



**150 YEARS**  
OF ADVANCING  
**PUBLIC**  
**HEALTH**

# Massachusetts Department of Public Health

## **MODERNA COVID-19 VACCINE TRAINING**



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# Recommendations are Rapidly Evolving...



**Always check the websites below  
and other websites provided within this presentation  
for the latest guidance and information.**

- ACIP's COVID-19 vaccine specific recommendations: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>
- Clinical Considerations for COVID-19 Vaccination: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html>
- Interim Clinical Considerations for Use of COVID-19 Vaccine:  
<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html>
- Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites:  
<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>
- COVID-19 Vaccine Product Information: <https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>

# Learning Objectives

At the conclusion of this session, the participant will be able to:

- Define ACIP COVID-19 Vaccine Recommendations
- Explain Vaccine Storage and Handling
- Describe COVID-19 Vaccine Screening
- Explain Provider's Role in Vaccine Administration
- List Recommended Infection Control Measures
- Summarize Principles of COVID-19 Vaccine Preparation
- Identify Vaccine Adverse Reactions
- Describe Vaccine Adverse Event Reporting
- Summarize Recommendations for Vaccinating during the COVID-19 Pandemic

# Outline

- Vaccine Information and Ancillary Kit Supplies
- Vaccine Storage and Handling
- Vaccine Preparation and Administration
  - Standing Orders
  - Screening
  - EUA fact sheets (Recipients and Healthcare Providers)
  - mRNA Dosing & Administration
  - Documenting the Vaccination
- Clinical Considerations
- ACIP COVID-19 Vaccine Recommendations

# Outline

- Contraindications & Precautions
- Managing Adverse Reactions
- Observation Period Following Vaccination
- Vaccine Safety
- Vaccine Adverse Event Reporting (VAERS & V-Safe)
- Vaccinating During the COVID-19 Pandemic
  - Infection Control Measures
  - Personal Protective Equipment (PPE)
  - Clinics held at Satellite, Temporary, or Off-site Locations
- Resources
- MDPH Contact Information



# VACCINE INFORMATION

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# Messenger RNA (mRNA) COVID-19 Vaccines

- mRNA vaccines are being held to the same rigorous safety and effectiveness standards as all other types of vaccines in the United States. The only COVID-19 vaccines the Food and Drug Administration (FDA) will make available for use in the United States (by approval or emergency use authorization) are those that meet these standards. mRNA vaccines do not use the live virus that causes COVID-19. They cannot give someone COVID-19
- mRNA doesn't enter the nucleus of the cell, which is where our genetic material (DNA) is kept. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions
- This means the mRNA vaccines do not affect or interact with our DNA

<https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html>

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits/facts.html>

# Moderna COVID-19 Vaccine

- Shipped in 100-dose increments
  - Comes with Ancillary Supply Kit
- Does Not require reconstitution
- 10-dose multidose vial
- 0.5mL dosage
- Do Not combine residual vaccine from multiple vials to obtain an additional dose
- 2-dose series separated by 1 month (28 days)

Source: CDC Moderna COVID-19 Vaccine Preparation and Administration Summary 12/20/2020



# Standard COVID-19 Vaccine Adult Ancillary Kit Contents

## Standard COVID-19 Vaccine Adult Ancillary Kit Supports administration of 100 doses

Product	Product Description	Quantity
Needles	22 – 25G, 1"	85
Needles	22 – 25G, 1.5"	20
Syringes	1 ml or 3 ml	105
Alcohol pads	Sterile, individual	210
Vaccination record card		100
Needle guide		1
Face shield		2
Face Mask		4
Standard Ancillary Adult Kit Dimensions: 14" x 13" x 9"		Weight: 3.5 lbs

[https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim\\_Playbook.pdf](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf) (pg. 30)

# Not Included in Vaccine Ancillary Supply Kits

- Ancillary supply kits will not include:
  - sharps containers
  - gloves
  - bandages
- Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs

# Preparing for COVID-19 Vaccine Second Doses

- Moderna and Pfizer vaccines require 2 doses:
  - **The 2<sup>nd</sup> dose must be the same product as the first dose**
  - Schedule the 2<sup>nd</sup> dose when administering the first dose
  - Develop a system for recalling vaccinees for 2<sup>nd</sup> dose
    - **Moderna doses: 28 days apart**
    - **Pfizer doses: 21 days apart**
    - Provide 2<sup>nd</sup> dose reminders:
    - Personal vaccination card, email, text or calls
- **Do not plan to hold COVID-19 vaccine from initial shipment for 2<sup>nd</sup> doses**
  - 2<sup>nd</sup> doses are being withheld by the federal government and will be shipped as needed for the 2<sup>nd</sup> dose
  - Upon receipt of future shipments, identify which will be needed for 2<sup>nd</sup> doses

# STORAGE & HANDLING

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# Moderna COVID-19 Vaccine

## Storage and Handling Summary



### » Basics

- Store vaccine in a freezer or refrigerator. See guidance below for each storage unit.
- Each box contains 10 multidose vials (100 doses).
- Use vaccine vials stored in the refrigerator before removing vials from frozen storage.
- This vaccine does not need to be mixed with a diluent before administration.
- Check and record storage unit temperature each workday. See guidance below for each type of temperature monitoring device. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

### » Deliveries

#### Vaccine

1. The vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F).
2. Examine the shipment for signs of damage.
3. Open the box and remove TagAlert Temperature Monitor from box (placed in the inner box next to vaccine).
4. Check the TagAlert temperature monitoring device by pressing the blue "start and stop" button.
  - Left arrow points to a **green checkmark**: The vaccine is ready to use. Store the vaccine at proper temperatures immediately.
  - Right arrow points to a **red X**: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label **DO NOT USE!** Call the phone number indicated in the instructions or your jurisdiction's immunization program **IMMEDIATELY!**



<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>

# Moderna COVID-19 Vaccine

## Thawing Frozen Vaccine

- Vaccine may be thawed in the refrigerator or at room temperature.
- Do Not refreeze thawed vaccine.
- Once a vial of vaccine has been thawed, it may be stored refrigerated at 2-8°C for up to 30 days.
- When thawed, the vaccine should be handled with care and protected from shocks, drops, vibration, etc.
- Vaccine being transported at temperatures others than frozen (-15 to -25°C) should begin with the vaccine in the frozen state if at all possible.

Source: CDC Moderna COVID-19 Vaccine Preparation and Administration Summary 12/20/2020

# Moderna COVID-19 Vaccine Storage & Handling

## Frozen Storage

Can be stored frozen until expiration date\*

-25° to -15°C (-13° to 5°F)

Do not store on dry ice or below -40°C (-40°F).  
Store in the original carton to protect from light.

\*Confirm vaccine expiration date by looking up the lot number at [modernatx.com/covid19vaccine-eua](https://www.modernatx.com/covid19vaccine-eua)



## Thaw Each Vial Before Use

Vial images for illustrative purposes only

2 hours and 30 minutes in refrigerator

2° to 8°C  
(36° to 46°F)



OR

1 hour at room temperature

15° to 25°C  
(59° to 77°F)



Let vial sit at room temperature for 15 minutes before administering

## Thawed Shelf Life

Unpunctured Vial

Maximum times

30  
days

Refrigerator

2° to 8°C (36° to 46°F)

12  
hours

Cool storage up to  
room temperature

8° to 25°C (46° to 77°F)



After First Dose Has Been Withdrawn

Maximum time

6  
hours

Refrigerator or  
room temperature

Vial should be held between  
2° to 25°C (36° to 77°F). Record the date  
and time of first use on the vial label.

Discard punctured vial after 6 hours.



**NEVER** refreeze thawed vaccine

<https://www.modernatx.com/covid19vaccine-eua/providers/>

# Moderna COVID-19 Vaccine

**If you must transport vaccine that has already been thawed, follow these general principles:**

- Punctured vials should not be transported.
- Care must be taken to ensure vaccine does not re-freeze during transport.
- Vaccine must be protected as much as possible from drops, shocks, and vibration whether in the carton, vial, case or cooler.
- Vaccine should be transported in the carton whenever possible.
- If transport must be conducted at the vial level, the vial should be placed with dunnage (padding material like bubble wrap or similar padding) to minimize movement during transport.
- The vaccine should always be transported in insulated containers qualified to maintain 2-8°C for the duration of transport.
- The transport containers must be secured when being transported to prevent unnecessary movement.
- After completion of transport, vaccine should immediately be placed into a vaccine storage unit at 2-8°C.
- **Vaccine should only be transported one time and should not be transported back again to the point of origin or to a new location.**

Source: CDC Moderna COVID-19 Vaccine Preparation and Administration Summary 12/20/2020



# Moderna COVID-19 Vaccine Storage

- Store vials in a refrigerator 2°C to 8°C (36°F to 46°F) for up to 30 days.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Use vaccine within 6 hours after vial is first punctured.
  - ❖ Keep this in mind when you plan and run your clinics to avoid wastage
- Vials that have not been punctured may be kept between 8°C and 25°C (46°F and 77°F) for up to 12 hours
- Do Not refreeze.

<https://www.modernatx.com/covid19vaccine-eua/>

# Expiration Dates for COVID-19 vaccines

Vaccine expiration dates should be checked prior to preparing or administering vaccine. NEVER use expired vaccine or diluent. As additional stability data become available, the expiration dates for some products may change.

CDC has set up an expiration date of 12/31/2069 to serve as a placeholder date in VTrckS for **EUA COVID-19 vaccines that do not have a final expiration date.**

- Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available.
- The placeholder date should serve as a prompt for the provider to check the latest expiry information on the manufacturer's website.

**Moderna COVID-19 vaccine:** Determine expiration dates by scanning the QR code located on the vial or carton or access the manufacturer's [website](#). On the website, once you enter the lot number, the expiration date will be displayed.

