

COVID-19 Vaccine Errors

Millions of doses of messenger RNA (mRNA) coronavirus disease-2019 (COVID-19) vaccines have been administered worldwide since they were approved last December. Given an extremely expeditious roll-out, several errors have been reported related to preparation and administration.

Dilution Errors

Dilution errors have occurred in the preparation of the COVID-19 vaccines that can result in an overdose or underdose of vaccine. If too much diluent is added, doses may not be effective; if not enough diluent is added, doses will be too strong and could cause adverse effects. The **Pfizer-BioNTech** multiple-dose vial contains 0.45 mL that should be diluted with 1.8 mL of preservative-free 0.9% sodium chloride injection. After dilution, the vial will contain six or seven doses, if a low dead-volume syringe is used to withdraw each 0.3 mL (30 mcg) dose. During clinical trials of the vaccine, doses up to 100 mcg were administered with only mild to moderate local injection site reactions and flu-like symptoms without serious adverse effects. In one report, an elderly patient received a dose twice the concentration but experienced no reaction. In another report, eight healthcare workers received the entire vial of vaccine without dilution. Four were hospitalized after developing flu-like symptoms from the overdose. The **Moderna** multiple-dose vial contains ten (or eleven) doses of 0.5 mL each. After thawing, the vaccine does not require dilution.

Vaccine Mix-up with Monoclonal Antibodies

In a report from a West Virginia clinic, 44 adults received IM injections of casirivimab, a Regeneron monoclonal antibody, instead of the intended Moderna vaccine. Two monoclonal antibodies, casirivimab and imdevimab received emergency use authorization to treat individuals with mild to moderate COVID-19 to prevent progressing to severe illness. These monoclonal antibodies should be administered together as an intravenous (IV) infusion. The error can be traced back to the distribution process. Two representatives from the county health department were asked to pick up vaccine supplies from a local medical center for the clinic. They signed for Moderna COVID-19 vaccine but were given a case that was labeled REGN10933, which they did not recognize. Inside the case, vial cartons and vials were also labeled REGN10933, not the product name. Both the vaccine and monoclonal antibodies are available in 5 mL glass vials with identical red caps. While a barcode is on the label, it is not functional or tied to the National Drug Code (NDC) number. Regeneron will manufacture a new version of the carton and vial label meant for EUA use which is color differentiated and includes a functional barcode. No serious adverse reactions were reported and all 44 patients were offered the vaccine.

Vaccine Waste

The government COVID-19 program, Operation Warp Speed, has shipped various types of syringes, many of which were not low dead-volume syringes. If low dead-volume syringes are not used, fewer doses of vaccine can be extracted from each vial. Utilizing a syringe that limits

Reference

1. Institute for Safe Medication Practices. (2021). *Nurse Advise-ERR*. Retrieved from Institute for Safe Medication Practices: <https://www.ismp.org/nursing/medication-safety-alert-february-2021>

the dead space between the syringe hub and needle reduces the amount of wasted vaccine and improves the ability to withdraw extra doses from the vaccine vials.

Another issue involves leftover vaccine doses due to canceled appointments or “no-shows”. Both the Pfizer-BioNTech and Moderna vaccines must be used within six hours after preparation and cannot be refrozen or refrigerated again. Leftover doses in vials or prefilled syringes at the end of the day are wasted.

Wrong Age Group

The Pfizer-BioNTech vaccine is approved for use in individuals age 16 years and older while the Moderna vaccine is approved for use in individuals age 18 years and older. There have been reports of vaccine administration to adolescents younger than these approved ages.

Second Dose Errors

It is important to obtain all patient information clearly and correctly, such as e-mail address and phone number, otherwise patients may not receive appointment confirmation for their second vaccine dose.

Administration of Wrong Vaccine for Second Dose

Patients should receive both first and second doses from the same vaccine manufacturer. The Pfizer-BioNTech and Moderna vaccines are not interchangeable. If two doses of different mRNA COVID-19 vaccines have been administered in error, the Centers for Disease Control and Prevention (CDC) does not recommend administering an additional dose.

