Moderna COVID-19 Vaccine Guide

INFORMATION TO ADMINISTER COVID-19 VACCINE

Last Update: 3.17.2021

Background

In March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. Immunization with a safe and effective COVID-19 vaccine is critical to reduce COVID-19-related illnesses, hospitalizations, and deaths. In the United States, the goal is to have enough COVID-19 vaccine for all people who wish to get vaccinated.

Initial vaccines will get Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) based on the data collected in clinical trials on their effectiveness and safety. In a global health pandemic, an EUA allows the FDA to review information from a vaccine manufacturer to determine if a vaccine can be released early. They weigh the benefits of early release against the known and unknown risks of a vaccine. If at any time vaccine data shows more risk than benefit, an EUA is re-evaluated.

This guide provides a summary of the Centers for Disease Control and Prevention's (CDC) COVID-19 vaccination recommendations, priority groups, and available products. For more details, read the Advisory Committee on Immunization Practices (ACIP) recommendations here.

COVID-19 Vaccine Supplies

Supplies will be packaged in adult and pediatric kits and will be automatically ordered in amounts to match vaccine orders. Each ancillary kit will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (22-25 gauge, 1 to 1.5 inch, depending on the population being vaccinated).
- Syringes, 105 per kit (ranging from 1-3 milliliters).
- Alcohol prep pads, 210 per kit.
- Four surgical masks and two face shields for vaccinators, per kit.
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit.
- Gauze
- Band-Aids
- Hand sanitizer

- Placemats
- Sharps containers
- Medium-sized powder-free and latex-free gloves
- Epinephrine Kit

A physician standing order for COVID-19 vaccinations and epinephrine injections is included at each event. Review these documents prior to your event.

COVID-19 Vaccine

Vaccine products vary based on dosage, the number of doses needed, intervals between doses, and how the vaccine must be stored and handled. There will likely be several COVID-19 vaccines out at the same time and more may become available as vaccine trials are completed. This will make COVID-19 vaccine more accessible, but it may also increase the risk of medication errors. Double-check the product-specific emergency use authorization fact sheet or package insert for age indication, route, dosage, and storage and handling requirements.

This guide focuses specifically on the Moderna vaccine.

COVID-19 Vaccine Website

TotalWellness is using a website to help register and track participants who receive a COVID-19 vaccine. The Immunization Record (IR) website allows participants to create a profile, complete consent forms, and view vaccination history. Vaccinators will use the site to review answers to consent form questions and document shot administration.

Login

Step 1 - Company

- Visit https://ir.totalwellnesshealth.com/records/auth/signin
- Enter Company Code (provided on your worksheet)
- Enter Password (provided on your worksheet)

Step 2 - Location

- Select your location from the dropdown

- Enter the Access Code (provided on your worksheet)
- Select the Role of Vaccinator

Step 3 – Vaccination Information

- Vaccinator's Name
  - Enter your full name.
- Vaccinator's Title
  - Enter your medical title (RN, LPN, LVN, etc.).
- Vaccine Name
  - Select the vaccine you'll be administering using the drop-down list.
- Vaccine Lot Number
  - Enter the vaccine lot number.
- Vaccine Expiration Date
  - Enter the vaccine expiration date.

This information will automatically load onto the participant vaccination record you submit. If at any point during the event you switch vaccine types, lot numbers, or someone else uses your iPad click on Change User to update the information.

Create a Vaccination Record

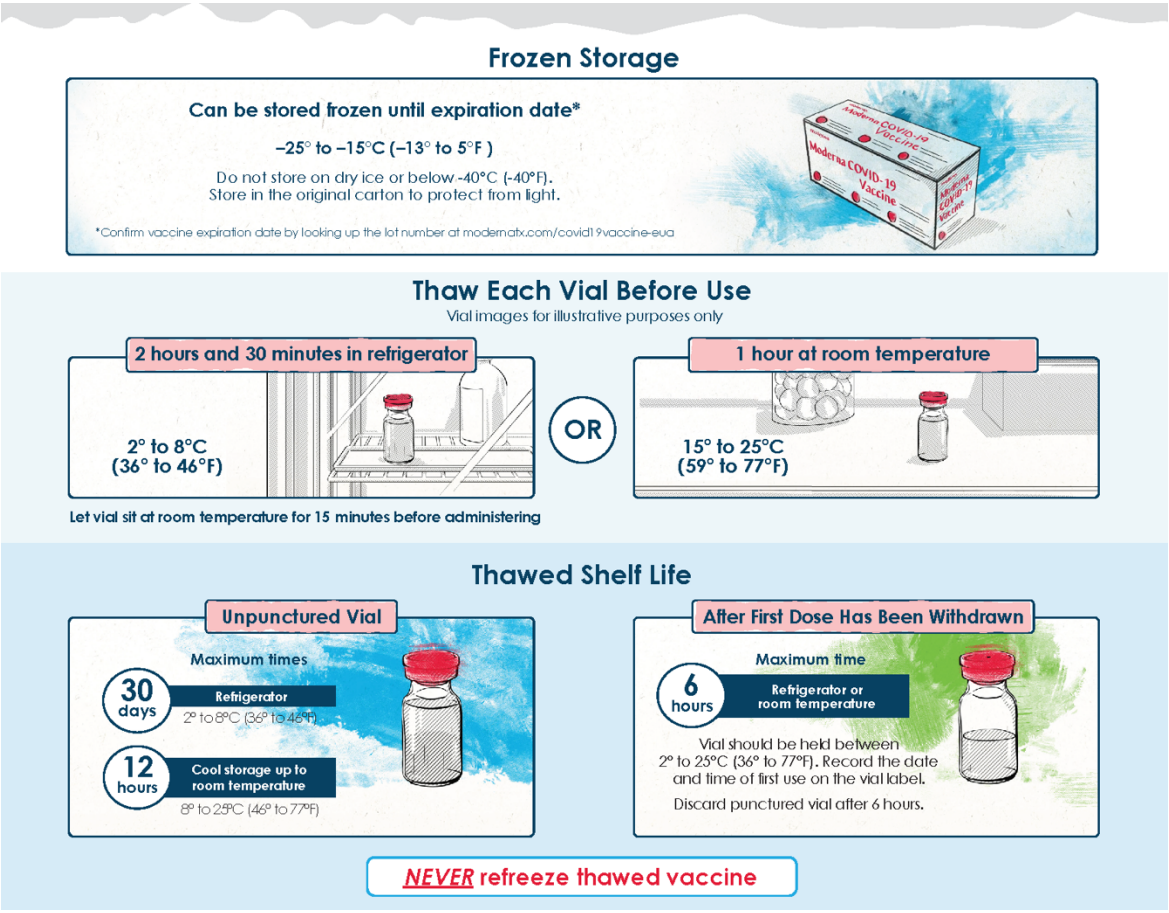
Each participant should have pre-registered, completed the consent form, and received a participant ID Code.