**Pfizer COVID-19 vaccine:** Expiration date is located on the vaccine vial. CDC will be updating VTrckS effective immediately to replace the placeholder date in VTrckS with the actual expiration date.

<https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>



# PREPARATION & ADMINISTRATION

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# COVID-19 Vaccine Eligibility Considerations

- Decisions about which eligible patients receive the COVID Vaccine should be based on the clinical judgement of hospitals and providers, consistent with the terms of the EUAs and with this guidance.
- Provider criteria for the COVID Vaccine use should be as clear, transparent, and objective as possible, and be based on biological factors related only to the likelihood and magnitude of benefit from the medical resources and should at all times minimize inequitable outcomes.
- Factors that have no bearing on the likelihood or magnitude of benefit, include but are not limited to, race, disability, gender, sexual orientation, gender identity, ethnicity, ability to pay or insurance status, socioeconomic status, English language proficiency, perceived social worth, perceived quality of life, immigration status, incarceration status, homelessness or past or future use of resources.

# Vaccination/Immunization Standing Orders

- Standing orders for vaccination facilitate the delivery of immunization services to patients
- Standing orders for COVID-19 vaccines are available at:
  - Moderna: <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf>
  - Pfizer-BioNTech: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf>
- Standing orders for many routine vaccines and Emergency Treatment are available from IAC: <https://www.immunize.org/standing-orders/>
  - Medical Management of Vaccine Reactions of Adults in a Community Setting: <https://www.immunize.org/catg.d/p3082.pdf>
  - Medical Management of Vaccine Reactions in Children and Teens in a Community Setting: <https://www.immunize.org/catg.d/p3082a.pdf>

## Useful CDC Guidance Links

- Clinical Considerations for COVID-19 Vaccination: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html>
- ACIP's COVID-19 vaccine specific recommendations: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>
- CDC's COVID Vaccination Training and Education: [https://www.cdc.gov/vaccines/covid-19/index.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Fvaccination-resources.html](https://www.cdc.gov/vaccines/covid-19/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Fvaccination-resources.html)

# Moderna COVID-19 Vaccine Standing Orders

## Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine  
to Persons 18 Years of Age and Older



**Note:** For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

### » Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

### » Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

### » Procedure

Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

- No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, a second dose of the same brand should be administered.
  - This vaccine is administered in a 2-dose series. Separate

#### ○ Contraindication

- » Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine for both Pfizer-BioNTech and Moderna COVID-19 vaccines. For a list of vaccine components, see the Emergency Use Authorization (EUA).

#### ○ Precautions

- » Severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous)
- » Moderate to severe illness

# Medical Management of Vaccine Reactions in Adults Standing Orders

## Medical Management of Vaccine Reactions in Adults in a Community Setting

*The table below describes steps to take if an adverse reaction occurs following vaccination.*

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see “Screening Checklist for Contraindications to Vaccines for Adults” at [www.immunize.org/catg.d/p4065.pdf](http://www.immunize.org/catg.d/p4065.pdf)). When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient’s heart.


<https://www.immunize.org/catg.d/p3082.pdf>



# Screening

- Is key to preventing serious adverse reactions
- Specific questions intended to identify contraindications or precautions to vaccination
- Screening must occur at every immunization encounter (not just before the first dose)

<https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf>




## Pre-Vaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals

### Clinical Consideration Questions

Responses to these questions are not (on their own) contraindications or precautions to vaccination. However, healthcare professionals should be prepared to discuss information and options with patients based on their responses to the following questions.



## Pre-Vaccination Checklist for COVID-19 Vaccines

For vaccine recipients:  
The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

Patient Name \_\_\_\_\_

Age \_\_\_\_\_

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
• If yes, which vaccine product? <input type="checkbox"/> Pfizer <input type="checkbox"/> Moderna <input type="checkbox"/> Another product _____			
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen*, or for which you had to go to the hospital?			
• Was the severe allergic reaction after receiving a COVID-19 vaccine?			
• Was the severe allergic reaction after receiving another vaccine or another injectable medication?			
4. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
5. Have you received another vaccine in the last 14 days?			
6. Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
7. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
8. Do you have a bleeding disorder or are you taking a blood thinner?			
9. Are you pregnant or breastfeeding?			

Form reviewed by \_\_\_\_\_ Date \_\_\_\_\_

12/21/20 CS321020-E Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists 1

of 14 days before or after administration with other cacy of mRNA COVID-19 vaccines administered

er told you that you had COVID-19? itic or asymptomatic SARS-CoV-2 infection. red until the person has recovered from the acute continue isolation.

may delay vaccination until near the end of this uring this time.

s for prior infection solely for the purposes of

ing such as HIV infection or cancer or

re immunosuppressive medications or therapies e administered to persons with underlying medical e counseled about the unknown vaccine safety ential for reduced immune responses and the need 9, including wearing a mask, social distancing, and

hinner? patient's bleeding risk determines that the mends the following technique for intramuscular auge needle (23-gauge or smaller caliber) should g, for at least 2 minutes.

9 vaccine (e.g., healthcare personnel), they may ision, pregnant people and their healthcare tient's personal risk of contracting COVID-19, the e vaccine, the side effects of the vaccine, and the

accine (e.g., healthcare personnel) may choose to eople or the effects of mRNA COVID-19 vaccines



# EUA Fact Sheet for Recipients

Each vaccine-specific EUA Fact Sheet for Recipients will provide the following information:

- Basic information on COVID-19, symptoms, and what to discuss with a healthcare provider before vaccination
- Who should and should not receive the vaccine
- That recipients have the choice to receive the vaccine
- Dosage and vaccine series information
- Risks and benefits of the vaccine, including common side effects
- Information on reporting side effects to VAERS
- An explanation of what an EUA is and why it is issued
- Any approved available alternatives for preventing COVID-19
- Additional resources

**Moderna EUA fact sheet:**  
<https://www.modernatx.com/covid19vaccine-eua/providers/>

<https://www2.cdc.gov/vaccines/ed/covid19/SHVA/10080.asp>

# EUA Fact Sheet for Healthcare Providers

Each vaccine-specific EUA Fact Sheet for Healthcare Providers will provide the following information:

- COVID-19 disease description
- Dosage and administration information
- Storage and handling instructions
- Dose preparation and administration information
- Requirements for use of vaccine under EUA
- Risks and benefits, including common adverse events (AEs)
- Any approved available alternatives for preventing COVID-19
- Reporting requirements, including reporting AEs to VAERS
- Additional resources

<https://www2.cdc.gov/vaccines/ed/covid19/SHVA/10070.asp>

**Moderna EUA fact sheet:**  
<https://www.modernatx.com/covid19vaccine-eua/providers/>

# Dosing and Administration

## Moderna COVID-19 Vaccine

### Dosing & Administration








#### Dosing and Schedule









<https://www.modernatx.com/covid19vaccine-eua/providers/>

# Moderna COVID-19 Vaccine Prep & Administration

## » Prepare and Administer the Vaccine

Assess recipient status: ○ Screen for contraindications and precautions. ○ Review vaccination history.	
Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*	
<b>Unpunctured vials:</b> Check the expiration date. Never use expired vaccine. <b>Punctured vials:</b> Check the beyond-use time. Never use vaccine after the beyond-use time.	
With the vial upright, gently swirl the vaccine. <b>Do NOT shake.</b> If the vial is shaken, contact the manufacturer. Note: Gently swirl the vaccine before withdrawing subsequent doses.	
Examine the vaccine. It should be white to off-white in color and may contain white particles. Do not use if liquid contains other particulate matter or is discolored.	
Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.	
Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.	

Withdraw 0.5 mL of vaccine into the syringe.† Ensure the prepared syringe is not cold to the touch.	
Note the date and time the vial was first punctured. <b>Keep the vaccine between 2°C and 25°C (36°F and 77°F) for up to 6 hours.</b> <b>Discard any unused vaccine after 6 hours.</b>	
Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.	
Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients older than 2 years of age (if tolerated).	
Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.	
Observe recipients after vaccination for an immediate adverse reaction: ○ Persons with a history of anaphylaxis (due to any cause): 30 minutes ○ All other persons: 15 minutes	

# Dosing and Administration

- Authorized age groups:
  - Pfizer-BioNTech:  $\geq 16$  years
  - Moderna:  $\geq 18$  years
- Administration: two-dose series administered intramuscularly
  - Pfizer-BioNTech: 21 days apart
  - Moderna: 28 days apart
- mRNA vaccines are not interchangeable with each other or other COVID-19 vaccines
  - Either vaccine series may be used; ACIP does not state a product preference
- mRNA vaccines should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines

# mRNA Vaccine Administration

- 2-dose series administered intramuscularly
  - Pfizer-BioNTech: 21 days apart
  - Moderna: 28 days apart
- Administration of 2<sup>nd</sup> dose within 4-day grace period considered valid  
(However, doses administered earlier do not need to be repeated)
- If greater than the recommended interval since 1<sup>st</sup> dose, 2<sup>nd</sup> dose should be administered at earliest opportunity  
(However, no doses need to be repeated)
- Both doses are necessary for protection; efficacy of a single dose has not been systematically evaluated

# Document the Vaccination

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system for the jurisdiction (i.e., immunization information system - - MIIS) as soon as practicable and no later than 72 hours after administration.

