit year format at the beginning of the expiration date. Options for month and day formats as part of the expiration date also are presented. This standard has implications for labels on all drug and dietary supplement products that comply with USP standards. The revisions were proposed and approved following USP's routine revision process, with a public comment period from November 1, 2019 to January 31, 2020. In light of the broad implications of this standard and to address potential implementation concerns, the new requirements have been given an extended official date of September 1, 2023.

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

Patient Safety Challenges[1]

The Nomenclature and Labeling Expert Committee (NL EC) evaluated patient safety data and concerns related to expiration date formats. Examples included the following:

- Difficulty determining if the numbers represent a lot number or expiration date.
- Confusion with 2-digit year formats. Example: 20MAR21 can be interpreted as March 20, 2021 or March 21, 2020.
  - Formats that included a 2-digit year were more easily confused with a day.
- Misinterpretation of 2-letter months. Example: MA – March or May; or JU – June or July.
- All-numeric (6-digit) formats without a hyphen or forward slash separating the 2-digit year, month, and day can be misinterpreted depending on the digits used. Example: 201222 can be interpreted as December 20, 2022, December 22, 2020, or a lot number.
- Multiple variations in the order of year, month, and day, which can lead to difficulty in the interpretation of expiration dates.

To address patient safety concerns, the NL EC agreed upon the following expiration date format changes:

- 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 3 letters for the month in alphanumeric formats to help minimize misinterpretations.
- The use of hyphens or forward slashes to help improve readability when used to separate the year, month, and day.

[1] Institute for Safe Medication Practices. National Medication Error Reporting Program.

July 31, 2020

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June 3, 2021 ▲ Volume 26 Issue 11

ISMP

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

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

Problem: Decades ago, ISMP became aware of multiple patient injuries and fatalities associated with the accidental intravenous (IV) administration of concentrated potassium chloride for injection prior to dilution. Back then, it was common to find potassium chloride vials on nursing units in US hospitals, and the occasional mix-ups due to look-alike medication vials or mental slips led to disastrous outcomes. By 1987, ISMP had already convened a national meeting that helped influence USP and the US Food and Drug Administration (FDA) to require vials of concentrated potassium chloride for injection to have black caps and closures as well as warning statements to prevent mix-ups with other parenteral drugs. Nevertheless, potassium chloride vials remained on nursing units, and unsafe practices, such as not labeling syringes of potassium chloride intended for IV admixture preparation, continued to contribute to fatalities.

In 1995, ISMP sent a nationwide mailing to US hospitals that strongly recommended the removal of vials of concentrated potassium chloride for injection from patient care areas. Three years later, in the very first *Sentinel Event Alert* (www.ismp.org/sea711), The Joint Commission (TJC) asked hospitals to consider ISMP's recommendation to not allow the vials outside of the pharmacy. By 2003, TJC required hospitals to remove concentrated potassium chloride and other concentrated electrolytes from all patient care units outside of the pharmacy in its inaugural *National Patient Safety Goals*. Since then, ISMP has been aware of only one case of accidental IV push of concentrated potassium chloride in the US in 2007 in a non-Joint Commission accredited hospital…until now.

ISMP recently received a report of an error in which concentrated potassium chloride was administered IV push to a patient during a cardiac arrest (code). In this hospital, concentrated potassium chloride vials were only stocked in the pharmacy, not on patient care units. Hands down, this is the most effective safeguard to prevent inadvertent IV administration of undiluted potassium chloride. Still, the event happened when a clinical pharmacist called the central pharmacy to ask staff to bring a vial of concentrated potassium chloride to a code he was attending. Through a series of miscommunications and incorrect assumptions, the drug was administered undiluted to the patient.

The Event

A 70-year-old intensive care unit (ICU) patient in isolation with a contagious infectious disease (not coronavirus disease 2019 [COVID-19]) experienced a cardiac arrest. To prevent unnecessary staff exposure to the infectious disease, the code was not announced overhead hospital-wide but only in the ICU. This resulted in a small team responding to the code—an experienced ICU intensivist, an experienced ICU pharmacist, and a nurse fellow and his preceptor (an experienced ICU nurse). In this hospital, the nursing fellowship program offered licensed nurses with some generalized experience the professional development necessary to become successful in a specialty field—in this case, ICU nursing.

