November 19, 2020 ▪ Volume 25 Issue 23

ISMP An ECRI Affiliate

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 >

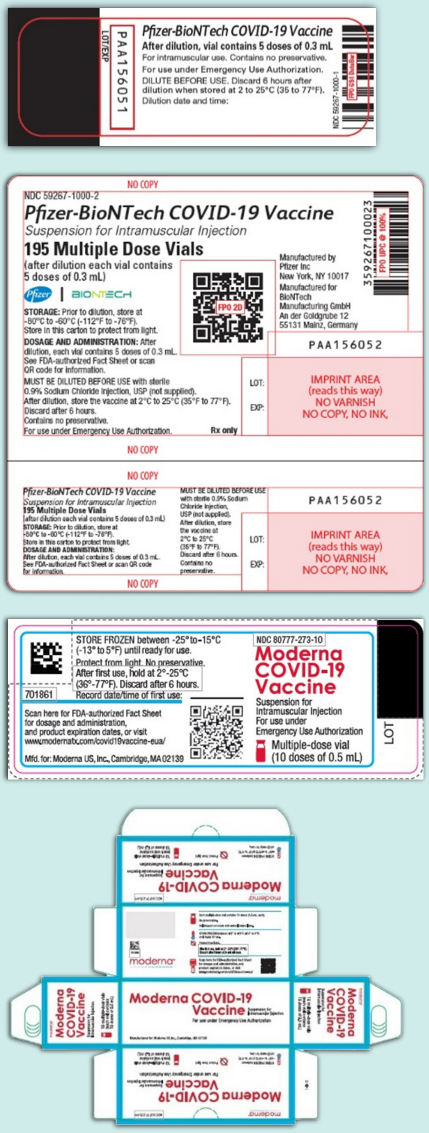

Figure 1. Current Pfizer-BioNTech (top) and Moderna (bottom) COVID-19 vaccine vial and carton labels, which could change.

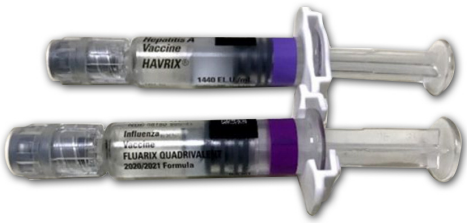

Figure 2. Havrix (top) and Fluarix Quadrivalent (bottom) prefilled syringes look similar in color and shape, and both are refrigerated, contributing to mix-ups.

> Vaccine errors — continued from page 1

Look-alike names, labels, packaging. Similar container labels, packaging, and/or vaccine names have contributed to numerous 2020-2021 flu vaccine errors. Name confusion with the flu vaccine is common given that most of the brand names begin with "FLU" (www.ismp.org/ext/581). An example of errors reported due to name confusion involve administering **FLUZONE QUADRIVALENT** instead of the intended **FLUZONE HIGH-DOSE QUADRIVALENT** to patients older than 65 years, or vice versa. Given that the COVID-19 vaccines authorized by an EUA will not be using proprietary brand names, there may be confusion related to similarities in the product name, "COVID-19 vaccine."

ISMP has also received reported flu vaccine-related errors related to look-alike labeling and/or packaging. For example, practitioners recently reported that prefilled syringes of the flu vaccine **FLUARIX QUADRIVALENT** and the hepatitis A vaccine **HAVRIX**, both from GlaxoSmithKline, look very similar.[5] Both syringes have a purple band in the same position on the barrel and are similar in shape (**Figure 2**, page 1, bottom right column).

We also received reports that the white and blue cartons of Fluzone Quadrivalent and **FLUBLOK QUADRIVALENT** prefilled syringes, both manufactured by Sanofi Pasteur, look very similar with the product names appearing with a similar blue and white color scheme. In one case, a carton of Flublok Quadrivalent was used to restock Fluzone Quadrivalent in an automated dispensing cabinet (ADC), leading to administration of the wrong flu vaccine.