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>

# CLINICAL CONSIDERATIONS

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*Check for latest guidance on the CDC website*



## COVID-19 Vaccination

Product Info by US Vaccine +

Clinical Considerations -

mRNA COVID-19 Vaccines

Managing Anaphylaxis

Lab Tests After Severe Allergic Reaction

Provider Requirements and Support

Training and Education

Recipient Education +

Planning & Partnerships +

Vaccination Toolkits +

COVID-19 Vaccination Reporting Data Systems

# Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States



[Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites](#)

## Summary of recent changes (last updated December 30, 2020):

- Additional information on antibody therapies and COVID-19 vaccination
- Information on COVID-19 vaccination and outbreak management
- Additional information on vaccination of immunocompromised persons
- Updates to contraindications and precautions to vaccination
- Information on COVID-19 vaccination and tuberculin skin testing

## Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of [Pfizer-BioNTech](#) and [Moderna](#) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. Both vaccines are lipid nanoparticle-formulated, nucleoside-modified

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[Vaccination of persons with a SARS-CoV-2 infection or exposure](#)

[Vaccination of persons with](#)

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

# mRNA COVID-19 Vaccines

- Two mRNA COVID-19 vaccines authorized under Emergency Use:
  - Pfizer-BioNTech
  - Moderna
- Both products demonstrate high vaccine efficacy
  - Across age groups, racial/ethnic groups, persons with underlying conditions
- Acceptable safety profile of both vaccines
  - Local and systemic reactogenicity, particularly after second dose

# Interim Recommendations for Use Moderna COVID-19 Vaccine in the U.S.

- On December 18, 2020, the Food and Drug Administration issued an Emergency Use Authorization for the Moderna COVID-19 vaccine.
- On December 19, 2020, after an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Moderna COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19:  
[https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s\\_cid=mm695152e1\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1_w)

The screenshot shows the CDC website with the title "Morbidity and Mortality Weekly Report (MMWR)". The article title is "The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020". It is labeled as an "Early Release" from December 20, 2020. The authors listed are Sara E. Oliver, MD; Julia W. Gargano, PhD; Mona Marin, MD; Megan Wallace, DrPH; Kathryn G. Curran, PhD; Mary Chamberland, MD; Nancy McClung, PhD; Doug Campos-Outcalt, MD; Rebecca L. Morgan, PhD; Sarah Mbaeyi, MD; José R. Romero, MD; H. Keipp Talbot, MD; Grace M. Lee, MD; Beth P. Bell, MD; Kathleen Dooling, MD. There is a link to "View author affiliations" and another to "View suggested citation". The "Summary" section is divided into three parts: "What is already known about this topic?" (On December 18, 2020, the Food and Drug Administration issued an Emergency Use Authorization (EUA) for the Moderna COVID-19 vaccine.), "What is added by this report?" (On December 19, 2020, after a transparent, evidence-based review of available data, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Moderna COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19.), and "What are the implications for public health practice?" (Use of all COVID-19 vaccines authorized under an EUA, including the Moderna COVID-19 vaccine, should be implemented in conjunction with ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines.). On the right side, there is an "Article Metrics" section with "Altmetric:", "Citations:", and "Views:" (Views equals page views plus PDF downloads) with a "Metric Details" button. Below that is an "On This Page" section with a link to "Reporting of Vaccine Adverse Events".

# COVID-19 Vaccine ACIP Recommendations

It is important that providers follow the Advisory Committee on Immunization Practices (ACIP) recommendations regarding COVID-19 vaccination.

- Their latest COVID-19 recommendations can be found at:  
<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>
- Clinical considerations link: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html>

## ACIP Recommendations



More

# Post-vaccination symptoms in Health Care Personnel (HCP)

- Based on available data, COVID-19 vaccination is expected to elicit systemic post-vaccination symptoms, such as fever, headache, and myalgias.
- Strategies are needed to mitigate possible HCP absenteeism and resulting personnel shortages due to the occurrence of these symptoms.
- Considerations might include:
  - Staggering delivery of vaccine to HCP in the facility so that personnel from a single department or unit are not all vaccinated at the same time. Based on greater reactogenicity observed following the second vaccine dose in phase I/II clinical trials, staggering considerations may be more important following the second dose.
  - Planning for personnel to have time away from work if they develop systemic symptoms following COVID-19 vaccination.
- Health care personnel who develop any symptoms consistent with COVID-19 after vaccination should remain out of work and receive a test for SARS-CoV-2 as soon as possible.
  - Health care personnel with certain minimal symptoms (e.g., low grade fever, headache) and without respiratory symptoms may be allowed to work.
  - See [MDPH memo December 16, 2020](#) for specific details

<https://www.mass.gov/info-details/covid-19-public-health-guidance-and-directives#health-care-organizations->

# Pregnant women

- COVID-19 and pregnancy
  - Increased risk of severe illness (ICU admission, mechanical ventilation and death)
  - Might be an increased risk of adverse pregnancy outcomes, such as preterm birth
- There are few data on the safety of COVID-19 vaccines in pregnant Women
  - Limited animal developmental and reproductive toxicity (DART) data
  - Studies in humans are ongoing and more planned
- mRNA vaccines are not live vaccines
- If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated.

# Pregnant women

- Considerations for vaccination:
  - level of COVID-19 community transmission, (risk of acquisition)
  - her personal risk of contracting COVID-19, (by occupation or other activities)
  - the risks of COVID-19 to her and potential risks to the fetus
  - the efficacy of the vaccine
  - the known side effects of the vaccine
  - the lack of data about the vaccine during pregnancy

# Breastfeeding/Lactating

- There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA vaccines on the breastfed infant or milk production/excretion
- mRNA vaccines are not thought to be a risk to the breastfeeding infant
- A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated



# Persons with a history of SARS-CoV-2 infection

- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
  - Data from clinical trials suggest vaccination safe in these persons
- Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making

# Persons with known current SARS-CoV-2 infection

- Vaccination should be deferred until recovery from the acute illness (if person had symptoms) and criteria have been met to discontinue isolation (usually 10 days after onset of symptoms or positive test)
- No minimal interval between infection and vaccination
- However, current evidence suggests reinfection uncommon in the 90 days after initial infection, and thus persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired

# Persons who previously received passive antibody therapy

- Currently there is no data on safety or efficacy of mRNA COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment
  - Vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid interference of the treatment with vaccine-induced immune responses
    - Based on estimated half-life of therapies and evidence suggesting reinfection is uncommon within 90 days of initial infection
- For persons receiving antibody therapies not specific to COVID-19 treatment (e.g., IVIG, RhoGAM) there is no recommended minimum interval between other antibody therapies (i.e., those that are not specific to COVID-19 treatment) and mRNA COVID-19 vaccination.

# Persons with a known SARS-CoV-2 exposure

- **Community or outpatient setting:**
  - Should not seek vaccination until their quarantine period has ended to avoid exposing healthcare personnel (HCP) or other persons to SARS-CoV-2 during the vaccination visit
- **Person residing in congregate healthcare settings (e.g., long-term care facilities):**
  - May be vaccinated
  - Healthcare personnel are already in close contact with residents and should employ appropriate infection prevention and control procedures
- **Residents of other congregate settings (e.g., correctional facilities, homeless shelters)**
  - May be vaccinated, in order to avoid delays and missed opportunities for vaccination
  - Where feasible, precautions should be taken to limit mixing exposed individuals with other residents or staff (except those essential for the provision of vaccination services, who should employ appropriate infection and control procedures)

# Persons with underlying medical conditions

- mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination.
- Clinical trials demonstrate similar safety and efficacy profiles in persons with some underlying medical conditions, including those that place them at increase risk for severe COVID-19, compared to persons without comorbidities.

# Immunocompromised persons

- Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19
- Data not currently available to establish safety and efficacy of vaccine in these groups
- These individuals may still receive COVID-19 vaccine if they have no contraindications to vaccination.
- Individuals should be counseled about:
  - Unknown vaccine safety profile and effectiveness in immunocompromised populations
  - Potential for reduced immune responses
  - Need to continue to follow all current guidance to protect themselves against COVID-19

# SARS-CoV-2 tests

- **Viral tests:** Prior receipt of an mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests
- **Antibody tests:**
  - Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to spike or nucleocapsid proteins
  - Both Pfizer-BioNTech and Moderna COVID-19 vaccine contains mRNA that encodes the spike protein; thus, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination
  - To evaluate for evidence of prior infection in an individual with a history of mRNA COVID-19 vaccination, a [test](#) specifically evaluating IgM/IgG to the nucleocapsid protein should be used
  - Antibody testing is not currently recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person

# Interchangeability with other COVID-19 vaccine products

- mRNA COVID-19 vaccines are not interchangeable with each other or with other COVID-19 products
  - Safety and efficacy of a mixed series has not been evaluated
- Persons initiating series with one mRNA COVID-19 vaccine should complete series with same product
- If two doses of different mRNA COVID-19 vaccine products inadvertently administered, no additional doses of either vaccine recommended at this time
  - Recommendations may be updated as further information becomes available or additional vaccine types authorized



# Coadministration with other vaccines

- mRNA COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines
  - Due to lack of data on safety and efficacy of the vaccine administered simultaneously with other vaccines
- If mRNA COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine

# Reactogenicity

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms
  - Depending on vaccine product, age group, and vaccine dose, approximately 80–89% of vaccinated persons develop at least one local symptom and 55-83% develop at least one systemic symptom following vaccination.
    - Most are mild-moderate, occur within 3 days, and resolve within 1-2 days
    - More frequent and severe following dose 2 and among younger age groups
- Unless a person develops a contraindication to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms in order to optimize protection against COVID-19
- Antipyretic or analgesic medications may be taken for treatment of post- vaccination symptoms
  - Routine prophylaxis for the purposes of preventing symptoms is not recommended at this time, due to lack of information on impact of use on vaccine-induced antibody responses

# What to Expect after Getting a COVID-19 Vaccine

Accessible version: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects **may feel like flu** and **may even affect your ability** to do daily activities, but they should go away in a few days.

## Common side effects

### On the arm where you got the shot:

- Pain
- Swelling

### Throughout the rest of your body:

- Fever
- Tiredness
- Chills
- Headache

## Helpful tips

If you have pain or discomfort, talk to your doctor about taking an over-the-counter medicine, such as ibuprofen or acetaminophen.

### To reduce pain and discomfort where you got the shot:

- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.

### To reduce discomfort from fever:

- Drink plenty of fluids.
- Dress lightly.

