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Top Medication Errors Reported to ISMP in 2020

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Learning Objectives

Following completion of this activity, participants will be able to:

- Identify globally relevant medication errors reported to ISMP in 2020.
- Apply strategies that can be employed to help reduce medication errors.

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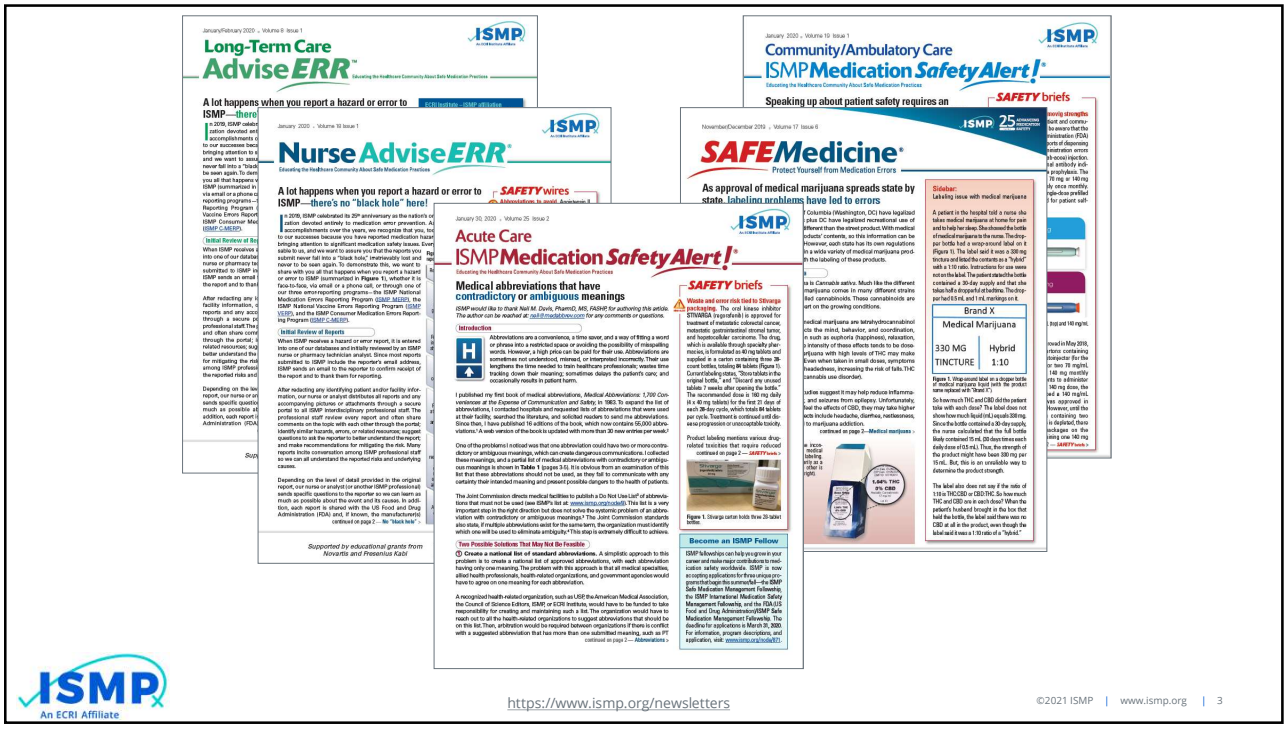
Top Medication Errors Reported to ISMP in 2020



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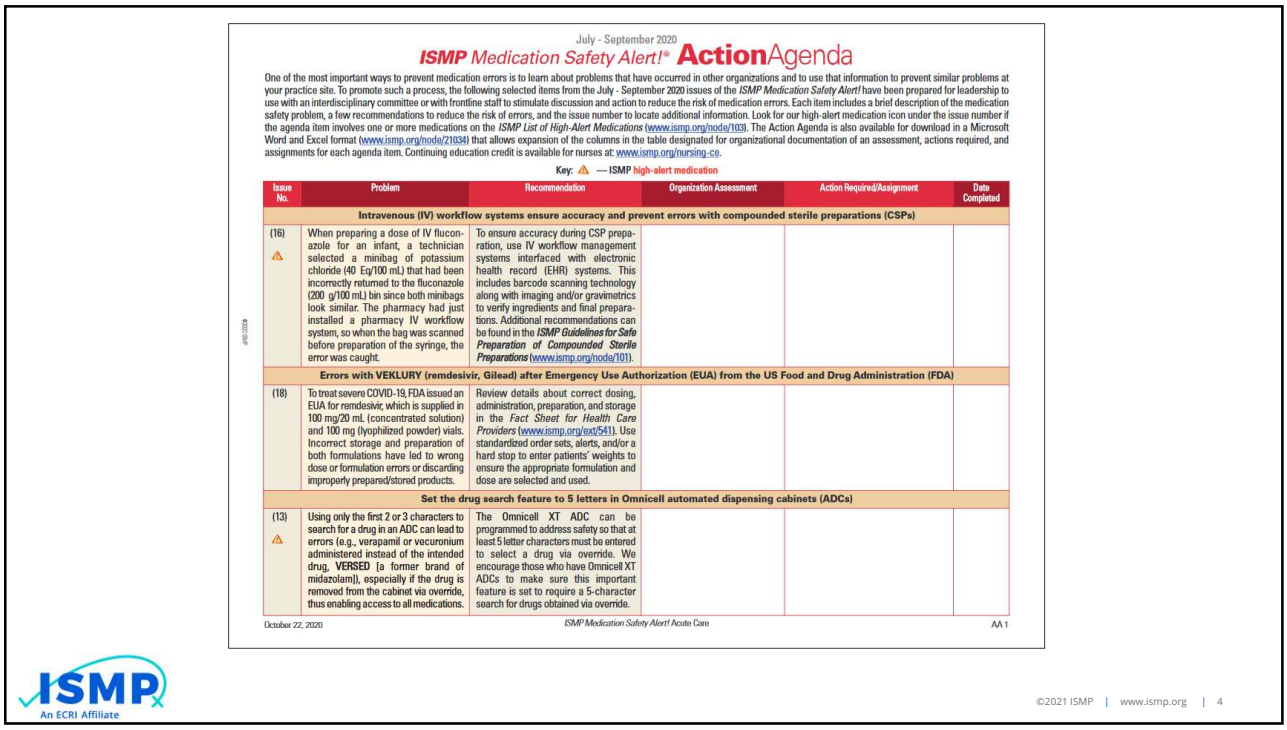

