COVID-19 VACCINE ADMINISTRATION TRAINING

Laurie A. Courtney, MSN, RN
and
Katie Reilly, MPH, MSN, RN, PHNA-BC, CIC

Bureau of Infectious Diseases and Laboratory Sciences
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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 main page: https://www.cdc.gov/vaccines/acip/index.html
Learning Objectives

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

• Define ACIP COVID-19 Vaccine Recommendations
• Describe COVID-19 Vaccine Screening
• Explain Provider’s Role in Vaccine Administration
• List Recommended Infection Control Measures
• Summarize Principles of COVID-19 Vaccine Preparation
• List vaccine documentation requirements
• Describe Vaccine Adverse Event Reporting
• Summarize Recommendations for Vaccinating during the COVID-19 Pandemic
Outline

- Vaccine Provider's Role
- Vaccine Information and Ancillary Kit Supplies
- Clinical Considerations
- ACIP COVID-19 Vaccine Recommendations
- Vaccine Administration
  - Standing Orders
  - Screening
  - EUA fact sheets (Recipients and Healthcare Providers)
  - Vaccine Preparation
  - Infection Control
  - IM Injection Procedure
Outline

- Vaccine Reactions
- Vaccine Safety
- Vaccine Adverse Event Reporting (VAERS & V-Safe)
- Vaccinating During the COVID-19 Pandemic
  - Enhanced Infection Control Measures
  - Personal Protective Equipment (PPE)
  - Best Practices for Holding Safe Vaccination Clinics
  - Clinics held at Satellite, Temporary, or Off-site Locations
- Resources
- MDPH Contact Information
THE VACCINE PROVIDER’S ROLE
The Provider’s Role & Responsibilities

Immunization providers can help to ensure the safety and efficacy of vaccines through proper:

- Benefit and risk communication (Communicate with Confidence)
- Vaccine storage/handling and administration
- Timing and spacing of vaccine doses
- Screening for contraindications and precautions
- Management of adverse reactions
  - Being able to access and use emergency equipment
  - Current CPR certification
- Reporting to VAERS (and any additional COVID specific databases)
- Documentation

https://www.cdc.gov/vaccines/pubs/pinkbook/safety.html
The Seven “Rights” of Vaccine Administration

• Right Patient
• Right Time
• Right Vaccine (and Diluent)
• Right Dosage
• Right Route, Needle, Technique
• Right Injection Site
• Right Documentation

http://www.immunize.org/technically-speaking/20141101.asp
Healthcare Provider Documentation Requirements

Providers must ensure that the recipient's permanent medical record (whether paper-based or electronic) contains all the required vaccine administration documentation, which shall consist of the following:

- Date of administration of the vaccine
- Vaccine manufacturer and lot number of the vaccine
- Name and title of person administering the vaccine
- The address of the facility where the permanent record will reside (if appropriate)
- Date printed on the appropriate VIS/EUA fact sheet*
- Date the VIS/EUA fact sheet* was given to the vaccine recipient, or the parents/legal representative

Best practice documentation guidelines also include: the vaccine type, dose, site, route of administration, and vaccine expiration date be documented, and any vaccine refusal (if appropriate).

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

* COVID-19 specific

CDC COVID-19 Vaccination Program Provider Requirements and Support
https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html
Preparation for COVID-19 Vaccine Second Doses

• Pfizer and Moderna vaccines require 2 doses:
  o The 2\textsuperscript{nd} dose must be the same product as the first dose
  o Schedule the 2\textsuperscript{nd} dose when administering the first dose
  o Develop a system for recalling vaccinees for 2\textsuperscript{nd} dose
    o Pfizer doses: at least 21 days apart
    o Moderna doses: at least 28 days apart
  o Provide 2\textsuperscript{nd} dose reminders:
    ▪ Personal vaccination card, email, text or calls

▪ Do not plan to hold COVID-19 vaccine in reserve for 2\textsuperscript{nd} doses
  ▪ 2\textsuperscript{nd} doses are being withheld by the federal government and will be shipped as needed for the 2\textsuperscript{nd} dose
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 in any way

https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html
Pfizer COVID-19 Vaccine

- Shipped in 975-dose increments
  - Comes with Ancillary Supply Kit
- Ultra-cold storage (-80° to -60° C)
- Requires reconstitution with a diluent
- 5-dose multidose vial
- 0.3mL dose volume
- 2 doses, at least 21 days apart