During the code, the ICU intensivist verbally requested "potassium chloride 20 mEq IV." The pharmacist, who was pulling and preparing the requested medications, assumed that the intensivist did not want to administer an infusion, which would have required an hour to administer. Instead, the pharmacist thought the intensivist had purposely

continued on page 2 — Potassium chloride >

SAFETY briefs

Adrenalin vials look similar to COVID-19 vaccine vials. It has been called to our attention that EPINEPHrine (ADRENALIN) vials from Par Pharmaceutical look similar to the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine vials. Both are about the same size and shape, with purple caps and mostly black print on white labels (Figure 1). A *Safety Brief* in our April 8, 2021, newsletter discussed two cases that occurred at a vaccination site where EPINEPHrine syringes were accidentally administered to patients instead of the Moderna COVID-19 vaccine, shedding light on the importance of ensuring separate storage of EPINEPHrine and COVID-19 vaccine syringes. It should not be difficult to see how the same mix-up could happen with these similar-looking vials.

Figure 1. Similar-looking vials of Par Pharmaceutical's Adrenalin (left) and the Pfizer-BioNTech COVID-19 vaccine (right).

Certainly, EPINEPHrine must be readily available to treat a rare anaphylactic reaction associated with the COVID-19 vaccines. However, avoid storing these vials near COVID-19 vaccines. If possible, consider utilizing barcode technology that requires scanning the EPINEPHrine vials prior to administration (despite the fast-paced environment during

continued on page 2 — SAFETY briefs >

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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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http://photos.prnewswire.com/prnh/20110422/NY88254
https://mms.mckesson.com

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Unfamiliarity with Mixing and Preparing 2 Component Vaccines

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https://www.gskdirect.com

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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

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Pentacel

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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

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The Sydney Morning Herald

MEASLES OUTBREAK

Why measles has 'spread like wildfire' in Samoa

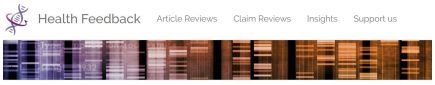
More than 60 people, including many children, have died as a measles outbreak sweeps the island nation. How big is the problem and where else in the world is measles on the march?

By Georgia Forrester

DECEMBER 6, 2019


REPORTS

SERIOUS ERRORS WITH TWO-COMPONENT VACCINES RISK HARM AND DAMAGE TRUST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Human error in vaccine preparation led to the deaths of two children in Samoa after MMR shot – MMR vaccine itself is safe and effective


NEWS / HEALTH

UN: vaccine mistake killed Syrian children

UN official says 15 children given muscle relaxant by mistake by NGO, in a case of "basic human error".

1 Oct 2014

Syria's conflict has caused the collapse of its health system [AFP]

The UN has admitted 15 Syrian children died after an NGO partner mistakenly gave them the wrong drug during a measles vaccination programme.

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


Watch Live President Obama chairs U.N. Security Council meeting on world terrorism

CBSNEWS Video US World Politics Entertainment Health MoneyWatch SciTech Crime Sports Photos

15 Syrian children die after measles vaccinations

BEIRUT -- At least 15 children died after receiving vaccinations in rebel-held parts of northwestern Syria, while the death toll from two days of government airstrikes on a central city climbed to nearly 50, a heavy toll even by the vicious standards of the country's civil war, activists said.

The children, some just babies, all exhibited signs of "severe allergic shock" about an hour after they were given a second round of measles vaccinations in Idlib province on Tuesday, with many suffocating to death as their bodies swelled, said physician Abdullah Ajaj, who administered the vaccinations in a medical center in the town of Jarjanaz.

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endnomophobia.com

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Most Popular

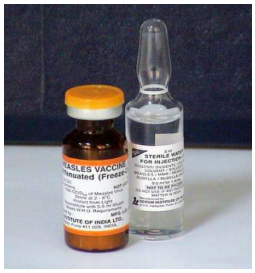
01 Wife of CBS Senior VP hit by bicyclist, dies