## When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:

- If the redness or tenderness where you got the shot increases after 24 hours
- If your side effects are worrying you or do not seem to be going away after a few days

## Remember

- Side effects may feel like flu and even affect your ability to do daily activities, but they should go away in a few days.
- With most COVID-19 vaccines, you will need 2 shots in order for them to work. Get the second shot even if you have side effects after the first one, unless a vaccination provider or your doctor tells you not to get a second shot.
- It takes time for your body to build protection after any vaccination. COVID-19 vaccines that require 2 shots may not protect you until a week or two after your second shot.
- It's important for everyone to continue using all the tools available to help stop this pandemic as we learn more about how COVID-19 vaccines work in real-world conditions. Cover your mouth and nose with a mask when around others, stay at least 6 feet away from others, avoid crowds, and wash your hands often.

### HEALTHCARE PROVIDER, PLEASE FILL IN THE INFORMATION BELOW:

If your temperature is \_\_\_\_°F or \_\_\_\_°C or higher or if you have questions, call your healthcare provider.

Tell your healthcare provider about: \_\_\_\_\_

**Healthcare provider phone number:** \_\_\_\_\_

### Medication (if needed):

Take \_\_\_\_\_ every \_\_\_\_\_ hours as needed.

(Type and dose or amount)



**Ask your healthcare provider about getting started with v-safe**

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second dose.

Learn more about v-safe.  
[www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

CS 527888-8 12/13/2020

[https://www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/321466-A\\_FS\\_What\\_Expect\\_COVID-19\\_Vax\\_Final\\_12.13.20.pdf](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/321466-A_FS_What_Expect_COVID-19_Vax_Final_12.13.20.pdf)

# Public health recommendations for vaccinated persons

- Protection from vaccine is not immediate; vaccine is a 2-dose series and will take 1 to 2 weeks following the second dose to be considered fully vaccinated
- No vaccine is 100% effective
- Given the currently limited information on how well the vaccine works in the general population; how much it may reduce disease, severity, or transmission; and how long protection lasts, vaccinated persons should continue to follow all [current guidance](#) to protect themselves and others, including:
  - Wearing a mask
  - Staying at least 6 feet away from others
  - Avoiding crowds
  - Washing hands often
  - Following [CDC travel guidance](#)
  - Following quarantine guidance after an exposure to someone with COVID-19
  - Following any applicable workplace or school guidance

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>



# CONTRAINDICATIONS & PRECAUTIONS

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# Updated contraindications and precautions to vaccination

- Recommendations apply to both Pfizer-BioNTech and Moderna COVID-19 vaccines
- Guidance may change as further information becomes available
- Definition of immediate allergic reaction to vaccine or medication:
  - Any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration

## Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States



[Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites](#)

Summary of recent changes (last updated December 30, 2020):

- Additional information on antibody therapies and COVID-19 vaccination
- Information on COVID-19 vaccination and outbreak management
- Additional information on vaccination of immunocompromised persons
- Updates to contraindications and precautions to vaccination
- Information on COVID-19 vaccination and tuberculin skin testing

### Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of [Pfizer-BioNTech](#) and [Moderna](#) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. Both vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the

#### On This Page

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[Vaccination of persons with](#)

# Contraindications to mRNA COVID-19 vaccination

Pfizer-BioNTech and Moderna COVID-19 vaccines

- Contraindications to either of the mRNA COVID-19 vaccines:
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or to 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)\*
- Persons with an immediate allergic reaction to the first dose of an mRNA vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines

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

# Ingredients\* included in mRNA COVID-19 vaccines

Description	Pfizer-BioNTech	Moderna
mRNA	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	cholesterol	cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	potassium chloride	Tromethamine
	monobasic potassium phosphate	Tromethamine hydrochloride
	sodium chloride	Acetic acid
	dibasic sodium phosphate dihydrate	Sodium acetate
	sucrose	sucrose

\*As reported in the prescribing information



# Polyethylene glycol (PEG)

- Primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures
- Inactive ingredient or excipient in medications
- Used in a process called pegylation to improve therapeutic activity of some medications
- Cross-reactive hypersensitivity between PEG and polysorbates can occur
  - Polysorbates are included as an excipient in some vaccines and other therapeutic agents

Information on whether a medication contains PEG, a PEG derivative, or polysorbates can be found in the package insert. The NIH [DailyMed database](#) may also be used as a resource. Medications that contain PEG and/or polysorbate are described in the supplemental materials of Stone CA, et al. "Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533-1540.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf>

# Distinguishing allergic reactions from other types of reactions

CDC COCA Call, 12/30/2020, COVID-19 Vaccines: Update on Allergic Reactions, Contraindications, and Precautions: Tom Shimabukuro, MD, MPH, MBA and Sarah Mbaeyi, MD, MPH

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
<b>Timing after vaccination</b>	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
<b>Signs and symptoms</b>			
<b>Constitutional</b>	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
<b>Cutaneous</b>	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site; lymphadenopathy in same arm as vaccination
<b>Neurologic</b>	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
<b>Respiratory</b>	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A
<b>Cardiovascular</b>	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A
<b>Gastrointestinal</b>	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
<b>Musculoskeletal</b>	N/A	N/A	Myalgia, arthralgia
<b>Vaccine recommendations</b>			
<b>Receive 2<sup>nd</sup> dose of mRNA COVID-19</b>	No	Yes	Yes

# Precautions to mRNA COVID-19 vaccines

Pfizer-BioNTech and Moderna COVID-19 vaccines

- 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)
- Unknown risks of developing a severe allergic reaction should be balanced against the benefits of vaccination
- Deferral of vaccination and/or consultation with an allergist-immunologist may be considered

# Considerations for risk assessment for mRNA COVID-19 vaccination in persons with a precaution to vaccination

- Risk of exposure to SARS-CoV-2
  - e.g., residence in a congregate setting such as a long-term care facility, occupation
- Risk of severe disease or death due to COVID-19
  - e.g., age, underlying medical conditions
- Previous infection with SARS-CoV-2
  - Vaccination is recommended for persons with a history of COVID-19; persons with a precaution to vaccination and recent COVID-19 may choose to defer vaccination until further information is available
- The unknown risk of anaphylaxis following mRNA COVID-19 vaccination persons 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

# Neither contraindications nor precautions to vaccination

Pfizer-BioNTech and Moderna COVID-19 vaccines

- History of allergic reactions not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines, or polysorbates, including:
  - Food
  - Pet dander
  - Venom
  - Environment
  - Oral medications
  - Latex
  - Eggs
  - Gelatin

# Summary: Triage of persons presenting for mRNA COVID-19 vaccination

MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
<p><b>ALLERGIES</b></p> <p>History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, or injectable therapies, such as:</p> <ul style="list-style-type: none"><li>• Allergy to oral medications (including the oral equivalent of an injectable medication)</li><li>• History of food, pet, insect, venom, environmental, latex, etc., allergies</li><li>• Family history of allergies</li></ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"><li>• 30 minute observation period: Persons with a history of anaphylaxis (due to any cause)</li><li>• 15 minute observation period: All other persons</li></ul>	<p><b>ALLERGIES</b></p> <ul style="list-style-type: none"><li>• History of any immediate allergic reaction‡ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccine† or polysorbate, as these are contraindicated)</li></ul> <p><b>ACTIONS:</b></p> <ul style="list-style-type: none"><li>• Risk assessment</li><li>• Consider deferral of vaccination and/or referral to allergist-immunologist</li><li>• 30 minute observation period if vaccinated</li></ul>	<p><b>ALLERGIES</b></p> <p>History of the following are contraindications to receiving either of the mRNA COVID-19 vaccine†:</p> <ul style="list-style-type: none"><li>• Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components</li><li>• Immediate allergic reaction‡ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components^ (including polyethylene glycol)^</li><li>• Immediate allergic reaction of any severity to polysorbate^#</li></ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"><li>• Do not vaccinate#</li><li>• Consider referral to allergist-immunologist</li></ul>

† Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

‡ 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.

^ See Appendix A for a list of ingredients. Note: Polyethylene glycol (PEG), an ingredient in both mRNA COVID-19 vaccines, is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur. Information on ingredients of a vaccine or medication (including PEG, a PEG derivative, or polysorbates) can be found in the package insert.

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

# Interim considerations: preparing for the potential management of anaphylaxis at COVID-19 vaccination sites

- Information for sites on:
  - Early recognition of anaphylaxis
  - Medications and supplies
  - Management of anaphylaxis at the vaccination site
  - Recommendation for immediate activation of emergency medical services and transportation to higher level medical care
  - Patient counseling
  - Reporting of anaphylaxis

The screenshot shows the CDC's 'Vaccines & Immunizations' section. The main heading is 'Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites'. The page includes a sidebar with navigation links such as 'Home', 'For Parents', 'For Adults', 'For Pregnant Women', 'For Healthcare Professionals', 'COVID-19 Vaccination', 'For Immunization Managers', 'For Specific Groups of People', 'Basics and Common Questions', 'Vaccines and Preventable Diseases', and 'News and Media Resources'. The main content area explains that anaphylaxis is a severe allergic reaction and provides information on preparing for its management. A yellow warning box states: 'Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 vaccine.' Below this, the 'Observation period following COVID-19 vaccination' section notes that CDC recommends observation for 30 minutes for those with a history of anaphylaxis and 15 minutes for all other persons. The 'Early recognition of anaphylaxis' section lists symptoms like throat closing, shortness of breath, wheezing, cough, nausea, vomiting, diarrhea, abdominal pain, dizziness, fainting, tachycardia, hypotension, and generalized hives or swelling.

CDC COCA Call, 12/18/2020, COVID-19 What Clinicians Need to Know About the Pfizer-BioNTech and Moderna COVID-19 Vaccines  
<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>

# Recommended medications and supplies for the management of anaphylaxis at COVID-19 vaccination sites

Should be available at all sites	Include at sites where feasible
Epinephrine prefilled syringe or autoinjector*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine)†	Oxygen
Blood pressure cuff	Bronchodilator (e.g., albuterol)
Stethoscope	H2 antihistamine (e.g., famotidine, cimetidine)
Timing device to assess pulse	Intravenous fluids
	Intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)

\*COVID-19 vaccination sites should have at least 5 doses of epinephrine on hand at any given time.