Another report indicated that, for 2 consecutive years, **BOOSTRIX** (diphtheria and tetanus toxoids, acellular pertussis [Tdap] vaccine) has been accidentally administered instead of the intended Fluarix Quadrivalent vaccine. The error occurred twice last year and three time this year at different clinics. Both vaccines, from GlaxoSmithKline, come in a white box with a green stylized arch along the left border of the front panel.

Similar mix-ups are possible with the new COVID-19 vaccines if other vaccines or medications have look-alike labels or are packaged in similar-sized and/or colored vials.

Unsegregated storage in a refrigerator. Storing vaccines with other unsegregated vaccines or medications in a refrigerator or freezer has led to mix-ups with serious outcomes. For example, vials of insulin have sometimes been mistaken as flu vaccines, and neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as the flu vaccine itself. While only temporary storage in a refrigerator is permitted with the new COVID-19 vaccines, if other medications or vaccines are also stored unsegregated in the same refrigerator, mix-ups should be anticipated. Usually look-alike packaging and/or labeling is a contributing factor, but not always. We would be remiss not to mention a few examples of particularly harmful or fatal vaccine errors that have happened during the last 6 years due to comingled, unsegregated refrigerator storage of vaccines and medications:

- 2019: Four newborns died in Iraq after insulin was administered instead of the intended hepatitis B vaccine (reported to ISMP in October 2020)
- 2019: Two workers and eight residents in a community health facility in Oklahoma were hospitalized, several unresponsive, after insulin was administered instead of the intended flu vaccine (www.ismp.org/ext/577)
- 2016: Fifty hospital employees in Brazil required hospitalization after insulin was administered instead of the intended flu vaccine (www.ismp.org/node/549)
- 2014: Five teachers in Missouri, two of whom required hospitalization, received insulin instead of the intended flu vaccine (www.ismp.org/ext/579)
- 2014: Several patients in a US hospital emergency department received pancuronium instead of the intended flu vaccine, leading to dyspnea and respiratory depression (www.ismp.org/node/21294)

continued on page 3 — Vaccine errors >

SAFETY briefs

Infusion rate instructions for new COVID-19 monoclonal antibody. Table 1 in the *Fact Sheet* for Eli Lilly's bamlanivimab (www.ismp.org/ext/584) provides confusing administration rate information. The drug is available as a concentrated solution and must be diluted prior to administration by intravenous (IV) infusion. The Table in the *Fact Sheet* mentions that the final prepared product of 700 mg/200 mL should infuse at a minimum infusion rate of 200 mL/hour; however, it also states that the prepared 200 mL volume must be infused over at least 60 minutes. The specified infusion rate is actually the maximum infusion rate, as confirmed with Lilly. If 200 mL/hour is considered the minimum infusion rate, then bamlanivimab could be administered at a faster rate than recommended, which would result in the dose being given in less than 60 minutes. A Table on the Lilly website (www.ismp.org/ext/585) mentions only "infusion rate," not "minimum infusion rate."

Bamlanivimab, a monoclonal antibody, was recently granted Emergency Use Authorization (EUA) for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and children (12 years or older weighing 40 kg or more) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing. The dose should be administered as soon as possible after a positive viral test and within 10 days of symptom onset. It is for patients who are at high risk for progressing to severe COVID-19 and/or hospitalization, but not for patients already hospitalized.

The hospital that reported this infusion rate discrepancy has created a hard stop within their smart infusion pump software that prevents infusion rates greater than 200 mL/hr for bamlanivimab infusions. Also, administration instructions state to administer the dose over at least 60 minutes. This issue was reported to the US Food and Drug Administration (FDA) and to Lilly. Both have indicated that the *Fact Sheet* will be revised.