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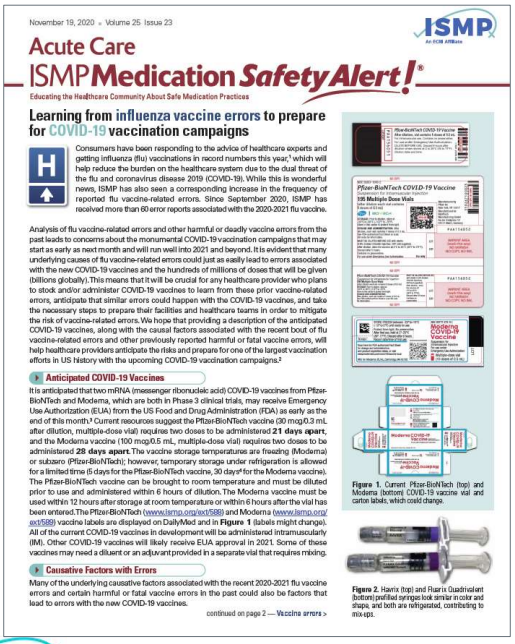

November 19, 2020 • Volume 25 Issue 23

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/589) 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.

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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 60 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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Medication Safety Issues with the COVID-19 Vaccines

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Top Medication Errors Reported to ISMP in 2020

Problem

- Dilution errors leading to under- or overdose of vaccine
- Mixing errors with 2-component vaccines (diluent instead of vaccine)
- Storage issues (unsegregated vaccines)
- Not checking/documenting in immunization information system
- Look-alike vials (vaccine-monoclonal antibody mix-up)
- Administration to wrong age group
- Waste of vaccine and not taking advantage of over-fill in vaccine vials
- Errors in scheduling second dose

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Recommendations

- Verify competency of vaccinators
- Dispense pharmacy prepared syringes where possible
- Implement independent double check
- 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

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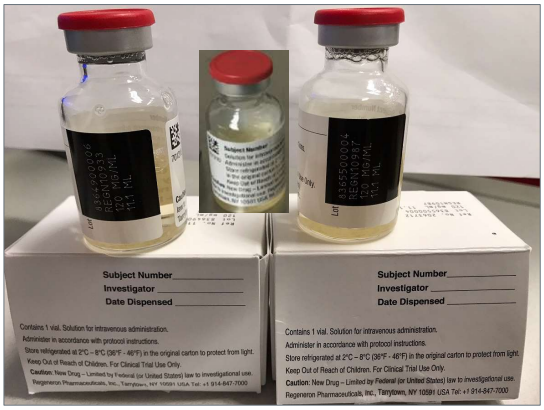

Casirivimab and imdevimab monoclonal antibodies

Moderna COVID-19 vaccine

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US Food and Drug Administration (FDA) removes syringe administration from vinCRIStine labeling

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Problem

- Syringes for IV use have been confused with syringes of drugs administered intraspinally (intrathecally)
- Accidental intrathecal administration of vinCRIStine has killed over 130 patients, many of whom were children with acute leukemia

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Problem, cont.

- In 2019, ISMP called on FDA to eliminate vin**CRIS**tine syringe administration in official product labeling
- No cases of accidental intrathecal injection of the drug have been reported with dilution of the drug in a minibag
- In June 2020, FDA asked Pfizer to revise the product labeling. Pfizer complied, removing all references to vincristine administration via syringe from the package insert

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GUYANA NEWS

Cancer drugs incorrectly administered to children who died at GPH

-probe finds


Sharezer Mendonca


Roshini Seegobin

By David Papannah March 9, 2019

Investigations into the deaths of three children who died at the George-town Public Hospital (GPH) in January after being administered pre-chemotherapy drugs have found that the medication was incorrectly administered and standard operating procedures were not followed.

The findings were revealed at a press conference yesterday which included Chairperson of the GPH Board Kessaundra Alves, Deputy Chief Medical Officer Dr Karen Gordon-Boyle, and Director of Medical and Professional Services at the GPH Dr Fawcett Jeffrey.

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ISMP strongly recommends against dispensing and administering intravenous Vincristine in a syringe.

ISMP strongly recommends dispensing and administering intravenous Vincristine in a minibag.

