Patient Safety Tip of the Week

October 19, 2021

COVID-19 Vaccine/ Flu Vaccine Mixups

On October 15, 2021 a headline read that 2 children in Indiana, aged 4- and 5-years old, were mistakenly administered the coronavirus vaccine rather than the intended flu vaccines (Genovese 2021). On the same day, ISMP (Institute for Safe Medication Practices) issued a NAN (National Alert Network) alert regarding mix-ups between the influenza (flu) vaccine and COVID-19 vaccines (ISMP 2021).

It was probably inevitable – COVID-19 vaccines get mistaken for influenza vaccines and vice versa. We've entered the time period where annual influenza vaccines are being administered at the same time we are seeing more patients receiving a COVID-19 vaccine or booster.

The ISMP NAN alert (ISMP 2021) notes that ISMP received reports of 16 cases of accidental influenza and coronavirus disease 2019 (COVID-19) vaccine mixups. All the events occurred in community/ambulatory care pharmacies. The alert goes on to describe multiple contributing factors:

- Increased demand and coadministration of the vaccines
- Syringes near each other
- Unlabeled syringes
- Distractions
- Staffing shortages

Since both patients and clinicians have been told that it is safe to get both the COVID-19 and influenza vaccines at the same time, it is increasingly likely that materials for both vaccines will be present at the same time in offices, clinics, pharmacies, and other venues where vaccinations are being offered.

The problem is not unique to the COVID-19 vaccine. Our November 19, 2019 Patient Safety Tip of the Week "An Astonishing Gap in Medication Safety" was all about mistakes made in community vaccination programs. We gave examples of patients being administered insulin instead of flu vaccines and neuromuscular blocking agents (NMBA's) instead of measles or hepatitis vaccines.

In hospitals and many clinic sites or physician offices we use a variety of tools to improve medication safety. These include barcoding, CPOE with clinical decision support, double checks, segregation of LASA (look-alike sound-alike) drugs in storage, ADC's (automated dispensing cabinets) with alerts, "Do Not Disturb" vests to minimize distractions and interruptions during nurse medication rounds, smart pumps, and others. But those valuable tools are not used in many of the other healthcare venues where vaccines are administered, such as community pharmacies and "drive-thru" vaccination sites.

In community pharmacies, the pharmacist is often busy both preparing and dispensing medications as well as administering vaccinations. And today's pharmacies are experiencing not only professional staff shortages, but many are also seeing shortages of non-professional staff. So, sometimes pharmacists are even performing tasks usually done by non-professional staff. Given how busy those pharmacies are, it is easy to see how distractions and interruptions might contribute to errors. The lack of a second clinician to perform an independent double check is also a problem in many community pharmacies.

The ISMP NANA alert goes on to describe measures to prevent such mixups from occurring:
- Schedule flu and/or COVID-19 vaccines during dedicated blocks of time each day and ensure adequate staffing is available.
- Explore the use of qualified and trained volunteers to assist in the vaccination process to alleviate some stress caused by professional staffing shortages.
- Provide a separate area for vaccine administration, away from distractions and interruptions.
- During the production and/or verification phase of the dispensing process, scan the vaccine barcode to verify the correct product has been retrieved. Ideally, prior to administration, barcode scanning should again confirm the correct vaccine.
- Clearly label all individual syringes containing vaccines. To facilitate proper labeling, provide vaccine preparers with any necessary labels (Moderna, Pfizer-BioNTech) to affix to the syringes.
- Only bring the intended and labeled vaccine syringe(s) for one patient into the vaccination area.
- Immediately before vaccination, ask the patient to provide at least two patient identifiers (i.e., full name and date of birth) and verify the patient's vaccine(s) with the patient's signed consent form(s).
- Prior to vaccine administration, ask the patient/parent to read the syringe label (and vial if present) and expiration date aloud to confirm the correct vaccine.
- Document the vaccine lot number and expiration date before vaccine administration. Document the vaccine administration afterward in the patient's profile, on vaccination records, and via state or other immunization registries.
- If a vaccine mix-up occurs, apologize to the patient and provide the intended vaccine either before the patient leaves or ask the patient to return to the vaccination site.