Veklury (remdesivir) update. As most readers are aware, the US Food and Drug Administration (FDA) recently approved **VEKLURY** (remdesivir) for the treatment of

continued on page 3 — SAFETY briefs >

> Vaccine errors — continued from page 2

- 2014: Fifteen children in Syria died after receiving the measles vaccine incorrectly reconstituted with atracurium instead of the provided diluent (Sterile Water) (www.ismp.org/node/21294)

Numerous 2020-2021 flu vaccine-related errors were caused by selecting the wrong product from a refrigerator. In one case, a nurse reached into the refrigerator and blindly removed a prefilled syringe from a carton of what she thought was Fluzone Quadrivalent but was instead **PREVNAR 13** (pneumococcal 13-valent conjugate vaccine), which she did not know was in the refrigerator. She administered the pneumococcal vaccine to a 5-year-old child instead of the flu vaccine. In several other cases during flu vaccination clinics, practitioners mistakenly removed the wrong age-specific flu vaccine from a cooler and administered it.

Mixing errors or omissions with 2-component vaccines. Flu vaccines are supplied as a single component, typically as a single dose in a prefilled syringe. However, the high incidence of error reports received by ISMP and others involving 2-component vaccines (e.g., vaccine and diluent, vaccine and adjuvant, vaccine liquid and powder components)[6] warrants mentioning given that the Pfizer-BioNTech COVID-19 vaccine requires a diluent (not supplied), and subsequent COVID-19 vaccines granted EUA or approval in 2021 may include 2 components (e.g., diluent or adjuvant liquid) in separate vials. The individual components of 2-component vaccines must be mixed together properly, a step that introduces an opportunity for errors. Errors have occurred when only the diluent, adjuvant liquid, or the undiluted vaccine itself were administered. Unique storage requirements exist for some of the 2-component vaccines, including different temperature ranges for each component. If the two components of a COVID-19 vaccine must be stored separately, or if the labeling on both components looks similar, the risk of an error is heightened. Due to the cold chain requirements of the new COVID-19 vaccines, it is possible that supplies and diluents may ship separately from the vaccine,[7] which may lead to confusion and the risk of using the wrong diluent. Using the wrong diluent (including a neuromuscular blocking agent as noted above) can result in disastrous outcomes.

Miscommunication. Several 2020-2021 flu vaccine-related errors were associated with language or communication barriers, which can also be expected during mass COVID-19 vaccinations. For example, intranasal **FLUMIST QUADRIVALENT** was administered to a patient older than 49 years (a contraindication) for whom English was not a primary language, even though the age parameters were fully discussed with the patient. Another flu vaccine-related error occurred due to miscommunication when wearing face masks—a similar condition that will exist and must be considered when administering the new COVID-19 vaccines. Initially, the practitioner administering the flu vaccine misread the patient's handwritten date of birth. Verbal confirmation of the date of birth was provided by the patient wearing a mask but misheard by the practitioner wearing a mask and face shield. The patient received Fluzone High-Dose Quadrivalent despite being younger than 65 years.

Two flu vaccine-related errors occurred due to incorrect directions provided to vaccinators when supplies of certain vaccines were running low or had been exhausted—again, a condition that will likely exist during COVID-19 vaccination campaigns as limited supplies are initially exhausted. For example, in one case, vaccinators were wrongly told that intranasal FluMist Quadrivalent could be administered to any adult in place of the IM flu vaccines when supplies had been exhausted. FluMist Quadrivalent was administered to numerous patients older than 49 years due to the miscommunication.

Not checking/documenting administration in the immunization information system (IIS). Several flu vaccine-related errors led to repeated doses that had already been administered to patients. However, the opposite type of error happens more often with vaccines that require more than one dose at specific intervals—much like the COVID-19 vaccines that will require two doses separated by 21 or 28 days. Either a patient has

continued on page 4 — Vaccine errors >

> SAFETY briefs cont'd from page 2

coronavirus disease 2019 (COVID-19) requiring hospitalization in adults and pediatric patients 12 years and older and weighing at least 40 kg (www.ismp.org/ext/571). A revised Emergency Use Authorization (EUA) is now available to permit emergency use of Veklury for hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg (www.ismp.org/ext/541). This is now the only purpose for the EUA, as Veklury is not yet FDA-approved for these uses. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

The drug is available as Veklury injection (supplied as a 100 mg/20 mL solution in a vial) and Veklury **for** injection (supplied as a 100 mg lyophilized powder in a vial). Veklury injection (100 mg/20 mL solution) contains twice as much of the solubilizing agent, betadex sulfobutyl ether sodium, as Veklury **for** injection (100 mg lyophilized powder) and, again, should only be used in patients weighing 40 kg or more.