Source: Product Information Guide for COVID-19 Vaccines and Associated Products

Image credit: Pfizer
## Pfizer COVID-19 Vaccine Adult Ancillary Kit Contents

Pfizer COVID-19 Vaccine Adult Ancillary Kit
Supports Administration of 975 Doses

<table>
<thead>
<tr>
<th>Product</th>
<th>Product Description</th>
<th>Quantity</th>
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<tr>
<td>Needles, for vaccine administration</td>
<td>22 – 25G, 1”</td>
<td>829</td>
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<tr>
<td>Needles, for vaccine administration</td>
<td>22 – 25G, 1.5”</td>
<td>200</td>
</tr>
<tr>
<td>Syringes, for vaccine administration</td>
<td>1 ml</td>
<td>1,024</td>
</tr>
<tr>
<td>Alcohol pads</td>
<td>Sterile, individual</td>
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<td>Vaccination record card</td>
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<td>1,000</td>
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<tr>
<td>Needle guide</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Face shield</td>
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<td>20</td>
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<tr>
<td>Face Mask</td>
<td></td>
<td>40</td>
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<tr>
<td>Diluent vials</td>
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<td>200</td>
</tr>
<tr>
<td>Needles, for vaccine reconstitution</td>
<td>21 – 25G, 1.5 “</td>
<td>205</td>
</tr>
<tr>
<td>Syringes, for vaccine reconstitution</td>
<td>3 ml or 5 ml</td>
<td>205</td>
</tr>
</tbody>
</table>

Pfizer Ancillary Adult Kit Dimensions: 24” x 20” x 24”  Weight: 40 lbs
Modernata COVID-19 Vaccine

- Shipped in 100-dose increments
  - Comes with Ancillary Supply Kit
- Does not require reconstitution
- 10-dose multidose vial
- 2 doses, at least 28 days apart

Source: Product Information Guide for COVID-19 Vaccines and Associated Products
# Standard COVID-19 Vaccine Adult Ancillary Kit Contents

Supports administration of 100 doses

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<tr>
<th>Product</th>
<th>Product Description</th>
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<td>Needles</td>
<td>22 – 25G, 1”</td>
<td>85</td>
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<tr>
<td>Needles</td>
<td>22 – 25G, 1.5”</td>
<td>20</td>
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<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>
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<td>100</td>
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<tr>
<td>Needle guide</td>
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<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

[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
CLINICAL CONSIDERATIONS

Check for latest guidance on the CDC website
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

• The ACIPs’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020: http://dx.doi.org/10.15585/mmwr.mm6949e1

• Clinical considerations link: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html

Healthcare Professionals: Preparing for COVID-19 Vaccination
https://www.cdc.gov/vaccines/covid-19/hcp/index.html
interim recommendations for use of pfizer-biontech covid-19 vaccine in the u.s.

• on december 11, 2020, the food and drug administration issued an emergency use authorization for the pfizer-biontech covid-19 vaccine.

• on december 12, 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 pfizer-biontech covid-19 vaccine in persons aged ≥16 years for the prevention of covid-19.

• the recommendation for the pfizer-biontech covid-19 vaccine should be implemented in conjunction with interim recommendations for allocating initial supplies of covid-19 vaccines.

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
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.

- While the incidence and timing of post-vaccination symptoms will be further informed by phase III clinical trial data, 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.
  - Further considerations on the management of post-COVID-19 vaccination symptoms among healthcare personnel is under development.

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html
Infection prevention and control recommendations for persons with post-vaccination symptoms

- Healthcare personnel
  

- Long-term care facility residents
  

https://www.cdc.gov/vaccines/covid-19/index.html
Pregnant women  (Final clinical considerations not yet posted as of 12/13/20)

- There are no data on the safety of COVID-19 vaccines in pregnant women
  - Animal developmental and reproductive toxicity (DART) studies are ongoing
  - Studies in humans are ongoing and more planned

- mRNA vaccines and pregnancy
  - Not live vaccines
  - They are degraded quickly by normal cellular processes and don’t enter the nucleus of the cell

- 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

- 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. A discussion with her healthcare provider can help her make an informed decision.

Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20

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Pregnant women (Final clinical considerations not yet posted as of 12/13/20)

- 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

- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes

- Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended.

Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20
Breastfeeding/Lactating women

- There are no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion

- mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant

- If a lactating woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated

Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20

(Final clinical considerations not yet posted as of 12/13/20)
Persons with a history of SARS-CoV-2 infection (Final clinical considerations not yet posted as of 12/13/20)

- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
  - Data from phase 2/3 clinical trials suggest vaccination safe and likely efficacious in these persons

- Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making

Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20
Persons with known current SARS-CoV-2 infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) and criteria have been met to discontinue isolation

- 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

Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20
Persons who previously received passive antibody therapy for COVID-19  
(Final clinical considerations not yet posted as of 12/13/20)

- Currently no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment

- Vaccination should be deferred for at least 90 days 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

Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20
Persons with a known SARS-CoV-2 exposure