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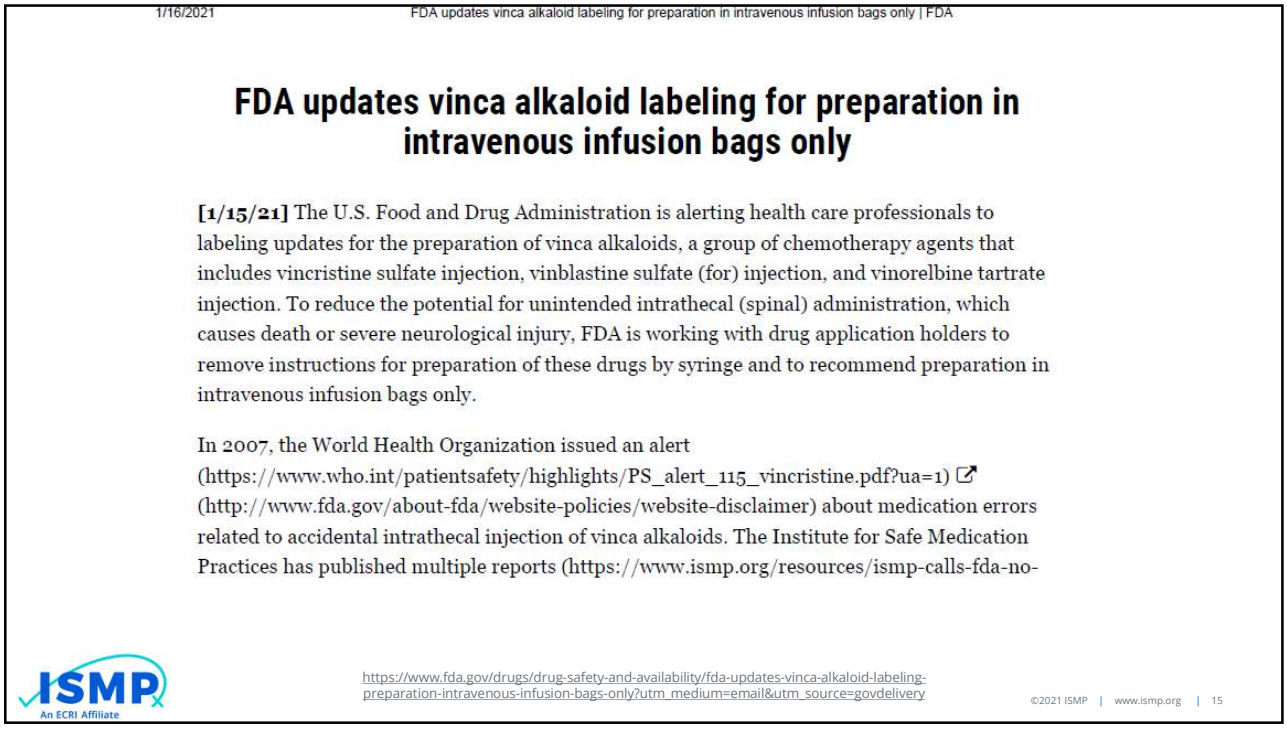

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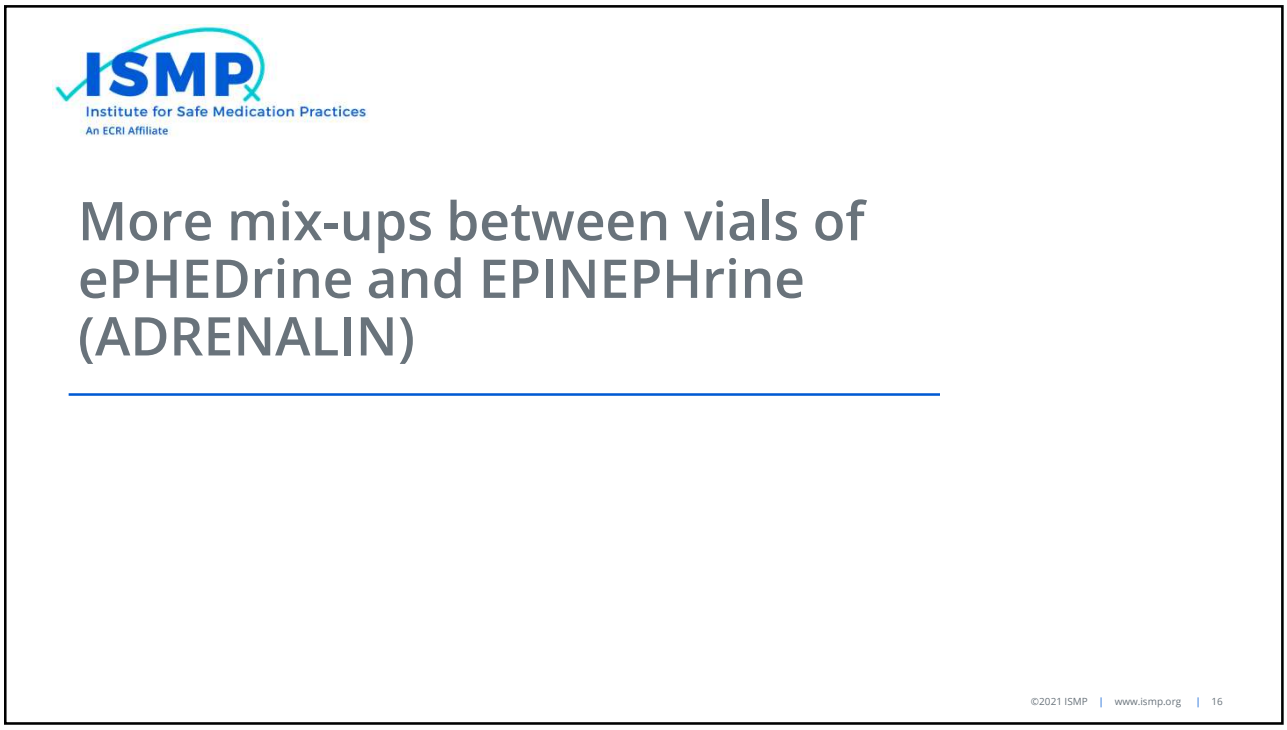