Both forms of Veklury (Veklury injection and Veklury **for** injection) must be further diluted before intravenous (IV) infusion. Veklury injection (100 mg/20 mL solution) must be diluted in a 250 mL 0.9% sodium chloride infusion bag after removing a volume of 0.9% sodium chloride equal to the volume of the intended remdesivir dose (40 mL or 20 mL). Veklury **for** injection (100 mg lyophilized powder) needs to be reconstituted with Sterile Water for Injection and further diluted in a 100 mL or 250 mL 0.9% sodium chloride infusion bag after removing a volume of 0.9% sodium chloride equal to the volume of the intended remdesivir dose.

Unopened, unreconstituted Veklury **for** injection lyophilized powder can be stored at room temperature. Vials of Veklury injection (100 mg/20 mL solution) require storage at refrigerated temperature and should be brought to room temperature prior to dilution. The EUA *Fact Sheet* originally indicated the diluted solutions could be stored for 4 hours at room temperature or up to 24 hours refrigerated. However, the approved labeling (and updated *Fact Sheet*, www.ismp.org/ext/541) now states that the prepared diluted solution is stable

continued on page 4 — SAFETY briefs >

> Vaccine errors — continued from page 3

received a subsequent dose at the wrong interval or failed to receive a subsequent dose as required. Previously, the vaccines most frequently involved in wrong interval errors reported to ISMP included those that target diphtheria, tetanus, and/or pertussis; hepatitis B; hepatitis A; and the human papillomavirus. More than three-quarters of these errors were associated with not checking the patient's record or IIS (immunization information system [vaccine registry]) to confirm the date of the prior vaccine; lack of prior vaccine documentation in the patient's record or IIS; or confusing or ambiguous entries in the IIS.

For the COVID-19 vaccines, healthcare providers must bring patients back for a second dose, which may prove to be challenging. Because different COVID-19 vaccines will not be interchangeable, a patient's second dose must be from the same manufacturer as their first dose.[7] Thus, providers need to accurately document the vaccine patients received for their first dose and check the IIS prior to administration of the second dose to confirm the required time interval and manufacturer. Providers eligible to administer COVID-19 vaccinations will be required to report this information daily in the IIS.[8]

Lack of usual procedures/technologies during mass immunizations. Three practitioners reported flu vaccine-related errors associated with the inability to employ the usual procedures and technologies that typically reduce the risk of errors during outpatient vaccinations. Manual activities may replace many of the automated safety checks that typically occur when a vaccine is prescribed and administered to an individual patient. In two events, Flublok Quadrivalent was administered to children under the age of 18 (a contraindication). Both reporters noted that they typically used barcode scanning verification or an independent double check prior to vaccine administration but were unable to do so. While the Centers for Disease Control and Prevention (CDC) has worked with FDA and the manufacturers to include a two-dimensional (2D) barcode with a National Drug Code (NDC) on COVID-19 vaccines, scanning to verify the patient, drug, and dose may not be possible without an individual order for each patient.[5]

Temperature excursions and expired vaccines. ISMP received numerous reports of repeated flu vaccinations because the original vaccinations were deemed invalid due to refrigerator temperature excursions, which were often due to inadequate refrigeration, faulty thermostat controls, and refrigeration units with inadequate space to allow good air circulation. With strict temperature requirements needed to maintain stability when storing the two anticipated COVID-19 vaccines, temperature excursions—even a single exposure in some instances—could reduce vaccine potency and lead to wasting precious vaccine doses already in short supply.