1. Scan the QR code or enter the participant's ID number in the Search ID field.
2. Verify you have the correct participant by confirming first name, last name, and date of birth.
3. Determine if this the participant is receiving a first or a second dose.
   a. Ask the participant if they have received a dose of COVID-19 vaccine.
   b. If the participant has received their first dose of COVID-19 vaccine from TotalWellness, the vaccination details will display on the screen. If the participant received a first dose of vaccine from another organization, the individual should provide their vaccination card showing the date of vaccination and type of vaccine received.
   c. Prior to administering a second dose of COVID-19 vaccine, ensure the following:
      i. The timing of the second dose is correct. The system will provide a note regarding this timing.
      ii. Ensure you administer the second dose using the same type/manufacturer of vaccine that was administered for the first dose.

4. Review the answers to the consent form questions to ensure the participant is a good candidate to receive the vaccine.
5. Select the Injection Site.
6. Select the Dose is Series (Dose 1 or Dose 2)
7. Click Process to save the record.
8. Click Create Record to return to the Search ID screen.

COVID-19 vaccine storage and handling

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit the risk of administering COVID-19 vaccine with reduced effectiveness. Follow specific information for Moderna COVID-19 vaccine:



Expiration and beyond-use date (BUD)

All vaccines have expiration dates. Sometimes vaccines must be used before the expiration date listed on the label. This is referred to as the beyond-use date" (BUD). For COVID-19 vaccines, the beyond-use date is determined based on the date and time a vial is first entered (pierced) and the storage information in the EUA fact sheet (or package insert). With COVID-19 vaccines, the beyond-use date will change if the vaccine is modified or stored in a certain way. The person who makes a change to the vaccine (e.g., pierces the vial, moves it from the ultra-cold storage or freezer into the refrigerator) must document the beyond-use date on a label.

Keep in mind that Moderna COVID-19 vaccine products do not contain any preservatives and expire six hours after the vial is first punctured.

Recommendations for mRNA COVID-19 vaccines

ACIP has issued interim recommendations for the use of Moderna COVID-19 vaccines for the prevention of COVID-19. These recommendations have been adapted from the Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.

Authorized age groups

Under the EUAs, the following age groups are authorized to receive vaccination:

- Moderna: Ages 18 years and older

Administration

The mRNA COVID-19 vaccine series consists of two doses administered intramuscularly:

- Moderna: 0.5 mL
  28 days (one month) apart

People should not be scheduled for their second dose earlier than recommended. However, second doses administered within a grace period of four days earlier than

the recommended date for the second dose are considered valid. Second doses administered earlier than the four-day grace period (in error), do not need to be repeated. There is no maximum interval between the first and second doses. Do not restart the series. Complete a VAERS report for all vaccine errors, including a second dose given earlier than recommended.

Interchangeability with other COVID-19 vaccine products

The two currently authorized mRNA COVID-19 vaccines are **not** interchangeable with each other or with other COVID-19 vaccine products. If two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.

ACIP does not state a product preference between the two currently authorized mRNA COVID-19 vaccines. Either COVID-19 vaccine can be used when indicated.

Co-administration with other vaccines

The COVID-19 Moderna vaccine should be **routinely** administered alone, with a minimum interval of 28 days before or after administration with any other vaccines.

Vaccination of people with a SARS-CoV-2 (COVID-19) infection or exposure

People with a history of COVID-19 infection

Clinical trial data indicates that mRNA COVID-19 vaccines are safe in people with evidence of a prior COVID-19 infection. Vaccination should be offered to people regardless of a prior COVID-19 infection (with or without symptoms).