†Antihistamines may be given as adjunctive treatment and should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to persons with impending airway obstruction.



# Managing Acute Vaccine Reactions

- Severe reactions are rare
- Screening can help prevent reactions
- Staff should be familiar with signs and symptoms of hypersensitivity/anaphylaxis
- There must be a clinic emergency plan for dealing with reactions and you need to ensure that all staff are familiar with that plan.
- Have Emergency Treatment Standing Orders signed before the clinic
- Staff must have had appropriate training and equipment to manage reactions
- All vaccination providers should be currently certified in CPR

<https://www.immunize.org/catg.d/p3082a.pdf>  
<https://www.immunize.org/catg.d/p3082.pdf>  
<https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html>  
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html>

## Medical Management of Vaccine Reactions in Children and Teens in a Community Setting

*The table below describes steps to take if an adverse reaction occurs following vaccination.*

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see "Screening Checklist for Contraindications to Vaccines for Children and Teens" at [www.immunize.org/catg.d/p4060.pdf](http://www.immunize.org/catg.d/p4060.pdf)). When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the	Apply a cold compress to the injection site.

## Medical Management of Vaccine Reactions in Adults in a Community Setting

*The table below describes steps to take if an adverse reaction occurs following vaccination.*

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see "Screening Checklist for Contraindications to Vaccines for Adults" at [www.immunize.org/catg.d/p4065.pdf](http://www.immunize.org/catg.d/p4065.pdf)). When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over

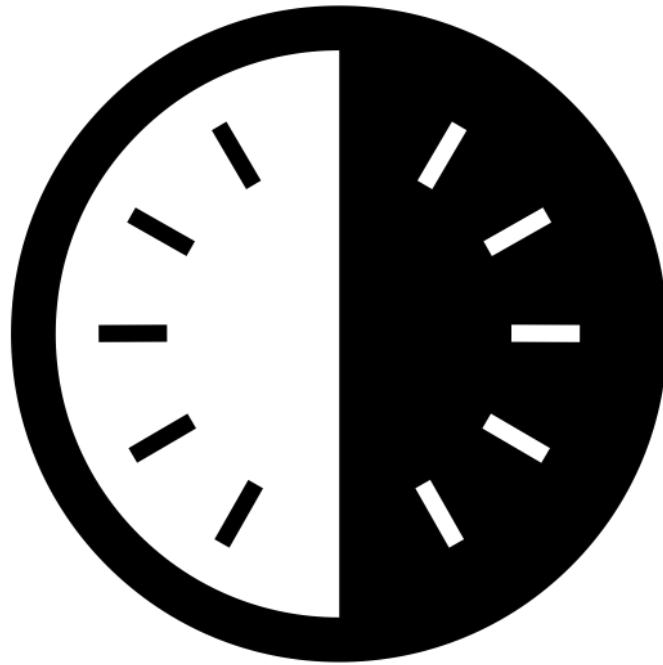
## Emergency medical protocol for management of anaphylactic reactions in adults in a community setting

- 1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.
- 3 **DRUG DOSING INFORMATION:** The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
  - a First-line treatment: EPINEPHRINE is the first-line treatment for anaphylaxis, and there is no known equivalent substitute. Use epinephrine in a 1.0 mg/mL

# Observation Period Following Vaccination

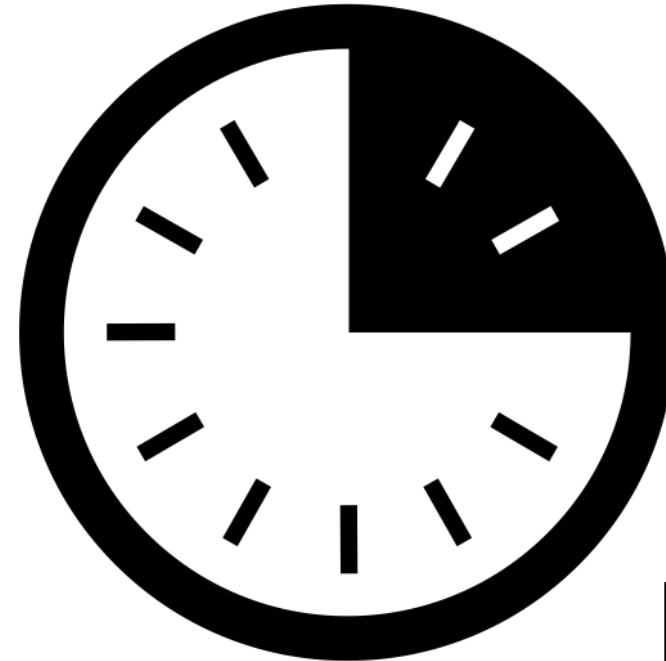
- Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:

**Persons with a precaution to  
vaccination or a history of anaphylaxis  
(due to any cause)**



**30 minutes**

**All other persons**



**15 minutes**

CDC COCA Call, 12/30/2020, COVID-19  
Vaccines: Update on Allergic Reactions,  
Contraindications, and Precautions: Tom  
Shimabukuro, MD, MPH, MBA and Sarah  
Mbaeyi, MD, MPH

# Key messages

## Preparing for the potential management of anaphylaxis at COVID-19 vaccination sites

**Early recognition of  
anaphylaxis symptoms**



**Prompt treatment with  
epinephrine**



**Activation of emergency  
medical services**



<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>

CDC Partner Update Call, 12/21/2020, COVID-19 Vaccine Implementation. Nancy Messonnier MD and Sarah Mbaeyi, MD

# VACCINE SAFETY

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# Vaccine Adverse Event Reporting System (VAERS)

- Jointly administered by the CDC & FDA
- Receives ~40,000 reports per year
- National reporting system
- Passive; depends on health care providers and others to report
- Detects:
  - New or rare events
  - Increases in rates of known events after immunization
  - Patient risk factors associated with higher rates of adverse reactions
  - “Signals”, possible adverse reactions that may warrant further study
- VAERS cannot establish causality, additional studies would be needed



**VAERS**  
Vaccine Adverse Event  
Reporting System

Co-managed by  
CDC and FDA  
<http://vaers.hhs.gov>



# VAERS Reporting

- Providers are required by law to report to VAERS:
  - Any adverse event listed on the [VAERS Table of Reportable Events Following Vaccination](#)
  - Any adverse event listed by the vaccine manufacturer as a contraindication to further doses
- Providers are encouraged to report:
  - Any adverse event following the administration of a vaccine, whether or not it is clear the vaccine caused the event
  - Vaccine administration errors
- Manufacturers are required to report:
  - All adverse events that come to their attention

<https://vaers.hhs.gov/resources/infoproviders.html>

<https://vaers.hhs.gov/reportevent.html>

# COVID-19 Adverse Event (AE) Reporting

COVID-19 vaccination providers are required to report the following to VAERS:

- vaccine administration errors whether or not associated with an adverse event
- serious adverse events\* (irrespective of attribution to vaccination)
- cases of Multisystem Inflammatory Syndrome (MIS) in adults
- cases of COVID-19 that result in hospitalization or death.

<https://www.fda.gov/media/144637/download>



# Active Safety Monitoring for COVID-19 Vaccines

- **V-safe** is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety
  - uses text messaging and web surveys to check-in with vaccine recipients after vaccination
  - participants can report any side effects or health problems after COVID-19 vaccination
  - includes active telephone follow-up by CDC for reports of significant health impact



Slide courtesy of CDC's Partner Call : COVID-19 Vaccine Distribution and Safety Overview (11/9/2020)



**Get vaccinated.  
Get your smartphone.  
Get started with v-safe.**



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

When you get your COVID-19 vaccination, ask your healthcare provider about getting started with v-safe

Learn more about **v-safe**  
[www.cdc.gov/vsafe](http://www.cdc.gov/vsafe)



12/01/20

**Get vaccinated.  
Get your smartphone.  
Get started with v-safe.**

### What is v-safe?

**V-safe** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

### How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2pm local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