Additionally, ISMP received three error reports associated with administration of expired flu vaccines from the 2019-2020 flu season. Because expiration dates may be updated based on vaccine stability studies occurring simultaneously with vaccine distribution, the COVID-19 vaccine vials and cartons may not contain a printed expiration date. The 2D barcode on the vaccine label (if possible) and carton (required) will include a placeholder expiration date of 12/31/2069.[7] A manufactured date will be on the packaging but this should not be confused with the expiration date. Additional information will be provided about how to access expiration information for individual COVID-19 vaccines. Meanwhile, the CDC is developing "beyond use date" (BUD) tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration.

Recommendations

Consider the following recommendations to help prepare for flu and COVID-19 vaccination campaigns.

Plan Vaccination Campaigns

- Establish plans for flu and COVID-19 vaccination campaigns well before implementation, taking into consideration the following:
  - ☐ Required infection control measures (i.e., scheduling patients, distancing, using

continued on page 5 — Vaccine errors >

> SAFETY briefs cont'd from page 3

for 24 hours at room temperature or 48 hours refrigerated. It is recommended to administer the IV medication immediately after preparation when possible.

As mentioned in an ***FDA Advise-ERR*** in our September 10, 2020, issue of the newsletter (www.ismp.org/node/20176), FDA has received numerous error reports related to incorrect preparation, administration, and storage of both remdesivir formulations. FDA informed us recently that the agency continues to receive reports of remdesivir errors that have resulted in administration of the wrong dose or formulation, missed doses, or the need for pharmacy to discard vials or solutions that had been improperly prepared or stored. We strongly encourage practitioners to review the September 10, 2020, publication as well as the revised EUA *Fact Sheet* and package insert for the approved product.

HIGH-ALERT

New ASPEN recommendations for in-line filters for PN. The American Society for Parenteral and Enteral Nutrition (ASPEN) published a position paper (www.ismp.org/ext/586) on the appropriate use of in-line filters during parenteral nutrition (PN) administration. The recommendations in this paper serve as an update to previously published recommendations. Based on best available evidence and guidance from scientific and regulatory agencies, ASPEN recommends using a 1.2 micron in-line filter for administration of total nutrient admixtures (TNAs), dextrose-amino acids admixtures, and lipid injectable emulsions (ILE).

The safety of using a single 1.2-micron filter for PN administration is supported by decades of experience in hospital and homecare settings and alleviates the confusion and errors associated with using two separate filters with different pore sizes. Simplifying filtering practices could increase compliance with recommendations for filter use with PN administration. For questions, please contact Peggi Guenter, PhD, RN, FAAN, FASPEN; ASPEN Senior Director of Clinical Practice, Quality, and Advocacy (peggig@nutritioncare.org).

Update on Epic's "fuzzy matching." In our January 31, 2019 newsletter (www.ismp.org/node/1350), we reported concerns with Epic's "fuzzy matching," a

continued on page 5 — SAFETY briefs >

> Vaccine errors — continued from page 4

personal protective equipment, cleaning/sanitation procedures) that may slow the vaccination process
  - ☐ Vaccine storage capacity, required storage equipment, and required temperature monitoring
  - ☐ Optimal staffing (significant reductions in vaccine errors, invalid doses, and missed opportunities to vaccinate have been documented when including pharmacists on the vaccination team[9])
  - ☐ Anticipated language and communication barriers and how they will be effectively handled
- Create and/or examine protocols (and/or standing orders) for flu and COVID-19 vaccines that will be used during a vaccination campaign; confirm that the protocols include:
  - ☐ Criteria for screening patients for contraindications and precautions
  - ☐ Directions for preparing and administering the vaccine, including the dose, any required dilution, vials/containers to use, route of administration, and any special precautions
  - ☐ Details regarding what (e.g., lot number, expiration date), where (e.g., vaccination record, IIS), and how to document vaccine administration and distribution of the Vaccine Information Statement (VIS) or EUA *Fact Sheet*
  - ☐ An emergency protocol to follow if the patient develops an adverse reaction
  - ☐ Information about reporting adverse vaccine events and errors
- Establish in writing how shortages or exhausted flu and/or COVID-19 vaccine supplies will be managed and share this document with all staff working on vaccination campaigns
- Confirm that policies and procedures require staff to verify the patient's current immunization status (and first dose manufacturer if receiving a second dose of the COVID-19 vaccine) *prior* to vaccination by checking the patient's health record, vaccination record, and/or IIS
- Plan to evaluate procedures during the first phase of essential worker COVID-19 vaccination campaigns to assess cold chain management and vaccine storage; vaccine preparation, administration, and documentation; risk-reduction strategies; traffic flow; and infection control measures[7]