People with known current COVID-19 infection

Postpone vaccination of people with a known current COVID-19 infection until the person has recovered from acute illness (if they had symptoms) and criteria have been met for them to complete isolation. This recommendation applies to people who develop COVID-19 infection before receiving any vaccine doses and those who develop an infection after the first dose but before receiving the second dose.

While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days after initial infection. Therefore, people with documented acute infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

People who previously received passive antibody therapy for COVID-19

Based on the estimated half-life of antibody therapies for COVID-19 (i.e., monoclonal antibodies or convalescent plasma), vaccination should be deferred for at least 90 days. This is a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses. This recommendation applies to people who received passive antibody therapy before receiving any COVID-19 vaccine doses and those who received passive antibody therapy after the first dose but before the second dose, in which case the second dose should be delayed for at least 90 days after receiving the antibody therapy.

For people receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administering mRNA COVID-19 vaccines is unlikely to significantly interfere with the development of a protective antibody response (for vaccine administration either at the same time or any interval before or after receiving antibody therapies). Therefore, there is no recommended minimum interval between other antibody therapies and mRNA COVID-19 vaccination.

People with a known COVID-19 exposure or during COVID-19 outbreaks

The mRNA vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis (i.e., vaccination to prevent developing COVID-19 infection in someone with a known exposure). People in the community or outpatient setting who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended.

Special populations

People with underlying medical conditions: People with underlying medical conditions who have no contraindications to vaccination are recommended to receive the COVID-19 vaccine. Clinical trials showed similar safety and efficacy profiles in people with underlying medical conditions.

Immunocompromised people: Data is not currently available for vaccine safety and effectiveness in people with HIV infection or other immunocompromising conditions, or in people who take immunosuppressive medications or therapies. These people may still receive the COVID-19 vaccine if they have no contraindications to vaccination. But they should be counseled about the unknown vaccine safety and effectiveness, and that there is potential they will not have a full protective response to the vaccine. Antibody testing is not recommended to measure immunity to COVID-19 following mRNA COVID-19 vaccination.
At this time, people who have received a complete COVID-19 vaccine series when they were immunosuppressed do not need to be re-vaccinated once immune competence is restored.

People with autoimmune conditions: People with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

People with a history of Guillain-Barré syndrome: To date, no cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the Moderna COVID-19 vaccine clinical trials. People with a history of GBS may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of GBS following mRNA COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

People with a history of Bell's palsy: Cases of Bell's palsy were reported following vaccination in participants in the Moderna COVID-19 vaccine clinical trials. However, the FDA does not consider these to be above the rate expected in the general population and has not concluded that these cases were causally related to vaccination. Since there is not more evidence, people with a history of Bell's palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of Bell's palsy following mRNA COVID-19 vaccination should be reported to VAERS.

Pregnant women: Currently, there is no available data on the safety of COVID-19 vaccines in pregnant women. The manufacturer is following outcomes on women in the clinical trials who became pregnant. Based on current knowledge of mRNA vaccines, experts believe they are unlikely to pose a risk for people who are pregnant; however more data is needed.

- While the risk is low, pregnant women with COVID-19 have an increased risk of severe illness including ICU admission, mechanical ventilation, and death. They also might be at increased risk of adverse pregnancy outcomes, such as preterm birth.
- If a pregnant woman is part of a group that is recommended to receive a

COVID-19 vaccine, she may choose to be vaccinated. Her health care provider can help her make an informed decision. Factors to consider include: community transmission, personal risk of contracting COVID-19, the risks to her and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

- Pregnant women who experience fever after vaccination may be counseled to take acetaminophen, since fever has been associated with adverse pregnancy outcomes. Acetaminophen may also be used for other post-vaccination symptoms. Routine testing for pregnancy prior to COVID-19 vaccination is not recommended. Women who are trying to become pregnant do not need to avoid pregnancy.

Lactating (breastfeeding) women: There are no data on the safety of COVID-19 vaccines in lactating women, or the effects on the breastfed infant or milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. If a lactating woman is part of a group who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated.

Screening for contraindications and precautions

Participant Screening

All participants need to be screened for contraindications and precautions prior to receiving a COVID-19 shot. TotalWellness is screening patients prior to appointment but it's still your responsibility to determine if the participant is a good candidate to receive the COVID-19 shot by reviewing the participant's answers to the questions on the Consent Form.

1. **Have you received any other vaccine within the past 14 days?**

   IF YES: Do Not Vaccinate
   Individuals who received a different vaccine, including a flu shot, within the past 14 days should wait to receive the COVID-19 vaccination until at least 14 days after the previous non-COVID vaccination.

2. **Have you received convalescent plasma or monoclonal/polyclonal antibody infusions for COVID-19 within the past 90 days?**

   IF YES: Do Not Vaccinate
   Individuals who have received monoclonal antibody therapy or convalescent plasma should wait 90 days after their treatment to receive the COVID-19 vaccine.

3. **Have you tested positive for and/or been diagnosed with COVID-19 in the last 10 days?**

   IF YES: Do Not Vaccinate.