02 New photos show age, decline of pop music icon in prison

03 Zuckerberg making few "friends" in new neighborhood

04 Khorasan: Behind the group "following bin Laden's vision"

05 The U.S. launches first airstrikes against ISIS in Syria.



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Look-alike vials


ISMP Medication Safety Alert! Acute Care

August 23, 2012 ■ Volume 17 Issue 17

Avoiding inadvertent IV injection of oral liquids

SafetyBriefs

Insulin pen misuse by patient. When you turn the dose selector to dial a dose of insulin using a NOVOLOG FLEXPEN (insulin aspart), the number of units that will be administered appears in a dose window. For example, in Figure 1, the dose that has been dialed is 46 units. We recently received an interesting report from a registered nurse (RN)/Certified Diabetes Educator (CDE) about a patient who suffered an overdose by misreading the amount dialed. The patient arrived at a hospital emergency department unconscious with a blood sugar of 20 mg/dL. She was treated and later questioned to understand how she gave herself insulin aspart (NovoLOG) using the NovoLOG FlexPen. She demonstrated how she dialed the dose by reading the numbers to the right of the dosing window, not within the window. She thought she was giving herself 6 units when she actually was giving herself 46 units! This is the first and only report we've received like this, but we thought we would make readers aware so they can double check that patients are reading the dose in the right location on the pen device. Incidentally, the CDE cited other problems we hadn't heard before either, such as patients inserting the needle but not pushing the push-button to release the insulin injection, or instead of pushing the push-button they turned the dial, expecting that action would lead to the release of the insulin. These examples demonstrate why it is important for patients to meet with a CDE, pharmacist, or other healthcare professional before using an insulin pen.

Figure 1. Patient using a FlexPen misidentified the dose as 6 units instead of the actual 46 units.

Diluent vial looks like drug vial. When powdered or lyophilized drugs require dilution and are co-packaged with a diluent that isn't clearly labeled, there is the danger that only the diluent may be used. Over the years this has been a recurring problem with products

continued on page 2 – SafetyBriefs

Figure 1. Oral syringes of morphine.

that oral syringes are available, their purpose, or even how to use them. Unfortunately, in some cases, oral syringes have been inserted into a needleless port and jury-rigged to fit, or simply held against the port to inject the oral medication, despite the fact that contents may leak out due to the poorly fit connection.

Recently a nurse caring for a combative patient who was going through alcohol withdrawal administered oral LORazepam intravenously. Another nurse had inadvertently grabbed an oral LORazepam syringe from an automated dispensing cabinet (ADC) refrigerator, brought it to the bedside, removed the large red cap, and handed the syringe to another nurse. That nurse expressed frustration that the pharmacy had put the LORazepam in a syringe that could not be connected to the IV cannula's needleless connector. He expelled the oral LORazepam into an IV syringe, attached it to an IV port, and administered the medication. It wasn't until 12 hours later when the controlled drug count was incorrect that the team

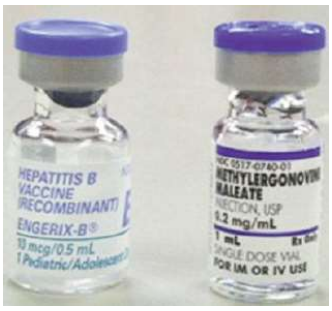
continued on page 2 – Oral liquids IV

Generic methylergonovine and Engerix-B mix-ups due to look-alike vials

Novartis Pharmaceuticals sent a letter dated July 2012 to hospitals that highlighted the accidental administration of METHERGINE injection (methylergonovine maleate) to newborns instead of hepatitis B injection. Novartis stopped selling Methergine in February 2012 but issued the letter since the company holds the application for the only brand drug product. The letter also mentioned a mix-up between vitamin K and Methergine; however, the mix-up involved oral liquid formulations which are available in Italy. An oral liquid Methergine formulation is not available in the US. Novartis also reported that it had changed the product labeling for Methergine to include information about medication errors, which will be required for the product labeling of generic products in the future.

The brand product Methergine injection used to be packaged in an ampul within an amber blister that looked quite different than vials of generic methylergonovine. Now, the generic products are being used exclusively because the brand product Methergine is no longer avail-

continued on page 3 – Look-alike vials



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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.