Safe Vaccine Storage

- Plan for safe storage of flu and COVID-19 vaccines, including:
  - ☐ Sufficient cold chain capacity to allow vaccines to be stored separately
  - ☐ Storage (and distribution/transportation) temperature monitoring at all times
  - ☐ Monitoring of vaccine expiration dates
- Separate the storage of vaccines and other medications in freezers and refrigerators, bins and containers, and coolers and other temporary storage containers
  - ☐ If possible, use a separate refrigerator/freezer to store vaccines (no other medications)
  - ☐ Adult and pediatric formulations of the same vaccine should be separated
  - ☐ Vaccines with similar names should not be stored in bins or containers next to each other
  - ☐ Consider purchasing differing age-specific formulations of the same flu vaccine from different manufacturers to help distinguish them
  - ☐ Ensure that there are no frozen or refrigerated look-alike products (e.g., similar container volume, shape, label) with which the vaccines might be confused
  - ☐ Sequester neuromuscular blocking agents in a sealed box or a rapid sequence intubation (RSI) kit
- Label the area where vaccines are stored
  - ☐ Labels may provide additional information unique to each vaccine[5]
  - ☐ Labels can draw attention to 2-component vaccines, reminding staff to mix them[6]
- Store vaccines in the original carton, which is fully labeled, to help prevent errors, protect the vaccine from light, and keep the vaccine within its recommended temperature range[5]

continued on page 6 — Vaccine errors >

> SAFETY briefs cont'd from page 4

system feature that engages if you misspell a word; for example, a medication name. Fuzzy matching, or typo correction, presents the user with a list of options that are within 1 to 3 typos of the search term that were entered, which may not be an exact match. At that time, users reported testing the feature using *ISMP's List of Confused Drug Names* (www.ismp.org/node/102) and found concerning matches. Based on those findings, ISMP noted that near hits for drug names are not safe since one could possibly choose the wrong drug.

We reported our concerns to Epic and learned shortly thereafter that the company had made changes to the logic and increased the list of stop (excluded) words that organizations can configure. Throughout 2019 and 2020, several individuals and organizations, including Epic, reached out to us to inquire whether we had heard of further issues with this feature. ISMP has not received additional close calls or actual medication errors related to fuzzy matching, nor has Epic.

ISMP no longer recommends avoiding the use of "fuzzy matching." However, we advise hospitals that plan to turn this feature on to test it first using our confused drug name list and to look for matches on synonyms that you may have configured. We also recommend that you monitor closely for any errors that might be linked to poor matches and report any concerns to us in addition to your Epic support team.

Special Announcement

ISMP Cheers Awards raffle and FREE virtual event

Enter our CHEERS AWARDS raffle for a chance to win one of several high-end prizes! There is an amazing array of raffle items, from a Nintendo Switch to a 12-piece cookware set valued at $670. Love to shop? Be sure to check out the raffle package for a $200 Amazon gift card. For details, please visit: https://go.rallyup.com/38dc9a. Also, please register to attend our FREE CHEERS AWARDS event on **December 8** at 6:00 p.m. (ET). You can register for the event by visiting: www.ismp.org/node/21094.