4. **Have you ever received a COVID-19 vaccination?**

   IF YES: Verify first dose vaccine type and timing for second dose prior to administering the second dose of vaccine.

5. **Do you have today or have you had at any time in the last 10 days a fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea, vomiting, or diarrhea?**

   IF YES: Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the illness.

6. **Have you had a severe allergic reaction to any vaccine?**

   IF YES: Please ask the patient whether they discussed vaccination with a medical provider. If they have, allow vaccination to proceed. Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:

   a. Persons with a history of anaphylaxis: 30 minutes
   b. All other persons: 15 minutes

7. **Have you had a severe allergic reaction?**

   IF YES: The CDC says that these individuals may still be vaccinated but should consult with their healthcare provider about the risks of developing a severe allergic reaction against the benefits of vaccination. In most cases, these people can be vaccinated safely, especially if the severe allergic reaction is to something other than a previous vaccination or other injectable medicine.

Only when people have a known severe reaction to an ingredient of the vaccine should they definitely not be vaccinated.

8. **Are you pregnant?**

   IF YES: Please ask the patient whether they discussed vaccination with a medical provider. Patients who are pregnant may choose to be vaccinated whether they discussed vaccination with a medical provider or not.

9. **Are you currently breastfeeding?**

   IF YES: Please ask the patient whether they discussed vaccination with a medical provider. Patients who are lactating may choose to be vaccinated whether they discussed vaccination with a medical provider or not.

10. **Have you ever had a reaction to latex?**

    IF YES: Check all products for latex prior to administration.

11. **Are you immunocompromised or on a medication that affects your immune system?**

    IF YES: Have patient discuss with a medical provider. Immunocompromised participants were not included in initial vaccine trials. The CDC notes that immunocompromised patients may receive the vaccines so long as they have no contraindications to vaccination, but that they should be counseled about the unknown safety profiles of the vaccines in immunocompromised populations.

12. **Do you have a bleeding disorder or are you taking a blood thinner?**

    IF YES: Have patient discuss with a medical provider. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: a fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

Use your best professional judgment to determine if you should proceed. If in doubt, don't give the shot! Refer the participant to his or her healthcare provider.

While rare, anaphylactic reactions have been reported following vaccination with mRNA COVID-19 vaccines. Although investigations are ongoing, people with a

history of an immediate allergic reaction (of any severity) to an mRNA COVID-19 vaccine or any of its components might be at greater risk for anaphylaxis upon re-exposure to either of the currently authorized mRNA COVID-19 vaccines. An immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria (hives), angioedema (painless swelling under the skin, often happens with hives), respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

Contraindications

CDC considers a history of the following to be a contraindication to vaccination with the Moderna COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components.
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*.
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*.

  *These people should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that they can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).

People with an immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either mRNA COVID-19 vaccines. Providers should attempt to determine whether reactions reported after vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction (fainting) or post-vaccination side effects (which are not contraindications to receiving the second vaccine dose).

Precautions

CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) as a precaution but not a contraindication to vaccination for Moderna COVID-19 vaccine. People with this history should be counseled about the unknown risks of

developing a severe allergic reaction after COVID-19 vaccination and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist may be considered until further information on the risk of anaphylaxis is available. The following considerations can be used to help the provider conduct a risk assessment for mRNA COVID-19 vaccination in these individuals:

- Risk of exposure to COVID-19 (e.g., because of living in a congregate setting, occupation).
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions).
- Whether the patient has previously been infected with COVID-19 and, if so, how long ago.

Note: Vaccination is recommended for people with a history of COVID-19; however, because reinfection is uncommon in the 90 days following infection, people with a precaution to vaccination and recent COVID-19 may choose to defer vaccination until further information is known about the risk of anaphylaxis following vaccination.

- The unknown risk of anaphylaxis (including fatal anaphylaxis) following mRNA 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 further discussion of risk assessment for mRNA COVID-19 vaccination, please refer to the Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.

Vaccine Ingredients:

Description	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol

	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Tromethamine
	Tromethamine hydrochloride
	Acetic acid
	Sodium acetate
	Sucrose

Observation period and anaphylaxis management

Appropriate medical treatment used to manage immediate allergic reactions (e.g., epinephrine) must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine. Vaccine providers should observe patients with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy or people with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination. All other people should be observed for 15 minutes.

Laboratory testing

Interpretation of SARS-CoV-2 test results in vaccinated people: For people who have received mRNA COVID-19 vaccine, the vaccine will not affect SARS-CoV-2 viral test results. Antibody testing is not currently recommended to assess for COVID-19 immunity or to assess the need for vaccination in unvaccinated people.

COVID-19 vaccine administration

EUA Fact Sheets and Vaccine Information Statement (VISs)

The FDA commissioner may authorize the use of vaccine during a public health emergency to protect the nation's health, even though the vaccine is not yet licensed. Under emergency use authorizations (EUA), EUA fact sheets are used instead of vaccine information statement, which are used when a vaccine is licensed.

You must provide a copy of either a fact sheet or a vaccine information sheet to the person receiving the vaccine prior to vaccination. Allow for any questions that a person getting vaccinated may have.