Key Differences	Zostavax	Shingrix
Vaccine Type	Live attenuated	Inactivate recombinant adjuvated
Age recommendation	60 years or older	50 years or older
Vaccine Schedule	1 dose, 0.65 mL	2 doses, 0.5 mL @ 0, 2-6 months
Administration Route	Subcutaneous	Intramuscular
Storage	Frozen, reconstituted	Refrigerated, reconstituted

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https://theabofpharmacsite.wordpress.com/2017/12/08/shots-for-the-new-year/

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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

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Position of Proper Name on Biologicals

- 1968 - 33 Fed. Reg. 367 (Jan. 10, 1968). "The proper name of the product on the package label shall be placed above any trade-mark or trade name identifying the product and symmetrically arranged with respect other printing on the label." 33 Fed. Reg. at 369.
- Inconsistent with all other drugs
- Patient safety issue with combination products

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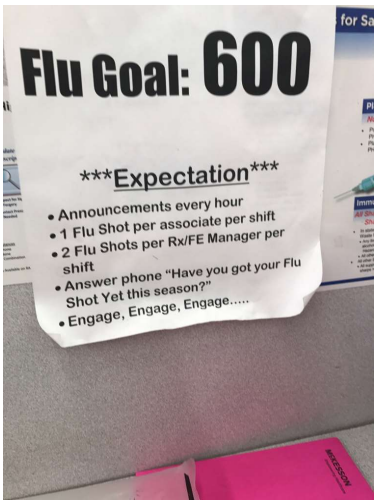
Chain Pharmacy



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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 January 2010 in Wellesley, Massachusetts staffers at a school there received insulin instead of influenza vaccine (http://www.flushots4u.com/press/article/61/How-Did-School-Staffers-Get-Insulin-Instead-of-Flu-Vaccine).
- In 2007 case where a teacher in nearby Attleboro received insulin instead of flu vaccine.
- In November 2009 in Holland, 11 elderly residents in a nursing home received insulin instead of influenza vaccine http://www.diabetesdaily.com/forum/diabetes-news/34510-insulin-instead-mexican-flu-shot.
- 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_inj.php.
- In 2008 in Bedford County Virginia, five school employees went to the hospital after the school nurse accidently gave insulin instead of the flu shot. http://www.newsadvance.com/news/local/bedford-school-employees-mistakenly-get-insulin-not-flu-vaccine/article_622f43da-189b-563d-b01d-1ce8f679a5db.html?mode=jqm
- May 5, 2016. Fifty hospital employees given insulin instead of influenza vaccine. https://www.ismp.org/resources/fifty-hospital-employees-given-insulin-instead-influenza-vaccine.
- November 2019. Oklahoma pharmacist accidentally gives 10 people insulin instead of flu shot. https://www.beckershospitalreview.com/quality/oklahoma-pharmacist-accidentally-gives-10-people-insulin-instead-of-flu-shot.html
- 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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Process for Administering Vaccines

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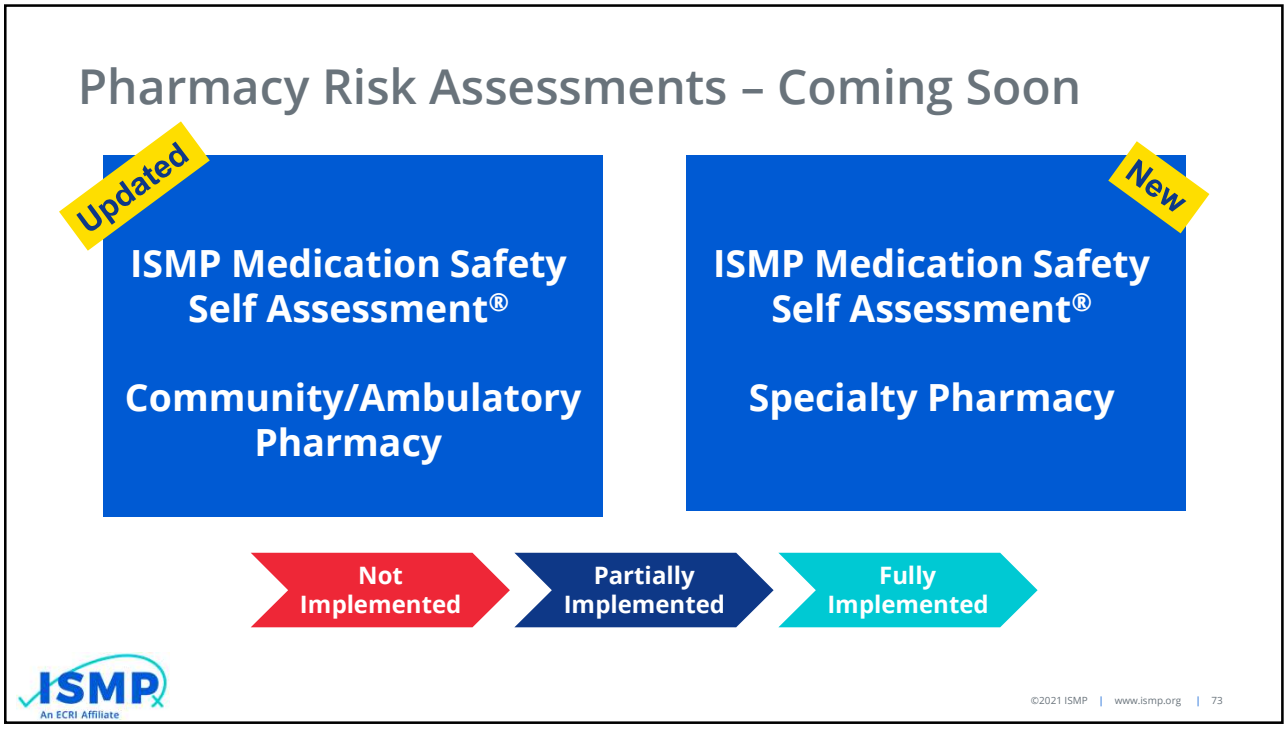
Important Actions Community Pharmacies Need To Take Now To Reduce Potentially Harmful Dispensing Errors



