Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Pfizer-BioNTech COVID-19 Vaccine Questions

Vaccine Supply and Distribution

How many doses of Pfizer-BioNTech COVID-19 Vaccine does each shipment contain? –

The minimum order size and increment for Pfizer-BioNTech COVID-19 Vaccine is 195 multidose vials (1 tray) per order (1,170 doses). A thermal shipping container can hold up to 5 trays or 975 multidose vials.

Vaccination Schedule and Use

Who can receive Pfizer-BioNTech COVID-19 Vaccine? –

Pfizer-BioNTech COVID-19 Vaccine is authorized and recommended for people 16 years of age and older.

The recommendation for Pfizer-BioNTech COVID-19 Vaccine should be implemented in conjunction with the Advisory Committee on Immunization Practices' (ACIP) interim recommendations for allocation of COVID-19 vaccine.

How many doses of Pfizer-BioNTech COVID-19 Vaccine do patients need? At what interval? –

All people for whom vaccination is indicated should receive 2 doses at least 3 weeks (21 days) apart. Do not schedule vaccine recipients to receive the second dose earlier than the recommended interval.

Does the 4-day grace period between doses of vaccine apply to Pfizer-BioNTech COVID-19 Vaccine? –

Second doses of Pfizer-BioNTech COVID-19 Vaccine administered up to 4 days before the recommended date (4-day grace period) are considered valid. This means that when reviewing records, a second dose of Pfizer-BioNTech COVID-19 Vaccine administered 17 or more days after the first dose is considered valid.

You should schedule the second dose of Pfizer-BioNTech COVID-19 Vaccine 21 days after the first dose (the recommended interval). Do not use the 4-day grace period to schedule appointments. Appointments for a second dose should be scheduled to meet the recommended interval.

If a dose is inadvertently administered before the 4-day grace period, it does not need to be repeated. This means that when reviewing records, a second dose of Pfizer-BioNTech COVID-19 Vaccine administered 16 or less days after the first dose does not need to be repeated. This is considered a vaccine administration error. Determine how the error occurred and implement strategies to prevent it from happening again. Additionally, you are required to report COVID-19 vaccine administration errors to the Vaccine Adverse Event Reporting System (VAERS).

Can the 4-day grace period be used to schedule second doses? –

No, the grace period cannot be used to schedule second doses. Administer doses as close to the 21-day interval as possible, but not earlier than recommended. The grace period should be used only for retrospectively reviewing records. If it is discovered a dose has been inadvertently administered within a grace period of ≤4 days from the recommended date for the second dose (i.e., 17–20 days after dose 1), the dose is considered valid.

Is there a maximum interval between doses of Pfizer-BioNTech COVID-19 Vaccine? –

You should administer the second dose as close as possible to the recommended interval of 21 days after dose 1. However, if it is not possible to follow the recommended interval, you may schedule the second dose of Pfizer-BioNTech COVID-19 Vaccine for administration **up to 6 weeks (42 days)** after the first dose. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered after these intervals, there is no need to restart the series.

Should I hold back stock for second doses of Pfizer-BioNTech COVID-19 Vaccine to ensure patients receive a matching product? –

We do not currently recommend that providers hold back stock for a second dose after administering a patient's first dose. You should inform the patient that they need to return for the second dose.

My patient cannot remember what vaccine they received for the first dose. Can I vaccinate them with a different product?

COVID-19 vaccines are **not** interchangeable. The safety and efficacy of a mixed-product series have not been evaluated. Every effort should be made to determine which vaccine product was administered as the first dose to ensure completion of the vaccine series with the same product. **In exceptional situations:**

- When the vaccine product administered for the first dose cannot be determined or is no longer available, you may administer any available mRNA COVID-19 vaccine, with a minimum of 28 days between doses. If two different mRNA COVID-19 vaccine products are administered, no additional doses of either product are recommended at this time.
- If a patient received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or a different mRNA COVID-19 vaccine (e.g., due to contraindication), you may consider administering a single dose of Janssen COVID-19 Vaccine, with a minimum of 28 days between doses. See contraindications and precautions for more information on use of Janssen COVID-19 Vaccine and additional precautions for people with a contraindication to mRNA COVID-19 vaccines.