(Additional clinical considerations not yet posted as of 12/13/20)

- **Community or outpatient setting:**
  - Defer vaccination until **quarantine period** has ended to avoid exposing healthcare personnel (HCP) or other persons during vaccination visit

- **Residents of congregate healthcare settings (e.g., long-term care facilities):**
  - May be vaccinated, as likely would not result in additional exposures. HCP 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 of these individuals with other residents or non-essential staff

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Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20
**Persons with underlying medical conditions** *(Final clinical considerations not yet posted as of 12/13/20)*

- Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination

- Phase 2/3 clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities

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Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20
Immunocompromised persons (Final clinical considerations not yet posted as of 12/13/20)

- 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 unless otherwise contraindicated

- Individuals should be counseled about:
  - Unknown vaccine safety and efficacy profiles in immunocompromised persons
  - Potential for reduced immune responses
  - Need to continue to follow all current guidance to protect themselves against COVID-19

Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20
SARS-CoV-2 tests  (Final clinical considerations not yet posted as of 12/13/20)

- **Viral tests:** Prior receipt of the Pfizer-BioNTech 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
  - Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 vaccination, a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used
Interchangeability with other COVID-19 vaccine products
(Final clinical considerations not yet posted as of 12/13/20)

- Pfizer-BioNTech COVID-19 vaccine not interchangeable with other COVID-19 vaccine products
  - Safety and efficacy of a mixed series has not been evaluated

- Persons initiating series with Pfizer-BioNTech 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 (Final clinical considerations not yet posted as of 12/13/20)

- Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine

Amanda Cohn and Sarah Mbaeyi. What Clinicians Need to Know about Pfizer-BioNTech COVID19 Vaccine. CDC Partner Call 12-13-20
Pfizer contraindications and precautions
(Final clinical considerations not yet posted as of 12/13/20)

- Package insert:
  - Severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine is a contraindication to vaccination
  - Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine

- Because of reports of anaphylactic reactions in persons vaccinated outside of clinical trials, the additional following guidance is proposed:
  - A severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) is a precaution to vaccination at this time
  - Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
    - Persons with a history of anaphylaxis: 30 minutes
    - All other persons: 15 mins

Algorithm for the triage of persons presenting for Pfizer-COVID-19 vaccine

(Final clinical considerations not yet posted as of 12/13/20)

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<thead>
<tr>
<th>CONDITIONS</th>
<th>CONDITIONS</th>
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<td>• Immunocompromising conditions</td>
<td>• Moderate/severe acute illness</td>
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<td>• Pregnancy</td>
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<td>• Potential deferral of vaccination</td>
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<tr>
<td>ACTIONS</td>
<td>• 15-minute observation period if vaccinated</td>
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<tr>
<td>• Additional counseling*</td>
<td>• 15-minute observation period</td>
<td>• Do not vaccinate</td>
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<tr>
<td>• History of food, pet, insect, venom, environmental, latex, etc., allergies</td>
</tr>
<tr>
<td>• History of allergy to oral medications (including the oral equivalent of an injectable medication)</td>
</tr>
<tr>
<td>• Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis)</td>
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<tr>
<td>• Family history of anaphylaxis</td>
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<tr>
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<td>• History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine)</td>
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<td>• History of severe allergic reaction (e.g., anaphylaxis) to an injectable medication</td>
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<td>• 30-minute observation period if vaccinated</td>
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* See Special Populations section for information on patient counseling in these group

Administration (Final clinical considerations not yet posted as of 12/13/20)

- 2-dose series administered intramuscularly 3 weeks apart

- Administration of 2\textsuperscript{nd} dose within 4-day grace period (e.g., day 17-21) considered valid (but no doses need to be repeated)*

- If >21 days since 1\textsuperscript{st} dose, 2\textsuperscript{nd} dose should be administered at earliest opportunity (but no doses need to be repeated)

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

*personal communication, CDC 12-14-20
Reactogenicity (Final clinical considerations not yet posted as of 12/13/20)

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms

- 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
Public health recommendations for vaccinated persons
(Final clinical considerations not yet posted as of 12/13/20)

- 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

COVID-19 VACCINE 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.
Vaccination/Immunization Standing Orders

- Standing orders for vaccination facilitate the delivery of immunization services to patients
- Model standing orders for many routine vaccines and Emergency Treatment are available from IAC: [https://www.immunize.org/standing-orders/](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](https://www.immunize.org/catg.d/p3082.pdf)

**AFTER EUA ISSUED**

Stay tuned for clinical guidance, forms and other resources from CDC. They will be posted at:

- They will also be posted on other websites, we will share when known.
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)
- Use of a standardized form will facilitate effective screening

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
http://www.immunize.org/handouts/screening-vaccines.asp
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