### How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

### Is my health information safe?

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.\*

\*To the extent v-safe uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

12/01/20



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



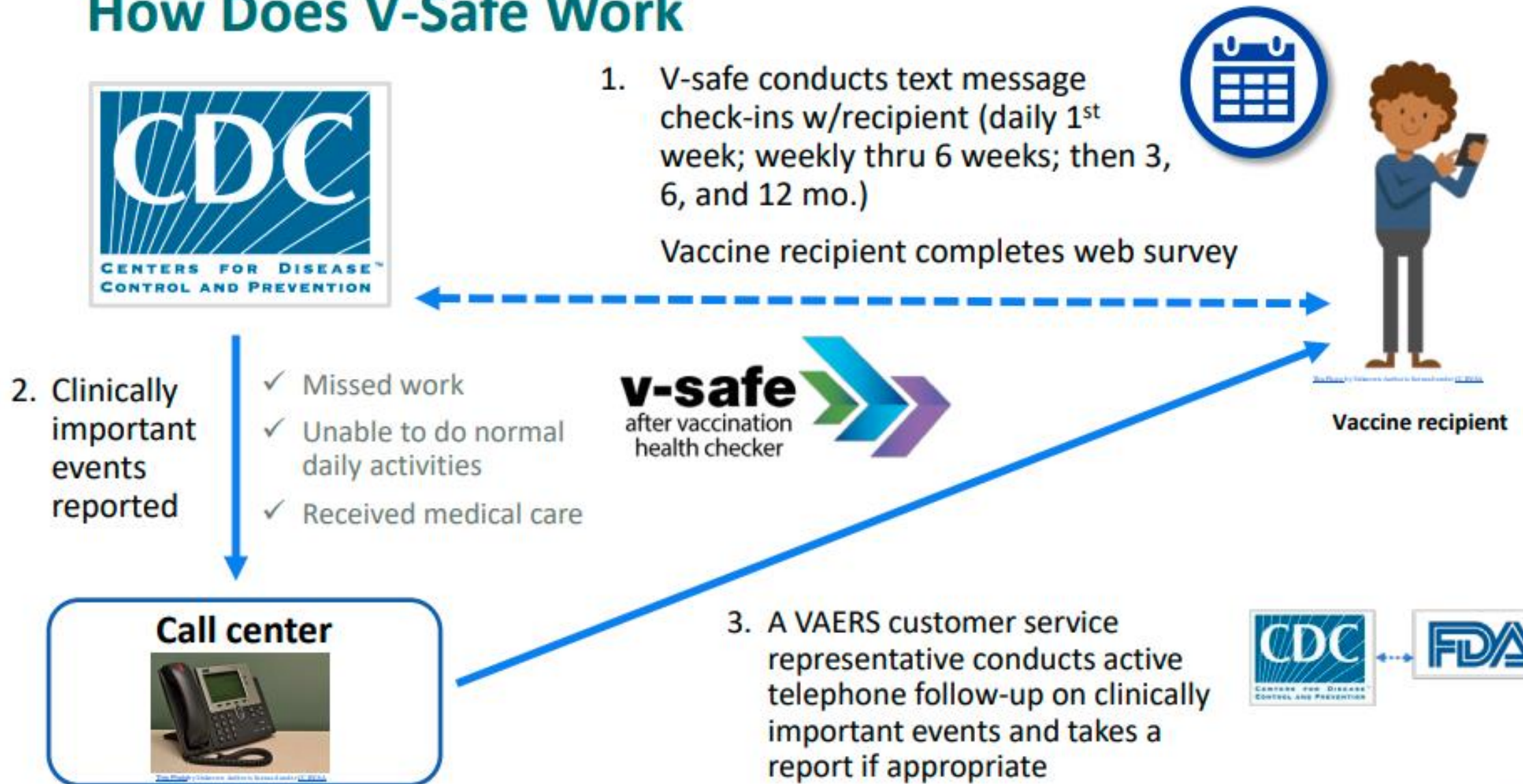
Sign up with your smartphone's browser at  
[vsafe.cdc.gov](http://vsafe.cdc.gov)

OR

Aim your smartphone's camera at this code



# How Does V-Safe Work



Slide courtesy of CDC's Partner Call: COVID-19 Vaccine Distribution and Safety Overview (11/9/2020)

# Your Role

**COVID-19 vaccine safety gets stronger  
with your participation**

## General Public

- participate in **v-safe** ✓
- report adverse event to **VAERS** ✓

## Healthcare Providers

- encourage patients to participate in **v-safe** ✓
- continue to report clinically important adverse events to **VAERS** ✓

Slide courtesy of CDC's Partner Call: COVID-19 Vaccine Distribution and Safety Overview (11/9/2020)



# How to report an adverse event to VAERS

- Go to [vaers.hhs.gov](https://vaers.hhs.gov) and submit a report online
- For help: call 1-800-822-7967, email [info@VAERS.org](mailto:info@VAERS.org)
- Video instructions <https://www.youtube.com/watch?v=sbCWWhcQADFE>

# How to contact CDC at CDC-INFO

- Go to <https://www.cdc.gov/cdc-info/index.html>
- Call 1-800-CDC-INFO (800-232-4636)



# Safety information resources

- <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html>
- <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>



# VACCINATING DURING THE COVID-19 PANDEMIC

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# Infection Control



- Wash hands or use alcohol-based hand sanitizer before vaccine preparation and between patients
- Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on their hands.
  - If gloves are worn, they should be changed between patients
  - Perform hand hygiene between patients, even if wearing gloves
- Gloves cannot prevent needle stick injuries
- Have a needle stick policy



<https://www.cdc.gov/handhygiene/index.html>

# Implement Enhanced Infection Control Measures

Refer to CDC guidance to prevent the spread of COVID-19 in [health care settings](https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html) , including [outpatient and ambulatory care settings](https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html).

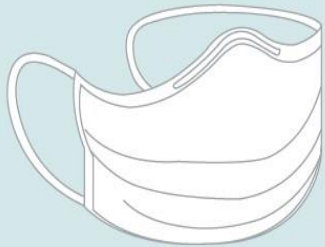
- Screen patients for COVID-19 symptoms before and during the visit.
- Physical distance (at least 6 feet apart, where possible)
- Limit and monitor facility points of entry and install barriers to limit physical contact with patients at triage.
- Respiratory hygiene (facemasks for staff and face coverings for patients over 2 years of age, if tolerated) and cough etiquette
- Hand hygiene (including at least 60% alcohol hand sanitizer for patients)
- Enhanced surface decontamination

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html>

# Use Personal Protection Equipment (PPE)

## Face mask



- **Recommended:** All health care providers (N95 masks not recommended)

## Eye protection



- **Recommended:** Areas of moderate/substantial community transmission
- **Optional:** Areas of minimal/no community transmission

## Gloves



- **Recommended:** intranasal or oral vaccines
- **Optional:** intramuscular or subcutaneous vaccines

Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on their hands.


- If gloves are worn, they should be changed between patients
- Perform hand hygiene between patients, even if wearing gloves



# Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations


- To assist with planning and implementation of satellite, temporary, or off-site vaccination clinics. The guidance provides information on additional considerations that are required during the COVID-19 pandemic, including physical distancing, PPE, and enhanced sanitation efforts.
- The guidance is broken down into four categories:
  - [Planning activities](#)
  - [Pre-clinic activities](#)
  - [During the clinic activities](#)
  - [Post-clinic activities](#)

<https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html>




Guidance during the COVID-19 pandemic


Planning for a satellite, temporary, or off-site vaccination clinic requires additional considerations during the COVID-19 pandemic, including physical distancing, personal protective equipment (PPE), and enhanced sanitation efforts. These additional considerations are called out in boxes throughout this guidance. However, because COVID-19 guidance is evolving, regularly check [infection control guidance for healthcare professionals about coronavirus \(COVID-19\)](#) for updated information. Consider signing up for the email updates on the website to stay informed of any changes.




Planning Activities



Pre-Clinic Activities



During the Clinic Activities



Post-Clinic Activities

Planners are encouraged to use

- [Resources for hosting an off-site vaccination clinic](#)
- The [Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#), which outlines CDC guidelines and best practices essential for patient safety and vaccine effectiveness, including guidance for vaccine shipment, transport, storage, handling, preparation, administration, and documentation at temporary clinics.



# Vaccination Process

During the vaccination process, ensure the following actions are occurring:

- Screening for eligibility, if vaccination is limited to certain populations
- Screening for contraindications and precautions
- Distribution of VIS(s) or EUA fact sheets prior to vaccine administration
- Signed consent, based on state or local requirements (there is no federal requirement for signed consent)
- Vaccine preparation
  - Vaccine is prepared in a designated area.
  - The cold chain is maintained until time for administration.
  - Staff is safely handling and disposing of needles and syringes.
  - No more than 1 multidose vial or number as indicated by the manufacturer's package insert is drawn up at one time by each vaccinator.
- Patient flow is being monitored to avoid drawing up unnecessary doses.
- [Hand hygiene](#) is being performed before vaccine preparation, between patients, and any time hands become soiled. If gloves are worn, they should be changed and hand hygiene should be performed between patients.
- Vaccinators are following manufacturer instructions and federal vaccine administration guidance related to dose, site, and route (see [Epidemiology and Prevention of Vaccine-Preventable Diseases](#) and [CDC Vaccine Administration Resource Library](#)).
- Each vaccination is being documented and patients are receiving documentation for their personal records, including information about scheduling a second vaccination appointment, if needed.
- **Patients are observed after vaccination:**



## During the Clinic Activities

# YOU CALL THE SHOTS

## Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist

Below are supplies that may be needed to conduct a satellite, temporary, or off-site vaccination clinic. The list may not be comprehensive. Your [state or local public health immunization program](#) may also have a checklist.

For large-scale clinics held at large facilities, such as stadiums and arenas, or over multiple days, additional supplies will be needed. Contact your state or local public health preparedness program and work with the clinic medical director for additional guidance and assistance.

Quantity of supplies needed will vary significantly between smaller, one-day clinics held in schools, churches, or pharmacies and large-scale clinics held in arenas or held over multiple days.

### VACCINES

#### Refrigerated vaccines

Select the vaccine(s) that will be offered at the clinic.

- ☐ Diphtheria, tetanus, and pertussis (DTaP)
- ☐ DTaP-HepB-IPV (Pediarix)
- ☐ DTaP-IPV/Hib\* (Pentacel)
- ☐ DTaP-IPV (Kinrix, Quadacel)
- ☐ *Haemophilus influenzae* type b\* (Hib)
- ☐ Hepatitis A (HepA)
- ☐ Hepatitis B (HepB)
- ☐ HepA-HepB (Twinrix)
- ☐ Human papillomavirus (9vHPV)
- ☐ Influenza, injectable (IIV) (in season)
- ☐ Influenza, live attenuated intranasal (LAIV) (in season)

- ☐ Measles, mumps, rubella\* (MMR)
- ☐ Meningococcal ACWY\* (MenACWY)
- ☐ Meningococcal B (MenB)
- ☐ Pneumococcal conjugate (PCV13)
- ☐ Pneumococcal polysaccharide (PPSV23)
- ☐ Polio, inactivated (IPV)
- ☐ Rotavirus\* (RV)
- ☐ Tetanus-diphtheria, adult (Td)
- ☐ Tetanus, diphtheria, and pertussis (Tdap)
- ☐ Zoster, recombinant (RZV, Shingrix\*)

#### Frozen vaccines

(Frozen vaccines may only be administered at satellite, temporary, and off-site clinics if they can be safely shipped to and monitored at the site. They should never be transported from one location to another.)

