MODERNA COVID-19 VACCINE TRAINING

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

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
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
Modern 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

 Supports administration of 100 doses

<table>
<thead>
<tr>
<th>Product</th>
<th>Product Description</th>
<th>Quantity</th>
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</thead>
<tbody>
<tr>
<td>Needles</td>
<td>22 – 25G, 1”</td>
<td>85</td>
</tr>
<tr>
<td>Needles</td>
<td>22 – 25G, 1.5”</td>
<td>20</td>
</tr>
<tr>
<td>Syringes</td>
<td>1 ml or 3 ml</td>
<td>105</td>
</tr>
<tr>
<td>Alcohol pads</td>
<td>Sterile, individual</td>
<td>210</td>
</tr>
<tr>
<td>Vaccination record card</td>
<td></td>
<td>100</td>
</tr>
<tr>
<td>Needle guide</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Face shield</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Face Mask</td>
<td></td>
<td>4</td>
</tr>
</tbody>
</table>

Standard Ancillary Adult Kit Dimensions: 14” x 13” x 9”  Weight: 3.5 lbs

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 2nd dose must be the same product as the first dose
  • Schedule the 2nd dose when administering the first dose
  • Develop a system for recalling vaccinees for 2nd dose
    • Moderna doses: 28 days apart
    • Pfizer doses: 21 days apart
    • Provide 2nd dose reminders:
      • Personal vaccination card, email, text or calls

• Do not plan to hold COVID-19 vaccine from initial shipment for 2nd doses
  • 2nd doses are being withheld by the federal government and will be shipped as needed for the 2nd dose
  • Upon receipt of future shipments, identify which will be needed for 2nd doses
STORAGE & HANDLING
**Preparation & Administration**

**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!

**McKesson**

-20° C Vaccine Inside

**ALERT:** Do **not** Place on Dry Ice

**INSTRUCTIONS**
- Remove TagAlert Temperature Monitor from Box (placed in inner box next to vaccine)
- Follow Receiver Instructions on the carton:
  - Press and hold the Start & Stop button until the Stop icon appears

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 (31° 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

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 time in vial
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/
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](https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html). 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.
PREPARATION & ADMINISTRATION
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.
Standing orders for vaccination facilitate the delivery of immunization services to patients.

Standing orders for COVID-19 vaccines are available at:

Standing orders for many routine vaccines and Emergency Treatment are available from IAC: https://www.immunize.org/standing-orders/

Useful CDC Guidance Links
Modernat COVID-19 Vaccine Standing Orders

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 in a Community Setting

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/p4063.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.

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

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)

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

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

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

1st Dose 0.5 mL
1 month apart

2nd Dose 0.5 mL

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

https://www.modernatx.com/covid19vaccine-eua/providers/
Moderna COVID-19 Vaccine Prep & Administration

Dosing and Administration

- Authorized age groups:
  - Pfizer-BioNTech: ≥ 16 years
  - Moderna: ≥ 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

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

- 2-dose series administered intramuscularly
  - Pfizer-BioNTech: 21 days apart
  - Moderna: 28 days apart

- Administration of 2\textsuperscript{nd} 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\textsuperscript{st} dose,
  2\textsuperscript{nd} 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

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

Check for latest guidance on the CDC website
Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

**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 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
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
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

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.

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

CDC Partner Update Call, 12/21/2020, COVID-19 Vaccine Implementation. Nancy Messonnier MD and Sarah Mbaeyi, MD
[https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)
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.

https://www.cdc.gov/vaccines/covid-19/info-by-product клинических-существований.html
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).

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

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

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

[www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](http://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)
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

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

[https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)
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

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
What to Expect after Getting a COVID-19 Vaccine

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布洛芬 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.

USE THE V-SAFE APP TO MONITOR SIDE EFFECTS

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

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:

Medication (if needed): 
Told to take every ___ hours as needed.

Visit cdc.gov/coronavirus for more information.

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


CONTRAINDICATIONS
& PRECAUTIONS
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

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 tuberculosis skin testing

On This Page
- Background
- Authorized age groups
- Administration
- Interchangeability with other COVID-19 vaccine products
- Coadministration with other vaccines
- Booster doses
- Vaccination of persons with a SARS-CoV-2 infection or exposure
- 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

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

*As reported in the prescribing information

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
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](https://www.nlm.nih.gov/dailymed/) 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.