> Vaccine errors — continued from page 5

Staffing and Training

- Staff vaccination campaigns with trained providers who have demonstrated competencies related to the flu and/or COVID-19 vaccine(s) and error-prevention strategies
- Confirm that staff involved in the vaccination campaigns know how to search the IIS, understand the information provided, and how to document immunizations in the IIS
- Verify that staff understand the need for read back and/or repeat back of oral communication among colleagues and patients while wearing a mask and/or face shield

Safe Vaccine Dispensing

- Use commercially available, prefilled syringes of flu vaccines whenever possible
- When space permits, affix auxiliary labels or highlight important label information with a marker for:
  - ☐ Vaccines with similar names or components, or different age formulations
  - ☐ Critical label information that is not prominent (e.g., dilution instructions)
  - ☐ Two-component vaccines, to ensure that they are mixed together prior to administration
- Establish a process to keep 2-component vaccines together if storage requirements do not differ
- If barcode technology is used prior to administration, affix a barcode to vaccines or ensure that the manufacturer's barcode is easily scannable
- Check for expired vaccines prior to a vaccination campaign

Safe Vaccine Administration

- Label all syringes of prepared COVID-19 (or flu) vaccines using preprinted or blank labels
- Employ barcode verification prior to administration when possible
- Immediately prior to administration, document the vaccine, manufacturer (particularly important for COVID-19 vaccines), lot number, and expiration date in the patient's electronic health record; document actual vaccine administration afterwards
- Within 24 hours of administering a dose of the COVID-19 vaccine, record it in the IIS and report required information to the relevant state/local public health authority[7]

Patient Education

- Provide a current VIS (or an EUA *Fact Sheet* for patients receiving COVID-19 vaccination) to patients or caregivers in their primary languages prior to vaccination (www.ismp.org/ext/46)
- Incorporate the patient or caregiver into the checking process and show them the vaccine prior to administration
- Educate the patient or caregiver about the need for a second COVID-19 vaccination, if appropriate; if possible, develop a process to send a reminder to the patient
- Provide a completed COVID-19 vaccination record card to every patient or caregiver, which clearly indicates when/if they need to return for a subsequent dose[7]

Report Adverse Vaccine Events

- Establish a vaccine safety monitoring system so that adverse events following vaccinations are identified, reported, and investigated; take action to prevent future adverse events
- Report serious adverse effects, multisystem inflammatory syndrome (MIS) in children or adults, and cases of COVID-19 that result in hospitalization or death to the Vaccine Adverse Event Reporting System (VAERS, www.ismp.org/ext/592)[7]
- Report any vaccine errors to the ISMP National Vaccine Errors Reporting Program (www.ismp.org/VERP)

references in right column >

References

1) Blank C. Pharmacy chains report higher than usual demand for flu vaccines. *Drug Topics*. November 4, 2020. www.ismp.org/ext/582

2) Paris C, Hopkins JS. Pfizer sets up its 'biggest ever' vaccination distribution campaign. *The Wall Street Journal*. October 21, 2020. www.ismp.org/ext/583

3) American Pharmacists Association. APhA weekly open forum webinar: COVID-19 vaccines in development. November 5, 2020.

4) Moderna announces longer shelf life for its COVID-19 vaccine candidate at refrigerated temperatures. Moderna website. www.ismp.org/ext/594. Published November 16, 2020.

5) Howard JJ. Look-alike vaccines: influenza (Fluarix Quadrivalent) and hepatitis A (Havrix). Veterans Administration Center for Medication Safety. *Medication Safety in Seconds*. 2020; 9(10):3.

6) Samad F, Burton SJ, Kwan D, et al. Strategies to reduce errors associated with 2-component vaccines [published online ahead of print November 5, 2020]. *Pharmaceut Med*. doi: 10.1007/s40290-020-00362-9.

7) Centers for Disease Control and Prevention. *COVID-19 vaccination program interim playbook for jurisdiction operations*. Version 2.0. Centers for Disease Control and Prevention, US Department of Health and Human Services; October 29, 2020. www.ismp.org/ext/593

8) Associated Press. As COVID-19 vaccine draws closer, states ramp up for biggest vaccination effort in U.S. history. November 12, 2020. www.ismp.org/ext/590

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

Editors: Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Ann Shastay, MSN, RN, AOCN; Russell Jenkins, MD; Ronald S. Litman, DO, ML. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.