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Problem

- Look-alike vials of e**PHED**rine and **EPINEPH**rine have been frequently mixed up due to name and packaging similarities.
- The latest mix-up occurred between Ameal Pharmaceuticals e**PHED**rine and PAR Pharmaceutical **EPINEPH**rine vials, both of which are similar in size (1 mL) and have purple caps.

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Recommendations

- Utilize barcode scanning when stocking, dispensing, and administering these medications.
- Store them apart in the pharmacy and in locked-lidded drawers in automated dispensing cabinets.
- Consider obtaining a different brand of e**PHED**rine with a different cap color, using prefilled **EPINEPH**rine syringes from an outsourcer when possible, or having pharmacy prepare infusions and bolus doses for these drugs except in emergencies.
- e**PHED**rine is available in the US in a prediluted form called EMERPHED

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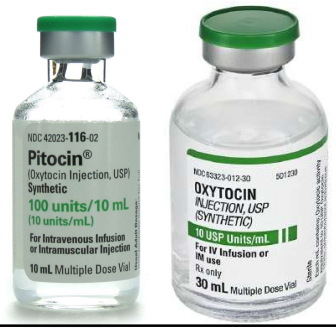
Errors associated with oxytocin (PITOCIN) use



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Oxytocin

- Intravenous (IV) oxytocin used antepartum is indicated to induce labor in patients with a medical indication, to stimulate or reinforce labor in selected cases of uterine inertia, and as an adjunct in the management of incomplete or inevitable abortion
- Postpartum IV oxytocin is used to produce uterine contractions during expulsion of the placenta and to control postpartum bleeding or hemorrhage
- Improper administration can cause hyperstimulation of the uterus, which in turn can result in fetal distress, the need for an emergency cesarean section, or uterine rupture
- A few maternal, fetal, and neonatal deaths have been reported

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Error Report Analysis

5 Main Themes Identified

1. Prescribing Errors
2. Look Alike Drug Packaging and Names
3. Preparation Challenges
4. Administration-Associated Errors
5. Communication Gaps

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Prescribing Errors

- Selecting the wrong drug on computerized prescriber order entry (CPOE) screen when searching using only 3 letters, “PIT,” “OXY,” or “OXY10”
- Example: A physician intended to prescribe oral **OXYCONTIN** (oxy**CODONE**) 10 mg every 12 hours as needed for pain for a postpartum patient. He entered “OXY10” into the CPOE search field but accidentally selected “oxytocin 10 units IV” from the menu, resulting in an order for oxytocin 10 units IV every 12 hours as needed for pain. By the time the pharmacist followed up with the prescriber and corrected the error, the patient had received one dose of IV oxytocin

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Look Alike Packaging

- 40% of all oxytocin-related reports submitted to ISMP described look-alike vials that had led to, or could have led to, mix-ups between oxytocin and another product
- Look-alike vials (e.g., ondansetron) and names (**PITRESSIN**, a discontinued brand of vasopressin) stored near **PITOCIN** or in ADC
  - **Often stored alphabetically near each other on pharmacy shelves and used for the same patient population, especially during cesarean sections**

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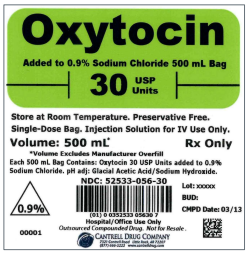
Preparation Challenges

- Nurse admixture on patient care units and incomplete or omitted labels for nurse-prepared infusions led to oxytocin given instead of plain IV fluid
- These labeling problems were typically due to interruptions, distractions, or competing priorities on the patient care unit
- Example: An unlabeled bag of what was presumed to be a plain IV solution was administered to a patient. Staff later noted maternal cramping and fetal heart rate deceleration. An investigation revealed that the bag contained oxytocin. The patient required an emergency cesarean section



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Administration Errors

- Mix-ups of IV lines and misconnections to the wrong infusion pump have resulted in drug or dose errors and omissions.
  - **Contributing factors: need for multiple IV lines, a fast-paced work environment, heavy workload, failure to trace lines, inexperienced staff, and distractions**
- Oxytocin infusion bag was mixed up with either a hydrating fluid or magnesium infusion, leading to significant under- or overdoses
  - **Contributing factor: availability of an oxytocin infusion during labor that was intended for use postpartum**
- Inconsistent terminology used to express an oxytocin infusion rate in the medication order, administration record, and/or pump library led to several errors
- Flushing IV tubing with unrecognized residual oxytocin can lead to adverse effects (10 mL or more in line and ports)