Implement the following strategies to help ensure patients receive the second dose with the appropriate product and interval between doses:

- Provide a COVID-19 vaccination record card to every vaccine recipient. Ask recipients to bring their card to their appointment for the second dose. Encourage them to make a backup copy (e.g., by taking a picture of the card with their phone).
- Encourage vaccine recipients to enroll in VaxTextSM, a free text-message-based platform, to receive reminders to get their second dose of COVID-19 vaccine.
- Record each recipient's vaccination in the immunization information system (IIS).
- Record vaccine administration information in the patient's medical record.
- Make an appointment for the second dose before the vaccine recipient leaves to increase the likelihood that patients will return to the same vaccination provider site for the second dose.

The mRNA COVID-19 vaccine my patient received for their first dose is temporarily unavailable. Should I administer another COVID-19 vaccine?

No. When the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the second dose up to 6 weeks following the first dose to administer the same product rather than administer a mixed series using a different product.

Learn more about interchangeability of COVID-19 vaccine products.

Is there a minimal interval between routine vaccines and Pfizer-BioNTech COVID-19 Vaccine? −

Yes. You should routinely administer Pfizer-BioNTech COVID-19 Vaccine alone, with a minimum interval of 14 days before or after administration of any other vaccine.

However, you may administer Pfizer-BioNTech COVID-19 Vaccine and other vaccines within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (such as tetanus-toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak) or to avoid barriers to or delays in COVID-19 vaccination (for example, in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to or upon admission or onboarding). If Pfizer-BioNTech COVID-19 Vaccine is administered within 14 days of another vaccine, do not repeat doses of either vaccine. This deviation from CDC guidance does not require reporting to the Vaccine Adverse Event Reporting System (VAERS).

Learn more about coadministration with other vaccines.

Vaccine Indications

Can I vaccinate patients with underlying medical conditions? +

Yes, you may administer any currently authorized COVID-19 vaccine to people with underlying medical conditions; the Advisory Committee on Immunization Practices (ACIP) does not state a product preference. This includes people with:

- Immunocompromising conditions or people who take immunosuppressive medication or therapies
- Autoimmune conditions
- A history of Guillain-Barré syndrome
- A history of Bell's palsy
- A history of dermal filler use

Learn more about vaccinating patients with underlying medical conditions.

Are there special considerations for vaccinating immunocompromised patients or timing immunosuppressive therapy?

Immunocompromised patients can receive any currently authorized COVID-19 vaccine; however, you should consider counseling them and timing immunosuppressive therapies.

Counsel immunocompromised patients about the:

- Unknown vaccine safety profile and effectiveness in immunocompromised populations
- Potential for reduced immune responses
- Need to continue to follow current guidance to protect themselves against COVID-19

Data are currently insufficient to inform optimal timing of COVID-19 vaccination and receipt of immunosuppressive therapies. However, based on general best practices for vaccination of immunocompromised people, ideally **COVID-19 vaccination should be completed at least two weeks before initiation of immunosuppressive therapies**. When it is not possible to administer a complete COVID-19 vaccine series (i.e., 2 doses of an mRNA vaccine or a single dose of Janssen COVID-19 Vaccine) in advance, you may still vaccinate patients on immunosuppressive therapy. Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the patient's risks related to their underlying condition.

At this time, revaccination is not recommended after patients regain immune competence. Recommendations on revaccination or additional doses of COVID-19 vaccines may be updated when more information is available.

Learn more about vaccinating patients with underlying medical conditions.

Can pregnant or lactating people be vaccinated? +

Yes. Pregnant or lactating people can receive any of the currently authorized COVID-19 vaccines; the Advisory Committee on Immunization Practices (ACIP) does not state a product preference.

When making a decision about vaccination, you and your pregnant patient should consider the:

- Level of COVID-19 community transmission
- Patient's personal risk of contracting COVID-19
- Risks of COVID-19 to the patient and potential risks to the fetus
- Efficacy of the vaccine
- Side effects of the vaccine
- Limited data about the vaccine during pregnancy

Encourage pregnant people who choose to be vaccinated to enroll in v-safe, a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. A v-safe pregnancy registry has been established to follow outcomes among pregnant people who are vaccinated.