Allergic Reactions

There have been reports of serious but not life-threatening allergic reactions to the Pfizer-BioNTech vaccine that have required emergency treatment and an overnight hospital stay. The CDC reports an anaphylactic rate of 11.1 cases per million doses of the Pfizer-BioNTech vaccine and 2.5 cases per million of the Moderna vaccine. This rate is considered rare and most individuals who have experienced a severe allergic reaction have a documented history of allergies.

Recommendations

The vaccine roll-out has occurred with unprecedented speed and mistakes are likely to happen due to human error and system challenges. The following strategies may help mitigate future issues.

- Carefully select vaccination locations that have adequate space to assess patients before and after vaccination, and treat patients who experience a reaction.
- Educate staff regarding the storage, preparation, and administration of COVID-19 vaccines and the common types of errors that may occur.
- Confirm the competency of vaccinating staff and their knowledge on the following topics:
 - Proper vaccine storage and temperature monitoring.
 - Patient assessment before vaccination.

Reference

1. Institute for Safe Medication Practices. (2021). *Nurse Advise-ERR*. Retrieved from Institute for Safe Medication Practices: <https://www.ismp.org/nursing/medication-safety-alert-february-2021>

- Age indications for each vaccine.
- Correct dilution procedure of Pfizer-BioNTech vaccine only
 - Prepare one vial at a time.
 - Avoid pre-opening syringe packages or drawing up air in advance.
- Withdraw the correct dose for each vaccine from multiple-dose vials using strict aseptic technique and low dead-volume syringes and needles.
- Proper administration of IM vaccines, including identification of the correct injection site.
- Observation of patient following vaccination and recognizing signs and symptoms of an allergic reaction.
- Emergency treatment of anaphylaxis (i.e. IM injection of epinephrine, transport for further medical care).
- Timing and scheduling of second vaccine dose.
- Implement an independent double check of the Pfizer-BioNTech vaccine dilution process, if adequate staffing is in place.
- Use low dead-volume syringes/needles to withdraw the maximum number of vaccine from each vial:
 - Six or seven doses from the Pfizer-BioNTech vial.
 - Ten or eleven doses from the Moderna vaccine vial.
- Differentiate monoclonal antibodies immediately if the drug packaging does not include the product name; add brightly colored labels with product name, strength and scannable barcode.
- To avoid mix-ups, store the Pfizer-BioNTech and Moderna vaccines in separate areas in the refrigerator or after thawing. Isolate the vaccines from Regeneron monoclonal antibodies.
- Create a plan for leftover vaccines to avoid waste:
 - Establish a daily list of available alternative patients.
 - Be sure to use vaccines within 6 hours of storage at room temperature.
 - Prepare vaccines in small batches for confirmed appointments only.
- Be prepared to treat allergic reactions:
 - Ensure emergency equipment and medications are immediately available (i.e. epinephrine prefilled syringe or autoinjector, H₁ antihistamine such as diphenhydramine).
 - Monitor patients for 15 minutes after vaccination for signs of adverse reactions.
 - Monitor for 30 minutes if patient has a history of allergic reaction to a vaccine or injectable therapy or a history of anaphylaxis due to any cause.
 - Avoid giving the vaccine to patients with a severe reaction to components of the vaccine such as polyethylene glycol or polysorbate.
 - Patients with general allergies should consult a health care provider prior to vaccination.
- Schedule appointments efficiently and accurately with a reliable communication system to remind patients and confirm their appointments.
 - The system should not allow underage patients to schedule appointments.
- When a patient schedules and arrives for the second dose, confirm the vaccine that should be administered with the patient and by verifying the information on the patient's vaccination card.
- Report errors and adverse reactions to the Vaccine Adverse Reporting System

Reference

1. Institute for Safe Medication Practices. (2021). *Nurse Advise-ERR*. Retrieved from Institute for Safe Medication Practices: <https://www.ismp.org/nursing/medication-safety-alert-february-2021>

- Provide patients with information on the “v-safe” application, a smart phone-based monitoring tool that provides a “check in” so patients can report adverse vaccine reactions.

Reference

1. Institute for Safe Medication Practices. (2021). *Nurse Advise-ERR*. Retrieved from Institute for Safe Medication Practices: <https://www.ismp.org/nursing/medication-safety-alert-february-2021>