EUA fact sheets

- EUA fact sheets for vaccination providers are product-specific information sheets that replace the usual package insert. A separate fact sheet for vaccine recipients is similar to a licensed product's vaccine information statement (VIS).
- The EUA fact sheet for vaccine recipients explains the vaccine risks and benefits, specific vaccine product information and its use, and information from clinical trials that support the FDA's emergency use authorization.
- You are legally required to provide an EUA fact sheet to each participant prior to vaccination.

We also require that a copy of the TotalWellness Privacy Practices Notice be available for participants to reference. A copy of the TotalWellness Privacy Practices Notice is provided for all events. We recommend displaying a copy at the registration table for easy participant access.

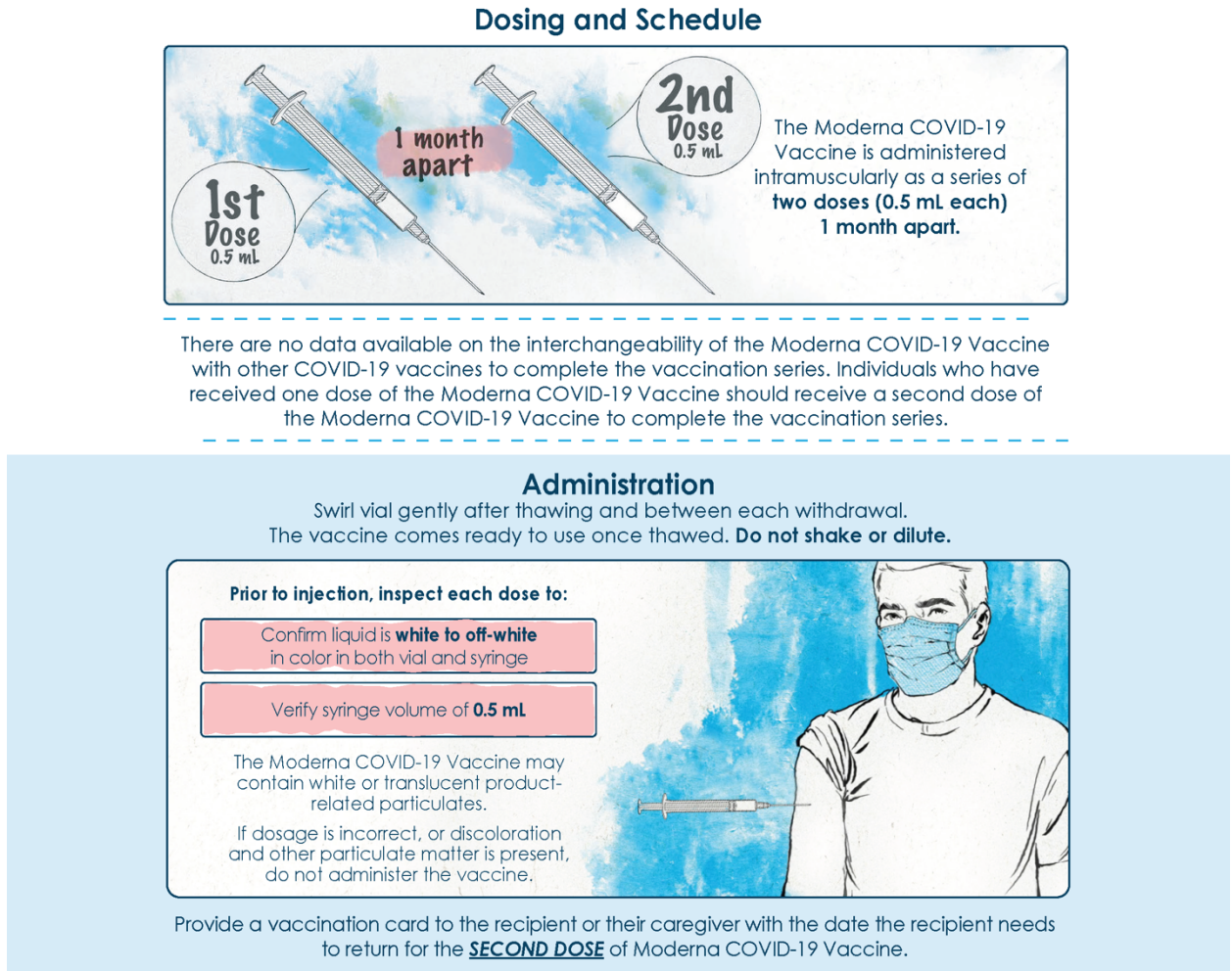
Participant Care

Some participants get very anxious at the thought of receiving a COVID-19 shot. It is important for you to display confidence and create an environment that promotes security and trust. We recommend that you:

1. Introduce yourself to each participant.
2. Display a positive attitude through body language, facial expressions, and comments.
3. Use a calm tone of voice.
4. Make eye contact with the participant.
5. Be honest in explaining what to expect.
6. Ask participants if they have any questions (and be prepared to answer them, of course).
7. Pull up the participant's profile in the IR website by scanning their QR code or searching their ID number.
    a. Verify the participant's first name, last name, and date of birth.