# Distinguishing allergic reactions from other types of reactions

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

ALLERGIES
History of allergies that are unrelated to components of an mRNA COVID-19 vaccine, other vaccines, or injectable therapies, such as:
- Allergy to oral medications (including the oral equivalent of an injectable medication)
- History of food, pet, insect, venom, environmental, latex, etc., allergies
- Family history of allergies

ACTIONS
- 30 minute observation period: Persons with a history of anaphylaxis (due to any cause)
- 15 minute observation period: All other persons

PRECAUTION TO VACCINATION

ALLERGIES
- History of any immediate allergic reaction to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines or polysorbate, as these are contraindicated)

ACTIONS:
- Risk assessment
- Consider deferral of vaccination and/or referral to allergist-immunologist
- 30 minute observation period if vaccinated

CONTRAINDICATION TO VACCINATION

ALLERGIES
History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines:
- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol)
- Immediate allergic reaction of any severity to polysorbate

ACTIONS:
- Do not vaccinate
- Consider referral to allergist-immunologist

† 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

CDC COCA Call, 12/18/2020, COVID-19What 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

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

*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.

CDC COCA Call, 12/18/2020, COVID-19 What Clinicians Need to Know About the Pfizer-BioNTech and Moderna COVID-19 Vaccines
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.cdc.gov/vaccines/pubs/pinkbook/vaccine-admin.html
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html
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)

  ![Clock showing 30 minutes](image)

  **All other persons**

  ![Clock showing 15 minutes](image)

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
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

https://vaers.hhs.gov/about.html
VAERS Reporting

• Providers are **required by law** to report to VAERS:
  o Any adverse event listed on the [VAERS Table of Reportable Events Following Vaccination](https://vaers.hhs.gov/resources/infoproviders.html)
  o Any adverse event listed by the vaccine manufacturer as a contraindication to further doses

• Providers are **encouraged** to report:
  o Any adverse event following the administration of a vaccine, whether or not it is clear the vaccine caused the event
  o Vaccine administration errors

• **Manufacturers are required** to report:
  o All adverse events that come to their attention

[https://vaers.hhs.gov/reportevent.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 Inflamatory 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)
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 6 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 will 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.

Learn more about v-safe

www.cdc.gov/vsafe
How Does V-Safe Work

1. V-safe conducts text message check-ins w/recipient (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)
   Vaccine recipient completes web survey

2. Clinically important events reported
   ✓ Missed work
   ✓ Unable to do normal daily activities
   ✓ Received medical care

3. A VAERS customer service representative conducts active telephone follow-up on clinically important events and takes a report if appropriate

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](http://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=sbCWhcQADFE](https://www.youtube.com/watch?v=sbCWhcQADFE)

How to contact CDC at CDC-INFO

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

Safety information resources

VACCINATING DURING THE COVID-19 PANDEMIC
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, including outpatient and ambulatory care settings.

▪ 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

Use Personal Protection Equipment (PPE)

Face mask

- **Recommended:** All health care providers (N95 masks not recommended)
- **Optional:** Areas of minimal/no community transmission

Eye protection

- **Recommended:** Areas of moderate/substantial 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

Image credit: Pan American Health Organization
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
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:
RESOURCES
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

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

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

V-Safe After Vaccination Health Checker:

FAQ’s About V-Safe:

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
- 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
  - 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:
  - 12/17/2020: Ten Truths about COVID-19
Moderna COVID-19 Vaccine Resources

MODERNA
Modern Call Center: 1-866-MODERNA (1-866-663-3762)
Modern COVID-19 Vaccine Website: https://www.modernatx.com/covid19vaccine-eua/
Modern COVID-19 Vaccine EUA Website (EUA's and exp date look-up): https://www.modernatx.com/covid19vaccine-eua/providers/

US FDA
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
Modern 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
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:
Pfizer BioNTech COVID-19 Vaccine EUA for Recipients:

US FDA
EUA Guidance:
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)
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 Pre Vaccination Screening Form
Pfizer-BioNtech COVID-19 Vaccine Standing Order
Pfizer-BioNTech COVID-19 Vaccine Preparation and Administration Summary Sheet
Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary:
Diluent poster
COVID-19 vaccine communication resources

- Engaging in Effective COVID-19 Vaccine Conversations
  - [https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.htm](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](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
Vaccine Administration

The COVID-19 pandemic is changing rapidly and requires different strategies to manage, including vaccination. Find up-to-date guidance on childhood and mass vaccination.
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](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](https://www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp)
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.

https://www.immunizationcoalitions.org/resource-repository/
ACIP Best Practice Guidelines for Immunization

General Best Practice Guidelines for Immunization

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/accp-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 Clinic Supplies Check List:  
  https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/vaccination-clinic-supply-checklist.html
- 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](https://www.mass.gov/topics/immunization)

**MIIS Help Desk**
Phone: 617-983-4335
Fax: 617-983-4301
Email: miishelpdesk@state.ma.us
Website: [https://www.mass.gov/service-details/massachusetts-immunization-information-system-miis](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](https://www.mass.gov/service-details/vaccine-management)
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Massachusetts Department of Public Health

DPH blog
https://blog.mass.gov/publichealth

www.mass.gov/dph
Thank You For Being a COVID-19 Vaccinator!