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Communication Gaps

- Lack of clear communication and/or documentation during transitions of care was a key contributor to oxytocin incidents
- Reporters attributed poor communication/documentation to heavy workload, a fast-paced environment, inexperience, and involvement of many individuals in the patient's care
- Example: Administration of oxytocin was put on hold when staff noted a deceleration in the fetal heart rate. Fifteen minutes later, the physician examined the patient and gave a verbal order to restart the oxytocin infusion, but at a lower rate. A few minutes later, a second physician, who was taking over for the first, gave an order to restart the oxytocin at the original dose. The lack of documentation regarding the decision to lower the rate of infusion was a factor in this incident

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Recommendations

- Require at least 5 letters of a drug name when searching electronic systems or keep typing until the drug name appears
- Develop standard order sets and have pharmacy dispense oxytocin in ready-to-administer, labeled bags in standardized concentrations
- Use barcode scanning technology.
- Standardize oxytocin dosing units and infuse through a smart infusion pump with engaged drug library
- Label and trace lines when starting infusions, and immediately discard discontinued infusion bags
- Use communication strategies (e.g., SBAR) during transitions of care
- Once oxytocin infusion completed, change IV line or flush tubing after disconnection

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Vials of Neuromuscular Blocking Agents Without Cap Warnings

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No Warnings on Caps

- Due to shortages, the US Food and Drug Administration (FDA) allowed temporary manufacturing of paralyzing agents without the vial cap warning, "Paralyzing Agent"
- Affected products include vecuronium (Fresenius Kabi) and rocuronium (Athenex, Alvogen)
- Vials are no longer being manufactured without a cap warning, expiration dates of vials without the warning extend through June 2022 and may be present until then The vial and carton labels will remain unchanged
- The absence of the cap warning may lead to potentially fatal drug selection errors with look-alike vials

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Problem

Currently approved cap (left) and temporary cap (right) for vecuronium bromide injection 10 mg vial and 20 mg vial

Currently approved cap (left) and temporary cap (right) for rocuronium bromide injection, 50 mg per 5 mL and 100 mg per 10 mL

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Problem, cont.

- When vials are standing upright in storage, staff may select a vial based on cap color and may not notice if they have the wrong vial in hand (Below: tranexamic acid, left, ropivacaine, right)

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Recommendations

- Make sure staff are aware of the absence of the warning statement on some paralyzing agents that may still be in stock
- Ensure storage of these products leaves the labels (which still carry a warning statement), not the caps, face up
- Affix auxiliary "Warning: Paralyzing Agent" labels to vial caps of affected products
- Use barcode scanning during preparation and administration

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Wrong-Route Tranexamic Acid Errors

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Problem

- Three cases of inadvertent spinal tranexamic acid administration instead of a local anesthetic were reported
- Prior mix-ups have occurred between tranexamic acid and bupivacaine or ropivacaine
- Activated the National Alert Network(NAN) in September 2020

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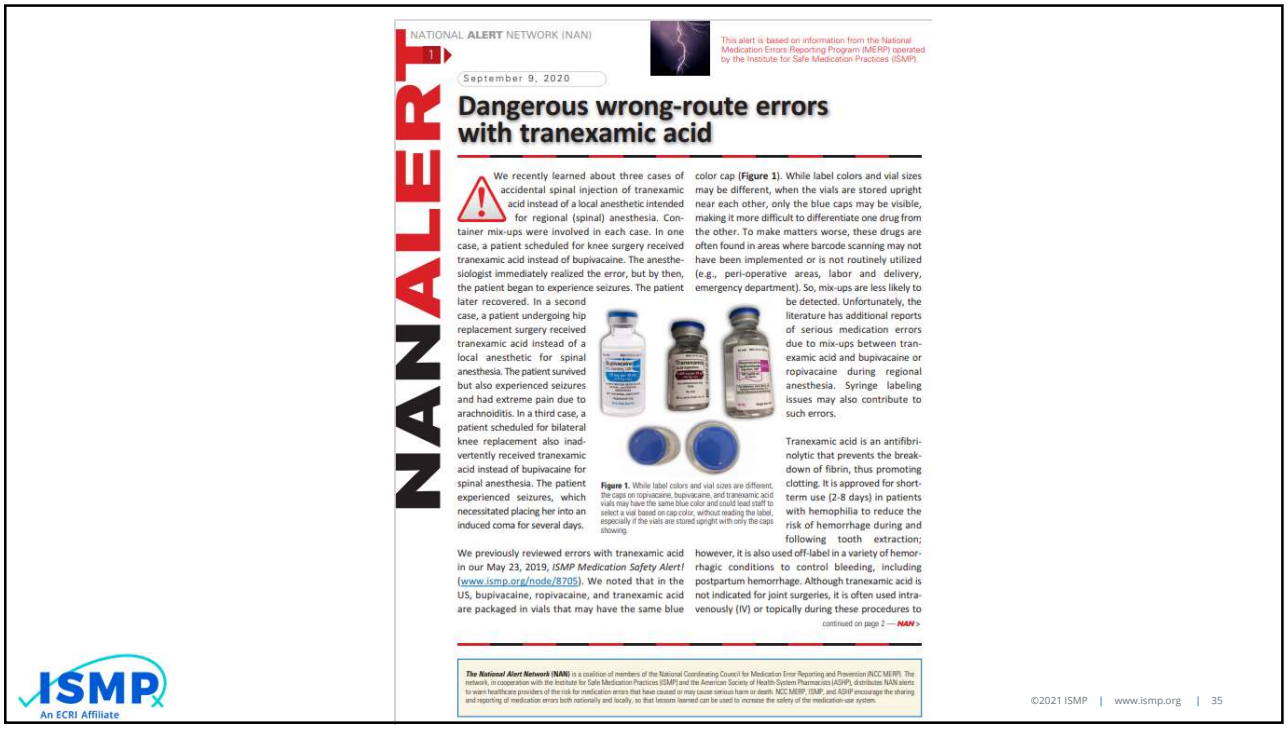