Before administering the COVID-19 shot, verbally inform participants of potential side effects including:

- Soreness and/or swelling at the injection site
- Fatigue
- Headache
- Chills
- Fever
- Muscle/joint pain and aches
- Allergic reaction such as hives and swelling—particularly around the mouth and eyes— itching, trouble breathing, etc. Inform the participant that they should seek immediate medical attention if an allergic reaction occurs.



Intramuscular administration

Always adhere to strict aseptic practices while preparing and giving injectable vaccines. Use good hand hygiene.

Follow the “seven rights” of vaccine administration: right patient; right vaccine/diluent; right time; right dose; right route; right site; right documentation.

A separate needle and syringe should be used for each injection. Always use one needle, one syringe, **only one time**! Never administer vaccine from the same syringe to more than one participant, even if the needle is changed.

Choose the correct syringe and needle based on the size of the individual. The needle should be long enough to reach the muscle mass and prevent vaccine from seeping into the subcutaneous tissue, but not so long as to involve underlying nerves, blood vessels, or bone. Needle size and site of injection must be decided for each person based on the size of the muscle and the thickness of adipose tissue around the muscle. This is usually a 1 to 1.5-inch needle for adults.

The table below provides general guidance; however, we ask that you utilize your best professional judgment when determining needle length.

Flu Shot Administration Needle Length Table		
Gender		Needle Length
Male	Female	
Up to 259 pounds	Up to 199 pounds	1 inch
260+ pounds	200+ pounds	1½ inch

Avoid shoulder injury related to vaccine administration (SIRVA) in adults by administering the vaccine correctly in the deltoid muscle. Giving the intramuscular injection too close to the shoulder joint can cause bursitis, fasciitis, and other injury. Report shoulder injury related to vaccine administration to the Vaccine Adverse Event Reporting System (VAERS).

Preparing the Injection Site

Ask the participant if he or she has an arm preference in which to receive the shot.

On the preferred arm, uncover the deltoid muscle (upper arm) and locate the center of the “upside-down triangle,” or pinpoint the spot between two imaginary, horizontal lines: below the shoulder bone and at the armpit. See illustrations on page 18.

If the participant is wearing a sleeved shirt, reach the site by having the participant pull his or her shirt down over the shoulder or push his or her sleeve up over the shoulder. If neither exposes the site sufficiently, have the participant remove his or her shirt in a private area.

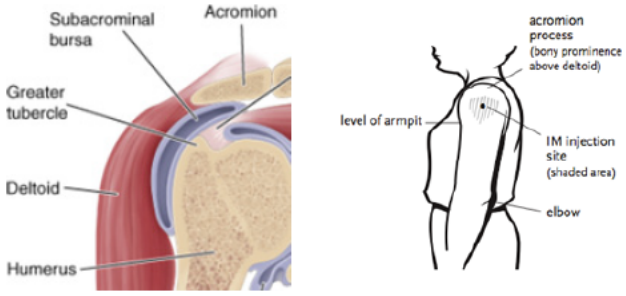
Choose an injection site that is free of moles, bruises, scars, rashes and visible blood vessels. Wipe the injection site with a new alcohol pad in a circular and outward motion and wait for the site to dry.

Mark the arm the participant will receive the shot in on the Consent Form in the Nurse's Box or within the IR website.

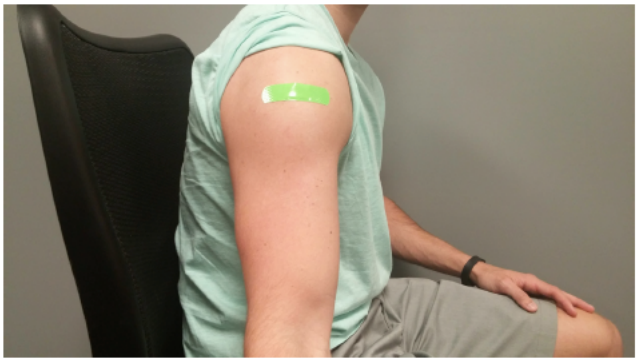
Please adhere to the following shot administration procedure:

- Make sure the participant is seated, preferably in a chair with arms.
- All shots should be administered at your (the vaccinator's) eye level, so it is recommended that you, the vaccinator, are seated when administering the vaccination.
- Ask the participant to get comfortable, sit still and relax his or her arm. The participant will feel less discomfort when relaxing the arm during injection.
- Be aware of symptoms that precede fainting such as weakness, dizziness, pallor, etc.
    - Provide supportive care and take appropriate measures to prevent injuries and embarrassment if such symptoms occur.
- Be sensitive to the comfort of the participant. If necessary, ask them to look away from the needle and envision they are on a beach.
- Double check the syringe for the correct dosage (0.5 mL), air bubbles, precipitate, etc. You should only administer vaccines that you have prepared yourself. Occasionally you may work with another nurse who can assist with preparing and drawing up vaccines for you to save time.
- In some cases, you may be able to obtain an 11th dose from a Moderna vaccine vial, and this may be used if it is truly a full dose.
- Discard vial when there is not enough vaccine to obtain a complete dose. Because the vaccine does not contain preservative, it is critical to note that if the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and content. Do not pool excess vaccine from multiple vials to create one dose.
- When the alcohol on the injection site is dry, isolate the muscle by stretching the skin taut between your thumb and forefinger to avoid injection into subcutaneous tissue. A technique for participants with very small arms is to grasp the tissue and 'bunch up' the muscle.