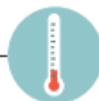
- ☐ Measles, mumps, rubella, varicella\* (MMRV, ProQuad)
- ☐ Varicella\*

\*Diluent for ActHib, Hibrix, Menveo, Pentacel, Rotarix, and Shingrix comes packaged in the same container as the lyophilized component. Diluent for MMR, MMRV, and varicella comes from the manufacturer packaged with the vaccine in separate containers.

### CLINICAL SUPPLIES

#### Administration supplies

- ☐ Adhesive bandages
- ☐ Appropriate needles (length, gauge) for the route of administration (Subcut, IM) and the expected patient population
- ☐ Sterile alcohol prep pads
- ☐ Syringes (1 or 3 cc)



## CDC | NCIRD | Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist

### Clinic supplies

- ☐ Alcohol-based hand sanitizer (at least 60% alcohol)
- ☐ Digital data logger for each storage unit/container
- ☐ Disposable table covers
- ☐ Gauze pads
- ☐ Medical gloves
- ☐ Partition screens
- ☐ Paper towels
- ☐ Sanitizing products for vaccination and preparation surfaces
- ☐ Sharps containers
- ☐ Table and chairs for patient and vaccination provider at each vaccination station
- ☐ Vaccine storage units (onsite) or portable refrigerators or packouts (for transport) that can maintain the appropriate vaccine cold chain
- ☐ Waste baskets

### Clinic documentation

- ☐ Billing forms, if needed
- ☐ Immunization record cards
- ☐ Immunization schedule for targeted audience(s)
- ☐ Internet access or hotspot
- ☐ Forms to record vaccine administration (this may be done by computer)
- ☐ Laptops, computers, tablets, or smartphones, as well as printers and 2D barcode readers (if using), including multiple plug outlet strips and extension cords
- ☐ Screening checklist for contraindications to vaccines for children, teens, and adults
- ☐ Vaccination standing orders and protocols, as necessary
- ☐ Vaccine information statements (VISs) for each vaccine being offered and in multiple languages as appropriate (in some instances, an emergency use authorization [EUA] form may be required)
- ☐ Vaccine storage temperature log(s)

### Office supplies

- ☐ Clipboards
- ☐ Notepads
- ☐ Pens
- ☐ Printer paper
- ☐ Printers, if applicable
- ☐ Rope, cones, and/or tape as needed to direct traffic flow
- ☐ Signage for clinic hours, future clinics, clinic flow, and easels or other equipment for displaying
- ☐ Trash bags
- ☐ Walkie-talkies or similar devices, depending on size of the clinic

### MEDICAL EMERGENCY SUPPLIES

If possible, it is preferable that emergency medical services (EMS) staff be available during the clinic. Clinical staff providing vaccine should be trained in CPR and able to respond to medical emergencies.

At a minimum, there should be:

- ☐ Antihistamines (diphenhydramine [Benadryl], hydroxyzine [Atarax, Vistaril], and syringes if needed)
- ☐ Cell phone or land line to call 911
- ☐ Epinephrine in prefilled autoinjector or prefilled syringe (various doses), prepackaged syringes, vials, or ampules (Epi-pens)
- ☐ First aid kit
- Additional supplies may include:
  - ☐ Blood pressure measuring device
  - ☐ Light source to examine mouth and throat
  - ☐ Oxygen
  - ☐ Stethoscope
  - ☐ Timing device for measuring pulse
  - ☐ Tongue depressors
  - ☐ Tourniquet

### Additional supplies needed during the COVID-19 pandemic

During the COVID-19 pandemic, additional supplies are needed to protect both staff and patients, including:

- Additional hand sanitizer with at least 60% alcohol for [hand hygiene](#)
- Additional cleaning equipment for more frequent cleanings, using [EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2](#)
- Additional signage, tape, ropes, and cones to encourage physical distancing and provide one-way flow through the clinic
- [Face coverings](#) for patients who arrive without one
- Hand soap, as appropriate
- [Personal protective equipment](#) (PPE) for staff. Gloves should be worn by anyone administering intranasal or oral vaccine. Depending on level of community transmission, eye protection may also be recommended.
- Thermometers for checking patient temperature before [entering the clinic](#), if required
- Tissues

05/06/20

# RESOURCES

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# CDC COVID-19 Vaccine Resources

## HEALTHCARE PROVIDERS/PUBLIC HEALTH:

COVID-19 Vaccination Clinical Resources

<https://www.cdc.gov/vaccines/covid-19/index.html>

COVID-19 Product Info – by US Vaccine

<https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>

Clinical Considerations

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html>

Training and Education

<https://www.cdc.gov/vaccines/covid-19/training.html>

Talking to Recipients about COVID-19 Vaccines

<https://www.cdc.gov/vaccines/covid-19/hcp/index.html>

Understanding and Explaining mRNA COVID-19 Vaccines

<https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html>

Making a Strong Recommendation for COVID Vaccination

<https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html>

Answering Patients' Questions

<https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>

Frequently Asked Questions about COVID-19 Vaccination

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>

COVID-19 Vaccination

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html>

COVID-19 Vaccination **Communication Toolkit** For Medical Centers, Clinics, and Clinicians

<https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>

## ACIP

Main page

<https://www.cdc.gov/vaccines/acip/index.html>

COVID-19 Recommendations

<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>

MMWR. The Advisory Committee on Immunization Practices' Interim Recommendation

for Use of Moderna COVID-19 Vaccine— United States, December 2020

<https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152e1-H.pdf>

MMWR. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020

<https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950e2-H.pdf>

MMWR. The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020

<https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152e2-H.pdf>



# COVID-19 Vaccine Resources

## VACCINE SAFETY:

Ensuring the Safety of COVID-19 Vaccines in the United States

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>

V-Safe After Vaccination Health Checker:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

FAQ's About V-Safe:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq.html>

## VACCINE STORAGE & HANDLING TOOLKIT

with Covid-19 Vaccine Addendum

<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

## GENERAL PUBLIC

COVID-19 Vaccine information <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

- [Frequently Asked Questions](#)
- [Facts About COVID-19 Vaccines](#)
- [Benefits of Getting a COVID-19 Vaccine](#)
- [Ensuring Safety of COVID-19 Vaccines](#)
- [Ensuring COVID-19 Vaccines Work](#)
- [How CDC is Making COVID-19 Vaccine Recommendations](#)
- [How COVID-19 Vaccines Work](#)
- [Understanding and Explaining mRNA Vaccines](#)

## TRAINING & RESOURCES:

### COVID-19 Training and Education for Healthcare Professionals

<https://www.cdc.gov/vaccines/covid-19/training.html>

COVID-19 Vaccine Training Module for Health Care Providers

<https://www2.cdc.gov/vaccines/ed/covid19/>

COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals

<https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf>

- Vaccine Storage and Handling
- Vaccine Administration
- Communicating with Patients about Vaccines
- COVID-19 Vaccine Training and Clinical Materials

### COCA Calls/Webinars:

<https://emergency.cdc.gov/coca/calls/index.asp>

- 12/30/2020: COVID-19 Vaccines: Update on Allergic Reactions, Contraindications, & Precautions
- 12/18/2020: What Clinicians Need to Know About the Pfizer-BioNTech and Moderna COVID-19 Vaccines
- 12/14/2020: What Every Clinician Should Know about COVID-19 Vaccine Safety

### CDC Partner Calls/Webinars:

<https://www.cdc.gov/coronavirus/2019-ncov/communication/videos-webinars-calls.html?Sort=Date%3A%3Adesc>

- 12/17/2020: Ten Truths about COVID-19

# Moderna COVID-19 Vaccine Resources

## MODERNA

Moderna Call Center: 1-866-MODERNA (1-866-663-3762)

Moderna COVID-19 Vaccine Website:

<https://www.modernatx.com/covid19vaccine-eua/>

Moderna COVID-19 Vaccine EUA Website (EUA's and exp date look-up):

<https://www.modernatx.com/covid19vaccine-eua/providers/>

Moderna COVID-19 Vaccine EUA for Providers:

<https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf>

Moderna COVID-19 Vaccine EUA for Recipients:

<https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf>

## US FDA

EUA Guidance:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization# covid19euas>

Moderna COVID-19 Vaccine: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine#additional>

EUA Letter, December 18, 2020

<https://www.fda.gov/media/144636/download>

MODERNA EUA Factsheet for Providers:

<https://www.fda.gov/media/144637/download>

MODERNA EUA Factsheet for Caregivers:

<https://www.fda.gov/media/144638/download>

## CDC

COVID-19 Vaccination

<https://www.cdc.gov/vaccines/covid-19/index.html>

Moderna COVID-19 Vaccine (general info, how to administer instructions, links to FAQs, EUAs, interim clinical considerations, storage and handling resources, screening form):

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>

Interim Considerations: Preparing for the Potential Management of **Anaphylaxis** at COVID-19 Vaccination Sites <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>

COVID-19 Vaccine Prevaccination Screening Form

<https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf>

Moderna COVID-19 Vaccine Standing Order:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf>

Moderna COVID-19 Vaccine Preparation and Administration Summary Sheet:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/prep-and-admin-summary.pdf>

Moderna COVID-19 Vaccine Storage and Handling Summary:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf>

COVID-19 Vaccine Expiration Date Tracking Tool

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf>

# Pfizer-BioNTech COVID-19 Vaccine Resources

## PFIZER BIONTECH

Pfizer Customer Service: 1-800-TRY-FIRST (1-800-879-3477)

Pfizer-BioNTech COVID-19 Vaccine Website:

<https://www.cvdvaccine.com/>

Pfizer BioNTech COVID-19 Vaccine EUA for Providers:

<http://labeling.pfizer.com/ShowLabeling.aspx?id=14471>

Pfizer BioNTech COVID-19 Vaccine EUA for Recipients:

<http://labeling.pfizer.com/ShowLabeling.aspx?id=14472>

## US FDA

EUA Guidance:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>

Pfizer-BioNTech COVID-19 Vaccine:

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>

EUA Letter, Dec 11, 2020:

<https://www.fda.gov/media/144412/download>

PFIZER-BIONTECH EUA Factsheet for Providers:

<https://www.fda.gov/media/144413/download>

PFIZER-BIONTECH EUA Factsheet for Recipients:

<https://www.fda.gov/media/144414/download>

## CDC

COVID-19 Vaccination

<https://www.cdc.gov/vaccines/covid-19/index.html>

Pfizer-BioNTech COVID-19 Vaccine (general info, screening form, standing orders, vaccine prep and administration summary, mixing diluent, and more)

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

Interim Considerations: Preparing for the Potential Management of **Anaphylaxis** at COVID-19 Vaccination Sites <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>

COVID-19 Vaccine Prevaccination Screening Form

<https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf>

Pfizer-BioNtech COVID-19 Vaccine Standing Order

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf>

Pfizer-BioNTech COVID-19 Vaccine Preparation and Administration Summary Sheet

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/prep-and-admin-summary.pdf>

Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf>

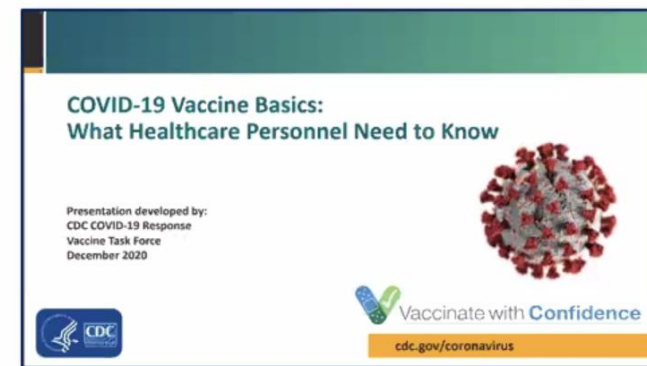
Diluent poster

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/diluent-poster.pdf>



# COVID-19 vaccine communication resources

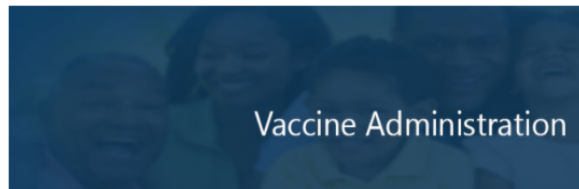
- Engaging in Effective COVID-19 Vaccine Conversations
  - <https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.htm>
- Toolkit for Medical Centers, Clinics, and Clinicians
  - <https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>
- More toolkits coming soon
  - Long-term care facilities
  - Health departments
  - Community-based organizations
  - Employers of essential workers



# CDC Vaccine Administration Resources

## Vaccine Administration

The COVID-19 pandemic is changing rapidly and requires different strategies to manage, including immunization. Find up-to-date guidance on [childhood](#) and [maternal](#) vaccine administration.



Proper vaccine administration is critical to ensure that vaccination is safe and effective. Personnel who administer vaccines receive comprehensive, competency-based training and procedures BEFORE administering vaccines. Comprehensive, skills-based training staff education programs such as new staff orientation and annual education require. Learn is available that offers continuing education for health care personnel, including:

### Review Immunization History

Reviewing and assessing a patient's immunization history should be done at every health care visit to help determine which vaccines may be needed.

### Assess for Needed Immunizations

Use the current Advisory Committee on Immunization Practices (ACIP) immunization schedule to determine what recommended vaccines are needed based on the patient's immunization history.

### Screen for Contraindications and Precautions

<https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html>



## Epidemiology and Prevention of Vaccine-Preventable Diseases

CDC > The Pink Book Home > Chapters

Home The Pink Book Home

Front Matter

### Chapters

Chapter 1: Principles of Vaccination

Chapter 2: General Recommendations on Immunization

Chapter 3: Immunization Strategies for Healthcare Practices and Providers

Chapter 4: Vaccine Safety

Chapter 5: Storage and Handling

Chapter 6: Vaccine Administration

## Vaccine Administration

Updated November 2020

JoEllen Wolicki, BSN, RN and Elaine Miller, RN, BSN, MPH

This chapter summarizes best practices related to vaccine administration. A key factor in ensuring vaccination is as safe and effective as possible is proper vaccine administration. Vaccine administration involves a series of actions: assessing patient status and determining needed vaccines, screening for contraindications and precautions, educating patients, preparing and administering vaccines properly, and documenting the vaccines administered. Professional standards for medication administration, manufacturer instructions, and organizational policies and procedures should always be followed when applicable.

## Staff Training and Education

Policies should be in place to validate health care professional knowledge, skills, and abilities in vaccine administration. All health care professionals should receive training in vaccine administration.

<https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html>

## Resource Library



Note: The materials listed on this page might be more current than vaccine administration information in previously published CDC documents, including the 13th edition of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (the [Pink Book](#)). Always follow the most up-to-date guidelines in the [Vaccine Storage and Handling Toolkit](#) or more recently dated materials.

## Web-based Training Courses

[Vaccine Administration e-Learn](#)

A self-paced vaccine administration course that provides comprehensive training using videos, job aids, and resources.

[You Call the Shots](#)

An interactive, web-based immunization training course that includes the latest guidelines and recommended vaccine practice.



Videos

<https://www.cdc.gov/vaccines/hcp/admin/resource-library.html>

### On This Page

[Web-based Training](#)

[Job Aids](#)

[References](#)

[Web Button](#)

# Clinical Resources for Proper Vaccine Administration

- CDC Vaccine administration & Resource Library webpages-- information and materials for health care personnel including:

- IM demonstration video
- Job aids and infographics

[www.cdc.gov/vaccines/hcp/admin/admin-protocols.html](http://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html)

<https://www.cdc.gov/vaccines/hcp/admin/resource-library.html>

- CDC Vaccine Admin E-Learn module:

<https://www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp>

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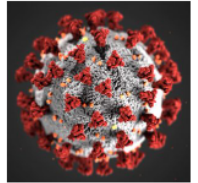
**Ask the Experts!**  
IAC experts answer more than 1,000 questions from healthcare professionals about vaccines and their use.

**>> Read Ask the Experts!**

**Vaccinating Adults:**  
A Step-by-Step Guide

## Repository of Resources for Maintaining Immunization during the COVID-19 Pandemic

This repository of resources is intended for use by healthcare settings, state and local health departments, professional societies, immunization coalitions, advocacy groups, and communities in their efforts to maintain immunization rates during the COVID-19 pandemic. The repository includes links to international, national, and state-level policies and guidance and advocacy materials, including talking points, webinars, press releases, media articles, and social media posts, as well as telehealth resources. The materials listed below can be sorted and searched by date, title, geographic area, source, type, category, or setting.



This repository will grow with your help. If you know of national, state, or local guidance documents or other resources that should be added, please send a message to [info@immunizationcoalitions.org](mailto:info@immunizationcoalitions.org).

Federal Guidance Document

Date	ID	Title	Area	Source	Type	Category	Setting
10/20/20	C213	Interim Guidance for Routine and Influenza Immunization Services During the...	US	CDC	Guidance/Policy	All Ages	Healthcare
10/20/20	C214	Interim Guidance for Routine and Influenza Immunization Services During the...	US	CDC	Guidance/Policy	All Ages	Healthcare



<https://www.immunizationcoalitions.org/resource-repository/>

<https://immunize.org/>



# ACIP Best Practice Guidelines for Immunization

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## General Best Practice Guidelines for Immunization

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### Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)

*Kroger AT, Duchin J, Vázquez M*

#### 1. Introduction

The Centers for Disease Control and Prevention (CDC) recommends routine vaccination to prevent 17 vaccine-preventable diseases that occur in infants, children, adolescents, or adults. This report provides information for clinicians and other health care providers about concerns that commonly arise when vaccinating persons of various ages.

- Describes the ACIPs recommendations and guidelines on vaccination practice
- Updated as needed online

<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

# Vaccination Clinic Planning Resources

- CDC Vaccination Guidance During a Pandemic: <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>
- CDC Guidance for Planning for Vaccination Clinics Held at Satellite, Temporary or Off-Site Locations: <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html>
- CDC Considerations for Planning Curbside/Drive-Through Vaccination Clinics: <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/curbside-vaccination-clinics.html>
- CDC Resources for Hosting a Vaccination Clinic (including a Best Practices Checklist): <https://www.cdc.gov/flu/business/hosting-vaccination-clinic.htm>
- CDC Clinic Supplies Check List:  
<https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/vaccination-clinic-supply-checklist.html>  
<https://www.cdc.gov/vaccines/hcp/admin/downloads/2020-vaccine-clinic-supply-checklist-508.pdf>
- CDC Infection Control Guidance: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html>  
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>
- IAC Protective Measures for Vaccinating During a Pandemic: <https://www.immunize.org/catg.d/p2009.pdf>
- IAC COVID Repository of Resources for Maintaining Immunizations during the COVID-19 Pandemic: <https://www.immunizationcoalitions.org/resource-repository/>

# MDPH Immunization Division Contact Information

## Immunization Division Main Number

For questions about immunization recommendations, disease reporting, etc.

Phone: 617-983-6800 (24/7 MDPH Epidemiology line)

Fax: 617-983-6840

Website: <https://www.mass.gov/topics/immunization>



## MIIS Help Desk

Phone: 617-983-4335

Fax: 617-983-4301

Email: [miishelpdesk@state.ma.us](mailto:miishelpdesk@state.ma.us)

Website: <https://www.mass.gov/service-details/massachusetts-immunization-information-system-miis>

## MDPH Vaccine Unit

Phone: 617-983-6828

Fax: 617-983-6924

Website: <https://www.mass.gov/service-details/vaccine-management>

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