Learn more about vaccination of pregnant or lactating people.

Can people with a prior or current SARS-CoV-2 infection or COVID-19 disease be vaccinated? What if they received passive antibody therapy for COVID-19 treatment?

Recommendations for vaccination depend on when a person has or had SARS-CoV-2 infection and when they received treatment.

People with a history of infection: Offer vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

While there is no recommended minimum interval between infection and vaccination, current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. **While vaccine supply remains limited**, people with recent documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired. However, they should recognize that the risk of reinfection and, therefore, the need for vaccination, can increase with time following initial infection.

People with a current infection: Defer vaccination of people with known current SARS-CoV-2 infection until the person has recovered from acute illness (if the person has symptoms) and until criteria have been met for them to discontinue isolation. This recommendation applies to any vaccine, including the first and second doses of COVID-19 vaccine.

People who previously received passive antibody therapy as part of COVID-19 treatment: Defer vaccination for at least 90 days after receipt of passive antibody therapy (monoclonal antibodies or convalescent plasma). This recommendation applies to people who receive passive antibody therapy before receiving any COVID-19 vaccine dose and to those who receive passive antibody therapy after the first dose of an mRNA COVID-19 vaccine but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy.

Learn more about COVID-19 vaccination and SARS-CoV-2 infection.

My patient is receiving intravenous immunoglobulin. Do they have to wait 90 days before receiving COVID-19 vaccine?

No, your patient may be vaccinated. Although people who have received passive antibody therapy as treatment for COVID-19 should wait 90 days before vaccination, there is **no minimum interval** between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.

My patient has shingles. Can they receive Pfizer-BioNTech COVID-19 Vaccine?

As with other vaccines, a moderate or severe illness is a precaution to receiving any currently authorized COVID-19 vaccine. It is not considered a contraindication. Generally, vaccination should be delayed until the acute illness has improved. However, if you and your patient feel the potential benefits of vaccination outweigh the potential risks, they may receive COVID-19 vaccine.

The following considerations can be used to help the provider conduct a risk assessment for COVID-19 vaccination:

- Risk of exposure to SARS-CoV-2 (e.g., living in a congregate setting, such as a long-term care facility; or occupation)
- Risk of severe disease or death due to COVID-19 (e.g., because of age or underlying medical conditions)
- Whether the patient has previously been infected with SARS-CoV-2 and, if so, how long ago
    - Note: Vaccination is recommended for people with a history of COVID-19; however, because the risk for reinfection is low in the months after initial infection, people with a precaution to vaccination and recent COVID-19 may choose to delay vaccination.

Contraindications and Precautions

What are contraindications to Pfizer-BioNTech COVID-19 Vaccine?

Contraindications to vaccination with Pfizer-BioNTech COVID-19 Vaccine include:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
- Immediate allergic reaction after a previous dose or known (diagnosed) allergy to a component of the vaccine (see Appendix C for a list of vaccine components)

Do not vaccinate people with a contraindication. Consider referral to an allergist-immunologist or other vaccine alternative. You may consider Janssen COVID-19 Vaccine for people with a contraindication to mRNA COVID-19 vaccines (including a contraindication due to a known polyethylene glycol [PEG] allergy). People with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine. In these cases, consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project. Vaccination of these people should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions. People who have received one mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least 28 days after the mRNA vaccine dose to receive Janssen COVID-19 Vaccine.

Learn more about COVID-19 vaccine contraindications and precautions.

What are precautions for Pfizer-BioNTech COVID-19 Vaccine?

Precautions for Pfizer-BioNTech COVID-19 Vaccine include:

- History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
- Contraindication to Janssen COVID-19 Vaccine
- Moderate or severe acute illness

The following considerations can be used to help the provider conduct a risk assessment for vaccination of patients with a precaution to vaccination:

- Risk of exposure to SARS-CoV-2
- Risk of severe disease or death due to COVID-19
- Unknown risk of anaphylaxis (including fatal anaphylaxis) following COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis. For people with a contraindication to another type of COVID-19 vaccine (e.g., Janssen viral vector vaccine), vaccination with another type (e.g., mRNA vaccines) should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

Learn more about COVID-19 vaccine contraindications and precautions.

What other medications and vaccines contain polyethylene glycol (PEG)?