- Introduce the needle at a 90-degree angle with a quick thrust and advance as necessary into the thickest part of the muscle tissue. Insertion should be quick yet firm and steady.



Many vaccinators don't properly administer deltoid IM injections, so pay special attention to where and how deep you administer the vaccination. You'll need to reach the proper site so the vaccine is absorbed correctly. If you don't administer the vaccine properly, you might as well not give it at all. You've gone to a lot of trouble to keep your vaccine viable and the participant needs this protection. What a waste it would be for the vaccine not to be administered properly.



The proper site is where the green Band-Aid is on this man's arm. Be careful to not administer shots too high, too low, toward the back of the arm, or too deep.

If administered incorrectly, it's likely that the vaccine is not injected into the muscle tissue and could cause damage. It's important that you administer the shot into the center of the deltoid muscle, away from blood vessels, nerves and bones.

SIRVA: As a vaccinator, you need to be aware of the risk of Shoulder Injury Related to Vaccine Administration (SIRVA). It's thought to result from the unintentional injection of a vaccine into tissues and structures underneath the deltoid muscle. While this is uncommon, SIRVA could lead to severe, persistent shoulder pain with

restriction of function. It might include a diagnosis like bursitis, tendinitis, rotator cuff tear, frozen shoulder, impingement syndrome and/or adhesive capsulitis.

Overpenetration: You don't want to go all the way through the muscle, either. This happens if you go too deep (overpenetration). Be aware of how deep you're injecting a shot. Picture the tip of the needle in the center of the muscle every which way.

Overpenetration & SIRVA can create terrible outcomes for people trying to protect themselves from COVID-19. To ensure the safety of participants, we want to reiterate the importance of injecting into the center of the muscle - from outside and inside the body.

Learn more about safe injection practices at One & Only Campaign.

Document the Injection
Select the injection site and dose in series within the IR system and click Process to save the record. If paper consent forms are being utilized at your event document the vaccine information in the Nurse's box including event number, event date, injection site, dosage, vaccine manufacturer, vaccine lot number, and your name and title.

COVID-19 vaccine second dose reminders

Second dose reminders will be critical to ensure compliance with vaccine dosing intervals and to achieve optimal vaccine effectiveness. COVID-19 vaccination providers should make every attempt to schedule a person's second dose appointment when they get their first dose, or schedule both appointments when scheduling the first appointment. Ideas to help ensure second doses are given include:

- Complete a COVID-19 vaccination record card (vaccine manufacturer, lot number, date of first dose, and date second dose due) for each person who is vaccinated. Encourage them to keep the card, so they can check to make sure their second dose comes from the same manufacturer as their first dose.

- If the patient has a smartphone, ask them to take a photo of their vaccination card and enter the date when the next vaccine is due into their electronic calendar.
- Suggest they visit cdc.gov/vsafe for more tools and to record any adverse reaction.

Emergency Procedures

We hope that every event runs smoothly, but unfortunately in any medical situation, emergencies are possible and need to be planned for.

An epinephrine injection must always be immediately available at all vaccination events in case an anaphylactic reaction occurs. Epinephrine is in a red tube.

Anaphylactic Reactions and Shock

Anaphylaxis is a serious, potentially life-threatening allergic response that is marked by swelling, hives, lowered blood pressure, and dilated blood vessels. In severe cases, a person will go into shock. If anaphylactic shock isn't treated immediately, it can be fatal.

Anaphylaxis symptoms usually occur within minutes of exposure to an allergen. Sometimes, however, anaphylaxis can occur a half-hour or longer after exposure. Generally, the sooner the symptoms, the more severe the reaction.

Anaphylaxis symptoms may begin subtly and quickly progress to more serious symptoms. They include:

- Skin reactions, including hives along with itching, and flushed or pale skin (almost always present with anaphylaxis)
- A feeling of warmth
- The sensation of a lump in your throat
- Constriction of the airways and a swollen tongue or throat, which can cause wheezing and trouble breathing and/or swallowing
- A weak and rapid pulse
- Nausea, cramps, abdominal pain, vomiting or diarrhea

- Dizziness or fainting

Intervention

It's important to be prepared for this type of emergency and make sure you have epinephrine readily available.

Reactions with delayed onset might give you time to question, observe, prepare and obtain a verbal consent to administer epinephrine. However, reactions can also occur immediately, so you need to be prepared to do the interventions simultaneously.

It's important that epinephrine is protected from light, so keep the epinephrine in the red tube until ready for use. Epinephrine should be stored at a controlled room temperature of 59°F - 86°F (15°C - 30°C). Do not expose epinephrine to extreme temperatures and do not refrigerate epinephrine.

Prior to the event start time, check the color and consistency of the epinephrine solution for particulate matter and discoloration. Do not use it if the solution is colored or cloudy, or if it contains particulate matter. Also, check the vial expiration date. Do not use it if expired.