NATIONAL ALERT NETWORK (NAN)

NANALERT 1

September 9, 2020

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

Dangerous wrong-route errors with tranexamic acid

We recently learned about three cases of accidental spinal injection of tranexamic acid instead of a local anesthetic intended for regional (spinal) anesthesia. Container mix-ups were involved in each case. In one case, a patient scheduled for knee surgery received tranexamic acid instead of bupivacaine. The anesthesiologist immediately realized the error, but by then, the patient began to experience seizures. The patient later recovered. In a second case, a patient undergoing hip replacement surgery received tranexamic acid instead of a local anesthetic for spinal anesthesia. The patient survived but also experienced seizures and had extreme pain due to arachnoiditis. In a third case, a patient scheduled for bilateral knee replacement also inadvertently received tranexamic acid instead of bupivacaine for spinal anesthesia. The patient experienced seizures, which necessitated placing her into an induced coma for several days.

We previously reviewed errors with tranexamic acid in our May 23, 2019, *ISMP Medication Safety Alert!* (www.ismp.org/node/8705). We noted that in the US, bupivacaine, ropivacaine, and tranexamic acid are packaged in vials that may have the same blue color cap (**Figure 1**). While label colors and vial sizes may be different, when the vials are stored upright near each other, only the blue caps may be visible, making it more difficult to differentiate one drug from the other. To make matters worse, these drugs are often found in areas where barcode scanning may not have been implemented or is not routinely utilized (e.g., peri-operative areas, labor and delivery, emergency department). So, mix-ups are less likely to be detected. Unfortunately, the literature has additional reports of serious medication errors due to mix-ups between tranexamic acid and bupivacaine or ropivacaine during regional anesthesia. Syringe labeling issues may also contribute to such errors.

Figure 1. While label colors and vial sizes are different, the caps on ropivacaine, bupivacaine, and tranexamic acid vials may have the same blue color and could lead staff to select a vial based on cap color, without reading the label, especially if the vials are stored upright with only the caps showing.

Tranexamic acid is an antifibrinolytic that prevents the breakdown of fibrin, thus promoting clotting. It is approved for short-term use (2-8 days) in patients with hemophilia to reduce the risk of hemorrhage during and following tooth extraction; however, it is also used off-label in a variety of hemorrhagic conditions to control bleeding, including postpartum hemorrhage. Although tranexamic acid is not indicated for joint surgeries, it is often used intravenously (IV) or topically during these procedures to

continued on page 2 — NAN >

The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCC MERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication-use system.

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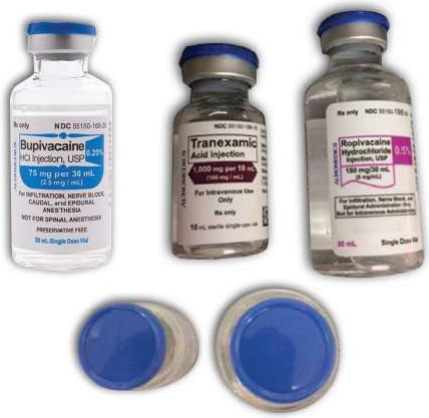
Problem, cont.

- All three products are available in vials with blue caps, which are often stored upright making labels difficult to read. These products are typically used in areas where barcode scanning is not utilized (e.g., operating room, labor and delivery).



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Recommendations

- Purchase these products from different manufacturers to help differentiate appearance and/or consider alternate preparations (e.g., premixed bag, pharmacy prepared syringes or infusions).
- Store tranexamic acid separately and avoid upright storage to ensure labels are always visible.
- Use an auxiliary label over the cap to indicate vial contents.
- Use barcode scanning prior to dispensing or administering.

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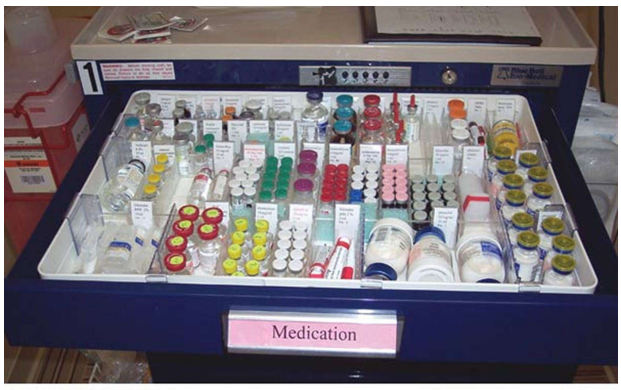

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Label Updates are Coming

- The US FDA has announced that it will be revising the labeling for tranexamic acid to reduce the risk of potentially fatal wrong route errors
- The FDA labeling changes will highlight the intravenous (IV) route of administration and strengthen the warnings in the prescribing information to include the risk of medication errors due to incorrect route of administration

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Mix-ups between conventional and liposomal drug products

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Problem

- Conventional **DOXO**rubicin is used to treat a greater variety of cancers and it can be given at higher doses than the liposomal form, which has slower plasma clearance
- A technician accidently used liposomal instead of conventional **DOXO**rubicin to prepare two infusions

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Problem, cont.