PEG can be found in:

- Osmotic laxatives and oral bowel preparations for colonoscopy procedures
- Many medications as an inactive ingredient or excipient (e.g., certain injectable contraceptives and steroids)
- Some therapeutic medications (e.g., some chemotherapeutics)

Additionally, cross-reactive hypersensitivity can occur between PEG and polysorbates.

Screen patients for contraindications and precautions prior to vaccination. If a patient identifies a history of allergic reaction to a medication with which you are unfamiliar, you may consider using the following resources to determine if a specific medication contains PEG, a PEG derivative, or polysorbates:

- FDA package insert for the specific medication
- National Institutes of Health DailyMed database
- CDC's vaccine excipient summary

My patient experienced fever and injection-site swelling after the first dose of an mRNA COVID-19 vaccine. Should they get a second dose?

Yes. **A side effect is not a contraindication to a second dose** of mRNA COVID-19 vaccine. Common side effects after vaccination may include:

- Injection site pain, redness, or swelling
- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea

For most people, side effects last no longer than 1–2 days. Encourage patients to enroll in v-safe to tell CDC about any side effects after getting a COVID-19 vaccine and to receive reminders for a second dose.

People with an **immediate allergic reaction** to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines. An immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration. Attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction or post-vaccination side effects (which are not contraindications to receiving the second vaccine dose).

People with a contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 Vaccine at least 28 days after the mRNA vaccine, but it is considered a precaution. In these cases, consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project. Vaccination of these people should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

See more information on:

- Contraindication and precautions
- Potential characteristics of allergic reactions

Vaccine Storage and Handling

How should I store Pfizer-BioNTech COVID-19 Vaccine?

There are four options for storing Pfizer-BioNTech COVID-19 Vaccine. It may be stored in:

1. Ultra-cold freezer between -80°C and -60°C (-112°F and -76°F) up to the expiration date. Keep vaccine vials upright and in their tray and protect from light.
2. Thermal shipping container using the Controlant temperature monitoring device (TMD). Maintain the appropriate temperature by adding dry ice to the shipping container according to the manufacturer's guidance. Keep vaccine vials upright and in their tray and protect from light.
3. Freezer between -25°C and -15°C (-13°F and 5°F) for up to 2 weeks. Keep vaccine vials upright and in their tray and protect from light.
4. Refrigerator between 2°C and 8°C (36°F and 46°F) for up to 5 days (120 hours).

Refer to the Pfizer-BioNTech COVID-19 Vaccine product information or Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary for more detailed information on storage.

Should I inspect the vials upon receiving a shipment?

Because of the ultra-cold storage requirements, the manufacturer recommends that you not open the vial tray and inspect individual vials. Rather, keep the trays closed and inspect only the outside of the package and trays. You may inspect vials when you are ready to thaw and use the vaccine.

If you have concerns about the condition of the package, contact the manufacturer.

See Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary for more storage and handling information.

If I remove a vial from a tray, can I place it back in the tray and return to ultra-cold storage?

No. Once an individual vial is removed from a vial tray at room temperature, it should not be returned to frozen storage; it should be thawed for use.

See Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary for more storage and handling information.

How often can I remove vials/doses from the thermal shipping container for use?

Determine the number of vials/doses needed before opening the thermal shipping container. Open the thermal shipping container **no more than twice per day for no more than 3 minutes each time**. Use vaccine vials stored in the refrigerator before removing additional vials from frozen storage.

See Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary for more storage and handling information.

Will I receive supplies to support ultra-cold storage?

If you are using the thermal shipping container for **temporary** storage, you will need to replenish dry ice pellets within 24 hours of delivery and every 5 days thereafter. Unless you opt out when placing the vaccine order, a kit to support **one** replenishment of dry ice in the thermal shipping container will be provided within 24 hours of vaccine receipt. It will contain:

- Dry ice (~35 pounds)
- Gloves for working with dry ice (1 pair)
- Face shield (1)
- Ice scoop (1)
- OSHA dry ice safety card (1)

Additional dry ice shipments will NOT be provided. Arrange for dry ice to maintain the temperature of the container after the first re-ice.