Each red epinephrine tube contains the following:

- 3 syringes (1mL, 1-inch VanishPoint® safety syringes)
- Alcohol wipes
- 1 single dose vial of Adrenalin - TotalWellness sends single dose vials of Adrenalin (epinephrine injection, USP) 1 mg/mL, 1:1000. Each single dose vials contains 1mL of epinephrine solution
- Administration instructions

Anaphylactic Response Steps

1. Check and maintain airway, breathing and circulation throughout intervention.
2. Designate someone to call 911/EMS and someone to clear the room for privacy.
3. Maintain the individual in a safe position, flat on his or her back. If the individual is having trouble breathing the head may be elevated provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.

4. Shake vial to re-suspend the epinephrine.
5. Carefully remove vial cover to expose rubber top without contaminating it.
6. Wipe rubber top with alcohol and allow to dry.
7. Carefully remove syringe cap without contaminating the needle or inside of cap.
    a. Epinephrine kit is supplied with a 1 mL syringe with an attached 1-inch needle.
8. Draw up the appropriate dose of epinephrine.
    a. Adults 66 pounds or more: 0.3 mL to 0.5 mL, with a maximum single dose of 0.5 mL.
9. Remove any air bubbles from the syringe carefully to avoid losing any of the epinephrine solution.
10. Administer the epinephrine into the anterolateral aspect of the thigh, intramuscularly or subcutaneously, using appropriate administration technique.
    a. Don't administer the injection into the buttocks.
    b. Administer the injection through clothing if necessary.
11. Properly dispose of the needle and syringe in the sharps container.
12. Massage the site to counteract possible vasoconstriction and to enhance absorption.
13. Monitor the individual until EMS arrives. Perform CPR if necessary.
14. If symptoms persist or become worse, you can repeat the epinephrine dose every 5 to 10 minutes up to 3 doses depending on the participant's response. The EMS usually arrives before that is necessary.

    a. You may draw up additional doses from the same single-dose vial as long as all doses drawn up from the vial are administered to the same participant and are only used for this single case/procedure.
    b. Use a new syringe with a new needle for each repeated dose.
    c. Do not administer repeated injections at the same site, as the resulting vasoconstriction may cause tissue necrosis.
    d. Discard the vial at the end of the procedure and do not store for future use.
15. Fill out an Incident Report for our TotalWellness records and call TotalWellness at 888-434-4358 ext. 0 to report the incident. Make note of the

epinephrine lot number on the Incident Report. If applicable, submit a VAERS report.

Vasodepressor Reactions/Vasovagal Syncope and Panic Attacks

Sometimes vasodepressor reactions/vasovagal syncope and panic attacks are confused with anaphylactic reactions. Vasodepressor reactions/vasovagal syncope and panic attacks are physiological responses to stress. That means the person is reacting to the stress of the service provided such as the physical injection, rather than the contents of the vaccine.

Be sure to distinguish between this physiological reaction, and anaphylaxis because the treatment for anaphylaxis - epinephrine - can make the anxiety of a vasodepressor reaction or panic attack worse.

Symptoms of vasodepressor reactions/vasovagal syncope can include:

- Fainting
- Pallor
- Weakness
- Hypotension
- Sweating
- Nausea
- Sometimes vomiting

Vasodepressor reactions/vasovagal syncope are characterized by a slow heartbeat (usually under 60 bpm), but cutaneous symptoms such as swelling, hives, itching and flushing won't be present. The skin usually appears pale, cool and moist. Remember these characteristics when distinguishing between reactions.

Panic attacks might include:

- Anxiety
- Feelings of intense apprehension or terror
- Dizziness
- Sweating
- Shortness of breath
- Chest pain or palpitations

None of the other symptoms of anaphylaxis, such as wheezing or itching, will be present in a panic attack. Keep that in mind when distinguishing between the two.

Intervention

If possible, have the individual lie down on his or her back with his or her feet elevated. Tell the participant to take slow, deep breaths. Have someone stay with him or her to maintain a safe position, provide comfort and place cool paper towels on the individual's forehead.

Complete an Incident Report and return it to TotalWellness.

Exposure Control Plan

TotalWellness is committed to providing a safe and healthy work environment. In pursuit of this endeavor, we have developed an exposure control plan. The plan is available within the TotalWellness Scheduling System under the "Training and Paperwork" link.

The most common on-site exposure to bloodborne pathogens is when a nurse accidentally sticks herself with a used needle. If this happens, follow the steps below.

1. Remain calm.
2. Politely excuse yourself and inform the involved participant and site contact that a needle stick injury has occurred.
    a. Ensure the participant understands that you, the nurse, are the one at risk.
3. Encourage bleeding of the site and clean it thoroughly with soap and water.
4. Fill out an Incident Report and attach it to the involved participant's Consent Form. Send both back to TotalWellness with the rest of the completed Consent Forms.
5. After your event is complete, call TotalWellness at 888-434-4358 ext. 0 to report the incident and receive further instruction.

Vaccine Adverse Event Reporting System (VAERS)

In an effort to assist the CDC and FDA to monitor the safety of all vaccines, any suspected adverse reaction to a COVID-19 shot will need to be reported by the nurse who administered the vaccination to the Vaccine Adverse Event Reporting System (VAERS) at the U.S. Department of Health and Humans Services (DHHS). VAERS reports can be submitted at https://vaers.hhs.gov.

A copy of the VAERS submission confirmation should be sent to TotalWellness along with the incident report and participant's Consent Form.