- During preparation, the technician received an alert when she scanned the wrong medication, which she overrode
  - **At risk behavior which may be common due to alert fatigue**
- The pharmacist did not catch the error during verification, and the preparations were dispensed and administered
- One order was compounded with a mixture of liposomal and conventional **DOXO**rubicin and the other order was compounded with liposomal instead of conventional **DOXO**rubicin

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Potential for other mix ups

- IV amphotericin also has the potential for mix-ups between formulations
  - **Either subtherapeutic or fatal dosing mistakes are possible**
- Liposomal amphotericin B (**AMBISOME)** generally dosed 7.5 mg/kg IV daily
- Conventional amphotericin B deoxycholate should not exceed 1.5 mg/kg/day

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Recommendations

- Require independent double check of drug and dose
- Prepare in pharmacy where pharmacist can verify the dose before preparation
- Vials of liposomal and conventional **DOXO**rubicin should be stored separately with a prominent sticker on the liposomal formulation
  - e.g., "DOUBLE CHECK: LIPOSOMAL DOXORUBICIN. DO NOT CONFUSE WITH CONVENTIONAL DOXORUBICIN
- A pharmacist should review all scanning overrides prior to final verification of the preparation

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Inappropriate Prescribing of Transdermal FentaNYL Patches for Opioid-Naïve, Elderly Patients

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Problem

- Fenta**NYL** patches have been inappropriately prescribed:
  - **For opioid-naïve patients to treat acute pain.**
  - **Due to an "allergy" to codeine that was only a minor drug intolerance.**
- Fenta**NYL** patches should only be used in opioid-tolerant patients for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment.

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Case Report

- A long-term care patient was inappropriately prescribed fentanyl patch after leaving the Emergency Department (ED)
  - Provider thought he was opioid-tolerant since he received 3 small intravenous push doses of fentanyl while in the ED
  - Provider thought fentanyl was the only option because the patient had a documented allergy to codeine

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Opioid-Tolerant Definition

- Patients taking the following for at least one week or longer:
  - 60 mg of oral morphine per day
  - 60 mg of oral **HYDRO**codone per day
  - 30 mg of oral oxy**CODONE** per day
  - 25 mg of oral oxy**MOR**phone per day
  - 8 mg of oral **HYDRO**morphone per day
  - 25 mcg of transdermal fenta**NYL** per hour
  - An equianalgesic dose of another opioid

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REMS for Opioid Analgesics

- Goals:
  - Educate prescribers and other healthcare providers on the treatment and monitoring of patients with pain
  - Informing patients about risks and how to use and store opioids safely
  - Reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of opioid analgesics while maintaining patient access to pain medications
- Strategies:
  - Training must be made available to all healthcare providers involved in pain management

Risk Evaluation Mitigation Strategy (REMS): a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks

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Recommendations

- Follow REMS recommendation to educate healthcare providers and patients.
- Document each patient's opioid status.
  - ISMP Best Practice #15
- Build interactive alerts to confirm opioid tolerance when prescribing fenta**NYL** patches.
- Distinguish between true allergies and drug intolerances when collecting allergy information.
- Provide patient education sheet for all patients taking fentanyl for the first time.

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Top Medication Errors Reported to ISMP in 2020

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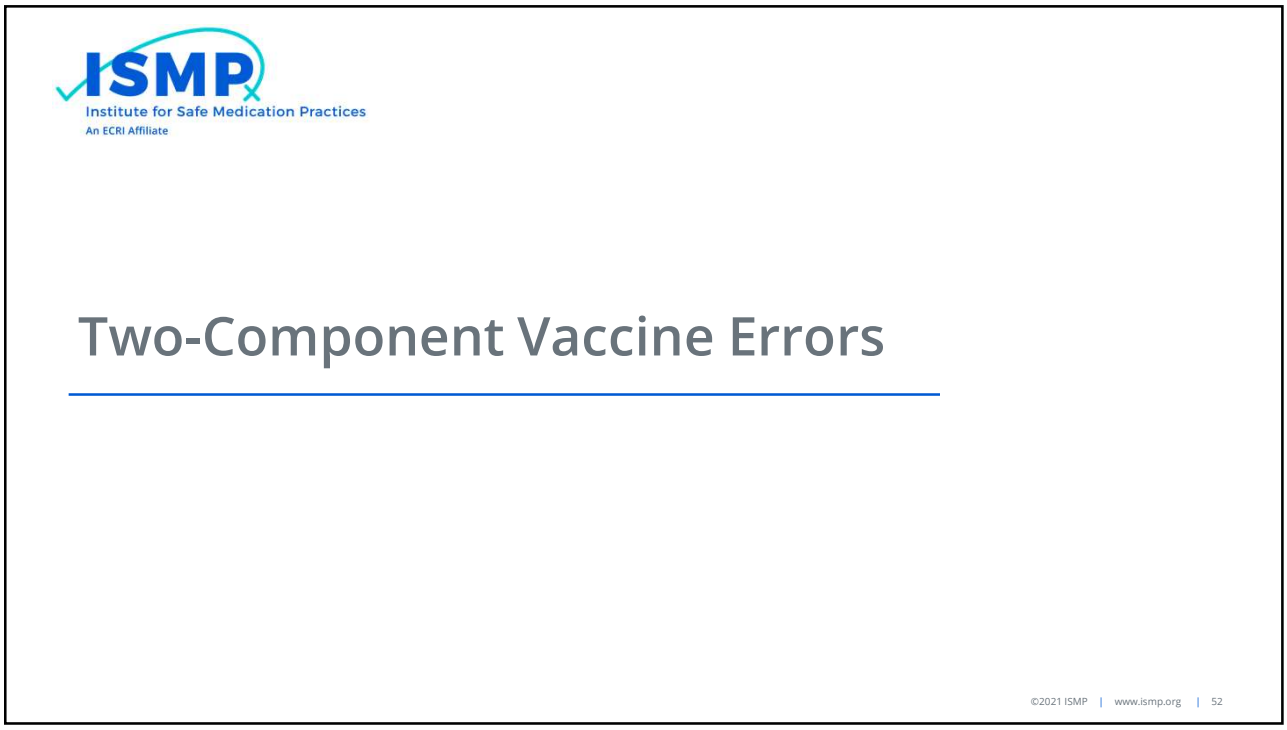