For more information, see:

- Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary
- Dry Ice Safety for Healthcare Professionals

Does Pfizer-BioNTech COVID-19 Vaccine have a beyond-use date (BUD)?

Yes, there are three time periods to track based on storage.

- Before mixing, vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 5 days (120 hours). After 5 days (120 hours), contact the manufacturer for guidance before discarding any vials.
- Before mixing, vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.
- Once mixed, vaccine must be discarded within 6 hours.

Resources:

- Pfizer-BioNTech COVID-19 Vaccine BUD Guidance and Labels
- Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Labels

After vaccine has been stored at frozen temperatures for 2 weeks, can it be stored at refrigerated temperatures for an additional 5 days?

Yes. After the 2-week time frame, you have two options:

- You may transfer vaccine to refrigerated storage between 2°C and 8°C (36°F and 46°F) for up to 120 hours (5 days). After 120 hours (5 days), contact the manufacturer for guidance.
- You may return vaccine **one time** to ultra-cold temperature storage (-80ºC to -60ºC [-112ºF to -76ºF]).

See Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary for more storage and handling information.

What type of temperature monitoring device (TMD) should be used to monitor storage unit temperatures?

If using an ultra-cold freezer, freezer, or refrigerator to store vaccine:

CDC requires vaccination providers participating in the COVID-19 Vaccination Program to use a specific type of TMD called a "digital data logger" (DDL) to monitor vaccine temperatures. A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). DDLs using a buffered temperature probe provide the most accurate way to measure actual vaccine temperatures. Always use DDLs with a current and valid Certificate of Calibration Testing. Note that not all DDLs can measure ultra-cold temperatures.

If using the thermal shipping container to store vaccine:

Use the Controlant TMD included with the shipping container.

For more storage and handling information, see:

- CDC's *Vaccine Storage and Handling Toolkit*
- Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary

Are there any special considerations for my existing DDL?

Not all DDLs are designed to register or measure ultra-cold temperatures. Check with the DDL manufacturer to verify your DDL can measure ultra-cold temperatures. Additionally, many DDL manufacturers use pure propylene glycol (freezing point -59°C) or a glycol mixture with a warmer freezing point. For accurate ultra-cold temperature monitoring, it is essential to use an air-probe or a probe designed specifically for ultra-cold temperatures with the DDL.

If I prepare a multidose vial but do not administer all doses in the multidose vial today, can I store it in the refrigerator for use the following day?

No. Each multidose vial contains 6 doses. After dilution, vials must be stored between 2°C and 25°C and used within 6 hours of dilution. Discard any remaining vaccine after 6 hours according to your state immunization program's directions for proper disposal.

Whom can I contact about a problem with COVID-19 vaccine (e.g., temperature excursion, damaged vaccine)?

If the vaccine experienced problems during shipment (for example, damage or temperature excursion), contact:

- Directly distributed vaccine (Pfizer): Contact Pfizer at 800-666-7248 (option 8) or CVGovernment@Pfizer.com.
- Centrally distributed vaccine (for example, Moderna): Contact McKesson Specialty Customer Service at (833) 343-2703, Monday–Friday, 8 AM–8 PM Eastern Time.

If the vaccine experienced problems after it was received and placed into storage, contact the vaccine manufacturer for guidance on improper storage and handling.

For temperature excursions (out-of-range temperatures), take immediate action:

- Label the vaccine "Do Not Use" and store at the recommended temperature range until you receive manufacturer guidance.
- Document the date and length of time of the excursion, storage unit temperature, room temperature, and inventory affected.
- Record any other relevant information.
- Contact the manufacturer for guidance on whether to use affected vaccines and whether patients need to be recalled for revaccination.
- Document the event and action taken for record-keeping requirements.

Vaccine Administration

The preparation instructions for Pfizer-BioNTech COVID-19 Vaccine indicate it is to be mixed with sterile 0.9% sodium chloride (normal saline, preservative-free). It is already a liquid. Should it be mixed before administering the vaccine?

Yes. The vaccine is concentrated and must be mixed with 0.9% sodium chloride (normal saline, preservative-free), provided in the ancillary supply kit, before administering.

See Pfizer-BioNTech COVID-19 Vaccine Preparation and Administration Summary and Preparation Infographic for more information.