- Report all vaccine errors internally as well as to the US Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS), which is mandatory for COVID-19 vaccine errors under an Emergency Use Authorization (EUA). ISMP also asks providers to report vaccine errors to the **ISMP National Vaccine Errors Reporting Program** (ISMP VERP).

In our November 19, 2019 Patient Safety Tip of the Week "An Astonishing Gap in Medication Safety" we noted there are guidelines for doing mass vaccination programs. The CDC has published "Guidelines for Large-Scale Influenza Vaccination Clinic Planning" (CDC 2015). The CDC guideline also has a link to a valuable skills checklist from Immunize.org for those administering the vaccines. CDC also has a "Vaccine Storage and Handling Toolkit" and Immunize.org also has a nice "Checklist for Safe Vaccine Storage and Handling". Immunize.org has a wealth of valuable materials for those providing immunizations. One of their resources is a handout "Don't Be Guilty of These Preventable Error s in Vaccine Administration!", which describes common mistakes in vaccine administration.

And we offered the following questions you should be asking if your organization provides vaccinations:
- Do you store your vaccines in a location separate from other medications that might be dangerous?
- Do you ever send your staff to a location that stores its own vaccines and other medications?
- Is any diluent intended for use with each vaccine stored with the vaccine so no one might use a vial of a different solution as a diluent?
- Do you use independent double checks? Prior to administration? Prior to preparation?
- If not true independent double checks, are at least 2 people involved in the process?
- Is the person administering the vaccine ever solo?
- How do you minimize distractions/interruptions at the location?
- What are your routines for monitoring patients after vaccination?
- How do you screen those who have impaired ability to communicate for contraindications?
- How do you monitor those who have impaired ability to communicate?
- Do you use a skill set checklist like the one noted above?
- How do you document vaccinations?

There are obviously many other considerations in vaccine programs. We are only considering some of the safety issues associated with the processes of vaccine programs. We refer you to many other good resources involving all those other vaccination program issues, such as the CDC guidelines, Immunize.org resources, and ACIP (ACIP, Ezeanolue 2019) recommendations.

Fortunately, such mixups related to vaccination are relatively rare, but we can anticipate that they will increase during this period where a flurry of both coronavirus vaccinations

and influenza vaccinations are being given. And, of course, there are numerous other vaccinations being given (shingles, hepatitis, HPV, etc.) that could also become part of similar vaccine mixups. Now is a good time for all organizations that provide vaccinations to review their practices. You could do a FMEA (Failure Mode and Effects Analysis) to identify potential vulnerabilities, but don't wait to do your FMEA. Heed the recommendations in the ISMP NAN alert and those in our November 19, 2019 Patient Safety Tip of the Week "An Astonishing Gap in Medication Safety".

References:

Genovese D. Walgreens says vaccine mix-ups are rare after Indiana family claims kids received COVID, not flu shots. Fox Business News 2021; October 15, 2021
https://www.foxbusiness.com/lifestyle/walgreens-vaccine-mixups-rare-covid-flu

ISMP (Institute for Safe Medication Practices). Mix-Ups Between the Influenza (Flu) Vaccine and COVID-19 Vaccines. ISMP NAN Alerts 2021; October 15, 2021
https://www.ismp.org/alerts/mix-ups-between-influenza-flu-vaccine-and-covid-19-vaccines

CDC. Guidelines for Large-Scale Influenza Vaccination Clinic Planning. CDC 2015; December 16, 2015
https://www.cdc.gov/flu/professionals/vaccination/vax_clinic.htm

Immunize.org
https://www.immunize.org/

Immunize.org. Skills Checklist
https://www.immunize.org/catg.d/p7010.pdf

Immunize.org. Don't Be Guilty of These Preventable Error s in Vaccine Administration!
https://www.immunize.org/catg.d/p3033.pdf

CDC. Vaccine Storage and Handling Toolkit. CDC
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Immunize.org. Checklist for Safe Vaccine Storage and Handling.
https://www.immunize.org/catg.d/p3035.pdf

ACIP (Advisory Committee on Immunization Practices). ACIP Vaccine Recommendations and Guidelines.
https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Accessed on November 16, 2019.
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

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