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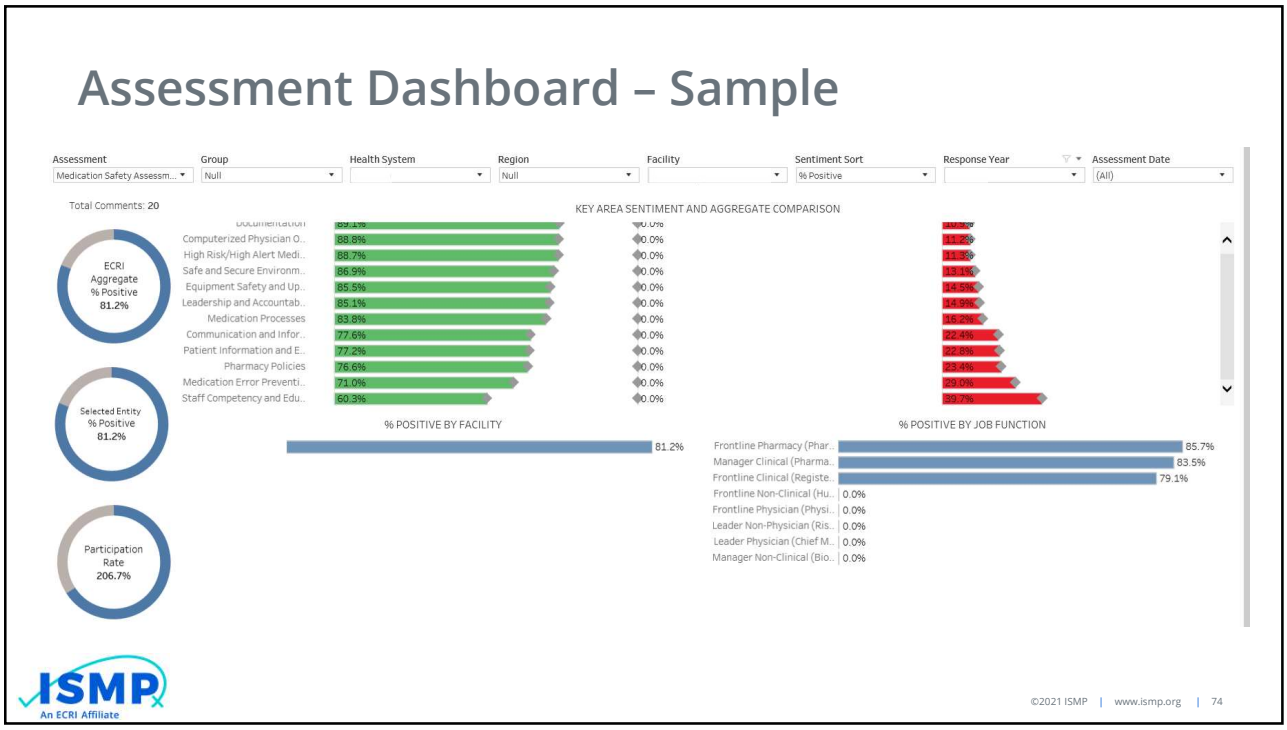

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Medication Safety Intensive (MSI) Workshops

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

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

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Questions?

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

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