Can I use bacteriostatic normal saline or sterile water/normal saline from a larger stock vial to mix Pfizer-BioNTech COVID-19 Vaccine?

No. Pfizer-BioNTech COVID-19 Vaccine requires mixing ONLY with sterile 0.9% sodium chloride (normal saline, preservative-free). NEVER use bacteriostatic normal saline or any other diluent. Diluent will arrive separately from vaccine in an ancillary supply kit. No other diluent can be used. CDC has developed an infographic that can be posted in medication preparation areas as a reference.

Can a vial of 0.9% sodium chloride (normal saline, preservative-free) be used for multiple doses?

No. You must mix the vaccine using a NEW vial of diluent and a NEW vial of vaccine EVERY TIME. You may receive diluent in 0.2 mL or 1.0 mL volume. These are both single-use vials. Discard the diluent vial after mixing the vaccine.

Because 0.9% sodium chloride (normal saline) is preservative-free, it is important to enter the vial only once. Inserting the needle twice could provide a direct route for microorganisms to enter the vial and contaminate the fluid in these devices. By entering the vial only once you will prevent inadvertent contamination of the vial that could lead to infection transmission.

See Questions about Single-Dose/Single-Use Vials for more information.

How many doses are in a multidose vial of Pfizer-BioNTech COVID-19 Vaccine?

After dilution, each multidose vial of Pfizer-BioNTech COVID-19 Vaccine contains **six** 0.3mL doses. The amount of excess vaccine left in the vial can vary based on provider technique and ancillary supplies. Always follow these practices when extracting the final dose:

- Extract the proper dose. Each dose MUST contain 0.3 mL of vaccine.
- Do NOT combine remaining vaccine from multiple vials to obtain a full dose.
- If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and contents.

See Pfizer-BioNTech COVID-19 Vaccine Preparation infographic to learn more about withdrawing 6 doses.

Can I draw extra doses of vaccine?

CDC recommends healthcare providers follow the dosing guidance from the manufacturer as outlined in the Emergency Use Authorization (EUA). CDC will update its guidance if the EUA and ancillary supply kits support obtaining additional doses per vial in the future.

I am not able to withdraw 6 doses from a Pfizer-BioNTech COVID-19 Vaccine vial. What can I do?

Low dead-volume syringes and/or needles can help you withdraw 6 doses. Your ancillary supply kit contains approximately 80% low dead-volume syringes and/or needles and 20% non-low dead-volume syringes and/or needles in various sizes.

To maximize the number of vaccine doses, use a combination of low dead-volume syringes and/or needles for each vial as follows:

- When supplies allow, use 5 low dead-volume syringes and 1 non-low dead-volume syringe per vial.
- Avoid extracting an entire vial with all low dead-volume syringes. This will leave you with too few low dead-volume syringes as you near the end of your ancillary supplies, and you may not be able to withdraw 6 doses.
- Do not prioritize using low dead-volume products over selecting the proper needle gauge and length for vaccine recipients.

See Pfizer-BioNTech COVID-19 Vaccine Preparation infographic to learn more about withdrawing 6 doses.

See USP's FAQ for Maximizing COVID-19 Vaccine Doses to identify specific low dead-volume products from ancillary supply kits.

We don't want to waste vaccine and can get more doses if we combine vaccine from multiple vials. Is it acceptable to combine or "pool" vaccine from more than one vial?

No. CDC recommends following these practices:

- **Never** combine or "pool" partial doses from two or more vials to obtain a full dose of vaccine.
- Withdraw only the number of doses authorized for the specific vaccine.
- Discard vaccine vial and remaining vaccine if the amount of vaccine left in the vial is not a full dose.

Although no one wants to waste vaccine, it is crucial for infection control and patient safety to administer vaccine properly. Combining vaccine doses from multiple vials can result in cross-contamination, potentially causing bacterial infection in patients.

We are using low dead-volume syringes and needles. How much vaccine should we withdraw into the syringe? Do we need to adjust the dosage (volume) for these syringes?

No, the dosage should NOT be adjusted regardless of the type of needles and syringes used. ALWAYS withdraw the amount of vaccine indicated by the manufacturer. After mixing with the diluent, withdraw 0.3 mL of vaccine into the syringe.