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Problem

Some vaccines come in two components:

1. Active ingredient- lyophilized (freeze dried) powder
2. Vaccine specific diluent (liquid to reconstitute) or liquid antigen or adjuvant

These two components need to be mixed before the vaccine is ready to be administered to the patient

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2-component vaccine error scenarios

Error State	Diluent	Active ingredient (e.g., lyophilized powder)	Example
No error ● Correct diluent ● Correct active ingredient			MMR lyophilized powder in sterile water injected
Error ● Correct diluent ● Wrong active ingredient			DTaP-IPV liquid by one company mixed with Haemophilus b Conjugate [Tetanus Toxoid Conjugate] Vaccine from different company
Error ● Correct diluent ● No active ingredient			Sterile water injected with no MMR lyophilized powder
Error ● Incorrect diluent ● Correct active ingredient			MMR lyophilized powder in neuromuscular blocker injected
Error ● Incorrect diluent alone			Insulin injected with no influenza vaccine lyophilized powder

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Top Medication Errors Reported to ISMP in 2020

Examples of Two-Component Vaccines

Haemophilus influenzae type b	Measles, mumps, rubella	Meningococcal group A
Rabies	Rotavirus oral vaccine	Tetanus toxoid
Varicella zoster	Yellow Fever	COVID-19

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Two-Component Vaccine Error in Samoa

- Medication error: measles, mumps, rubella vaccine reconstituted with atracurium (paralyzing agent)
  - **2 children died**
- The public concerned that vaccines were not "safe", causing low vaccination rates in Samoa
  - **Measles outbreak resulting in:**
    - 200,000+ infections
    - 85+ deaths


UPPSALA REPORTS

SERIOUS ERRORS WITH TWO-COMPONENT VACCINES RISK HARM AND DAMAGE TRUST

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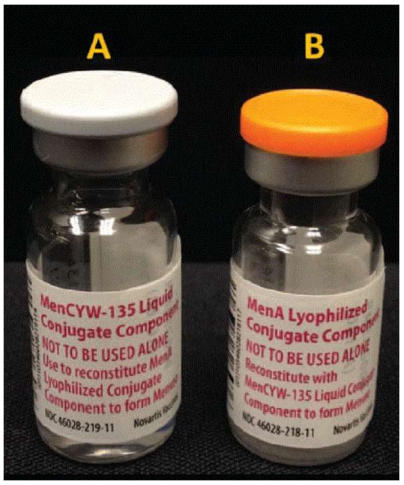
Error with Meningococcal Vaccine (Menveo)

- Menveo: 2 vials must be combined before administration for patient to get full immune response
- 390 reports of administering only one component of Menveo to a total of 407 recipients
  - 269 patients received only the liquid component
  - 138 patients received only the lyophilized component (reconstituted in a different diluent)



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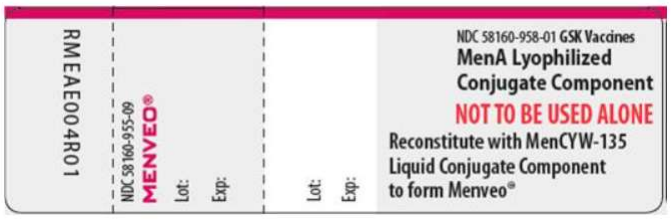
Menveo Updated Label



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Recommendations

- Review International Medication Safety Network (IMSN) Targeted Medication Safety Best Practices #4: Prevent errors with two-component vaccines.
- Circle or highlight critical information, use flag-type reminders.
- Dangerous drugs (paralyzing agents) should not be stored in proximity with vaccines.
- Use barcode scanning systems to ensure correct components are utilized.
  - **Scan both components during vaccine preparation.**
- Incorporate the patient or family member in the checking process if possible.

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Recommendations, cont.

- Manufacturers, technology companies, regulatory organizations work to improve the process
  - **Manufacturers should provide both components in a single container or package them in a way that provides fail-safe preparation**
  - **Labels should provide clear instructions for mixing**
- Establish a process to keep both vaccine components together

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Recommendations, cont.

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Questions?

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

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- https://ceinsider.org/ismp/
- Deadline: **January 30, 2021**
- Attendance Code: **2133**

This activity is approved for 1.25 contact hours for pharmacists and pharmacy technicians.

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