While preparing Pfizer-BioNTech COVID-19 Vaccine, I shook the vial instead of gently inverting 10 times. What should I do?

Discard the vaccine. mRNA vaccine is very fragile and should not be shaken. Vials should only be gently inverted.

Do I need to change needles between reconstitution and administration?

Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated. See ACIP's *General Best Practice Guidelines for Immunization*, "Vaccine Administration," for more information.

How should I administer Pfizer-BioNTech COVID-19 Vaccine?

The route of administration for this vaccine is an intramuscular injection. Refer to the following CDC resources

- Pfizer COVID-19 Vaccine Preparation and Administration Summary
- Vaccine Administration: Intramuscular (IM) Injection Adults 19 years of age and older
- Vaccine Administration: Intramuscular (IM) Injection Children 7 through 18 years of age
- Resource Library includes demonstration videos for intramuscular injections

Pfizer-BioNTech COVID-19 Vaccine was mistakenly administered to a 15-year-old patient. What should we do?

If Pfizer-BioNTech COVID-19 Vaccine is administered, do not administer the second dose until the person becomes eligible to receive vaccination (either by reaching the authorized age or if the authorization is extended to include additional age groups), even if this results in the second dose being administered after the recommended interval between doses.

This is considered a vaccine administration error. Determine how the error occurred and implement strategies to prevent it from happening again. Report this error to VAERS.

Pfizer-BioNTech COVID-19 Vaccine was administered to a patient subcutaneously. What should we do?

If any of the currently authorized COVID-19 vaccines are administered subcutaneously, do **not** repeat the dose. If the dose given in error is the first dose, administer the second dose at the recommended interval of 21 days. If this dose is the second dose, the series is complete, and no additional doses are needed.

Inform the recipient of the potential for local and systemic adverse events.

This is considered a vaccine administration error. Determine how the error occurred and implement strategies to prevent it from happening again. Report this error to VAERS.

Review resources on vaccine administration:

- Vaccine Administration: Intramuscular (IM) Injection Adults 19 years of age and older
- You Call the Shots: Vaccine Administration

While vaccinating a patient, the needle and syringe were not tightly secured together, and vaccine leaked from the syringe. What should we do?

If a lower-than-authorized dose volume is administered for any of the currently authorized vaccines, adhere to the following interim recommendation:

- **If more than half of the dose was administered, do not repeat the dose**. If the dose given in error is the first dose, administer the second dose at the recommended interval of 21 days. If this dose is the second dose, the series is complete, and no additional doses are needed.
- **If less than half of the dose was administered or the proportion of the dose cannot be estimated, administer the authorized dose immediately in the opposite arm**. If the dose given in error is the first dose, administer the second dose at the recommended interval of 21 days from the date of receipt of the valid dose (not the date of receipt of the erroneous dose).

This is considered a vaccine administration error. Determine how the error occurred and implement strategies to prevent it from happening again. Report this error to VAERS.

Is there general guidance for what we should do when vaccine administration errors occur?

Interim recommendations for COVID-19 vaccine administration errors differ from ACIP's general best practice guidelines. Review vaccine administration errors and deviations for COVID-19 vaccines to learn about the interim recommendation for each type of error.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS) unless otherwise indicated in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the "Vaccine Administration" chapter of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.

How do I dispose of COVID-19 vaccine vials and packaging?

To reduce the risk of fake or counterfeit vaccines, dispose of vials and packaging as medical waste by placing vials in a sharps container and packaging in a red medical waste bag. If medical waste containers are in short supply, deface or safely crush packaging materials so they cannot be reintroduced or reproduced. After the products are sufficiently defaced or destroyed, dispose with regular waste.

The disposal process for unused COVID-19 vaccine and diluent may be different. For guidance, contact your jurisdiction's immunization program.

Do I need to observe patients after vaccination?

Yes. CDC recommends the following observation periods after COVID-19 vaccination:

- 30 minutes for people with:
  - A history of an immediate allergic reaction of any severity to another vaccine or injectable therapy
  - A contraindication to Janssen COVID-19 Vaccine who receive Pfizer-BioNTech COVID-19 Vaccine
  - History of anaphylaxis due to any cause
- 15 minutes for all other people

Vaccine Safety and Efficacy

What side effects might occur following vaccination?

Common side effects include:

Local reactions:

- Pain
- Redness
- Swelling

Systemic reactions:

- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea

How effective is the Pfizer-BioNTech COVID-19 Vaccine?

Clinical trial data demonstrated vaccine efficacy was 95.0% against symptomatic, laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection following receipt of 2 doses of Pfizer-BioNTech COVID-19 Vaccine.

Will my patient be protected by 1 dose of Pfizer-BioNTech COVID-19 Vaccine?

Both doses are necessary for protection; efficacy of a single dose has not been systematically evaluated.

Off-Site Clinics

Can I predraw vaccine?

CDC does not recommend predrawing vaccine. If vaccine must be predrawn:

- Set up a separate administration station for each vaccine type to prevent medication errors.
- Draw up vaccines only after arriving at the clinic site or mass vaccination event.
- Each person administering vaccines should draw up no more than one multidose vial or 10 doses* at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Predraw reconstituted vaccine into a syringe only when ready for administration.
- If predrawn vaccine is not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits.

*You may withdraw a total of 12 doses (2 multidose vials) of Pfizer-BioNTech COVID-19 Vaccine. This applies only to Pfizer-BioNTech COVID-19 Vaccine.

See CDC's *Vaccine Storage and Handling Toolkit* for more information.

Can I transport vaccine in a syringe?

CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.

Vaccination of Minors

Is consent required to administer COVID-19 vaccine to an eligible minor?

The federal government does not have specific requirements for medical consent for vaccination. States/jurisdictions have medical consent laws that address the circumstances under which a medical provider must seek consent prior to a medical procedure and the processes for obtaining that consent. These laws vary across jurisdictions. Providers may also be subject to policy requirements for consent within their own organizations.

To access COVID-19 vaccine in the United States, a provider must enroll in the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program and sign the applicable CDC Provider Agreement. The CDC COVID-19 Vaccination Program Provider Agreement requires the provider to comply with applicable patient assent and consent laws in their state/jurisdiction for administration of COVID-19 vaccines.

Is a parent or legal guardian required to accompany an eligible minor to receive a COVID-19 vaccine?

The Emergency Use Authorization (EUA) does not require the parent or legal guardian to be physically present. However, some state, tribal, and territorial laws may require a parent or legal guardian to accompany an eligible minor to receive vaccinations. Some jurisdictions' laws may allow parent/guardian consent without a requirement to be present for the vaccination if the provider is given evidence of the consent prior to vaccination. Providers may also have to comply with policy requirements determined by their organizations.

Is a vaccination provider required to give the parent or legal guardian a copy of the EUA Fact Sheet for Patients and Caregivers in person? If not, can it be provided on paper or electronically prior to the visit?

No, in-person provision of the EUA Fact Sheet is not a federal requirement. Under the CDC COVID-19 Vaccination Program Provider Agreement, the vaccine provider may provide the EUA Fact Sheet to the parent or legal guardian prior to the visit on paper, or through an electronic link if the individual agrees to receive it electronically.

Is a parent or legal guardian required to complete vaccination prescreening questions for the minor?

There is no such federal requirement. If a state, tribal, or territorial patient consent law requires a parent or legal guardian to complete the prescreening questions for the minor, the CDC COVID-19 Vaccination Program Provider Agreement requires the provider to comply with such a requirement. In addition, if a jurisdiction authorizes a minor to consent to receipt of COVID-19 vaccine, the minor can complete the prescreening questions themselves, but the provider must confirm that this complies with state, tribal, or territorial laws.

Can the vaccination prescreening questions be completed by a parent or legal guardian online?

A parent or legal guardian may complete the prescreening questions online provided this is done prior to administration of COVID-19 vaccine to the minor. Providers must comply with any applicable state, tribal, or territorial laws.

Does CDC have a consent form that should be used for eligible minors to receive a COVID-19 vaccine?

No. Since applicable medical consent laws are a matter of state, tribal, or territorial law, providers are advised to consult with legal counsel to assure compliance with the scope of those consent laws.

Need more Information?

Get your Questions answered about other specific COVID-19 vaccines, including:

Janssen (J&J) | Moderna | General Information

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