Pfizer EUA fact sheet can be found at: https://www.fda.gov/media/144414/download

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

Pfizer EUA fact sheet can be found at: https://www.fda.gov/media/144413/download

https://www2.cdc.gov/vaccines/ed/covid19/SHVA/10070.asp
OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

<table>
<thead>
<tr>
<th>Website</th>
<th>Fax number</th>
<th>Telephone number</th>
</tr>
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ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

<table>
<thead>
<tr>
<th>Global website</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.cvdyvaccine.com">www.cvdyvaccine.com</a></td>
<td>1-877-829-2619 (1-877-VAX-CO19)</td>
</tr>
</tbody>
</table>

Pfizer EUA Factsheet for Providers: https://www.fda.gov/media/144413/download
### THAWING PRIOR TO DILUTION

<table>
<thead>
<tr>
<th>No more than 2 hours at room temperature (up to 25°C / 77°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:</td>
</tr>
<tr>
<td>- Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours).</td>
</tr>
<tr>
<td>- Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.</td>
</tr>
<tr>
<td>- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gently x 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Before dilution invert vaccine vial gently 10 times.</td>
</tr>
<tr>
<td>- Do not shake.</td>
</tr>
<tr>
<td>- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.</td>
</tr>
<tr>
<td>- Do not use if liquid is discolored or if other particles are observed.</td>
</tr>
</tbody>
</table>
**DILUTION**

- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.

COVID-19 EUA Factsheet for Providers: [https://www.fda.gov/media/144413/download](https://www.fda.gov/media/144413/download)
<table>
<thead>
<tr>
<th><strong>DILUTION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.</strong></td>
</tr>
<tr>
<td><strong>Do not shake.</strong></td>
</tr>
<tr>
<td><strong>Inspect the vaccine in the vial.</strong></td>
</tr>
<tr>
<td><strong>The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.</strong></td>
</tr>
<tr>
<td><strong>Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.</strong></td>
</tr>
<tr>
<td><strong>Store between 2°C to 25°C (35°F to 77°F).</strong></td>
</tr>
<tr>
<td><strong>Discard any unused vaccine 6 hours after dilution.</strong></td>
</tr>
</tbody>
</table>
**PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE**

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine.
- Administer immediately.

**Administration**

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,
- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

COVID-19 EUA Factsheet for Providers: [https://www.fda.gov/media/144413/download](https://www.fda.gov/media/144413/download)
After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Any vaccine remaining in vials must be discarded after 6 hours.

Do not refreeze.

COVID-19 EUA Factsheet for Providers: https://www.fda.gov/media/144413/download
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
Intramuscular (IM) Injection Procedure

Child/Adult: IM landmarks deltoid muscle; two-three fingers below acromion and above armpit

Note: Incorrect IM technique can result in should injury related to vaccine administration (SIRVA), manifests as shoulder pain and limited range of motion

# IM Injection Procedures: Needle sizes

<table>
<thead>
<tr>
<th>Route</th>
<th>Age</th>
<th>Needle gauge and length</th>
<th>Injection site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonate, 28 days and younger</td>
<td>22–25-gauge 5/8 inch (16 mm²)</td>
<td>Vastus lateralis muscle of anterolateral thigh</td>
<td></td>
</tr>
<tr>
<td>Infants, 1–12 months</td>
<td>22–25-gauge 1 inch (25 mm)</td>
<td>Vastus lateralis muscle of anterolateral thigh</td>
<td></td>
</tr>
<tr>
<td>Toddlers, 1–2 years</td>
<td>22–25-gauge 1–1.25 inches (25–32 mm)</td>
<td>Vastus lateralis muscle of anterolateral thigh ²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>22–25-gauge 5/8²–1 inch (16–25 mm)</td>
<td>Deltoid muscle of arm</td>
<td></td>
</tr>
<tr>
<td>Children, 3–10 years</td>
<td>22–25-gauge 5/8²–1 inch (16–25 mm)</td>
<td>Deltoid muscle of arm ³</td>
<td></td>
</tr>
<tr>
<td>Children, 11–18 years</td>
<td>22–25-gauge 5/8²–1 inch (16–25 mm)</td>
<td>Deltoid muscle of arm ³ ⁵</td>
<td></td>
</tr>
<tr>
<td>Adults, 19 years and older</td>
<td>22–25-gauge 1 inch (25 mm) ⁴</td>
<td>1 inch (25 mm) ⁴</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1-1.5 inches (25–38 mm)</td>
<td>1.5 inches (38 mm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women, 152–200 lbs (70–90 kg)</td>
<td>1.5 inches (38 mm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Men, 260 lbs (118 kg) or more</td>
<td>1.5 inches (38 mm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women, 200 lbs (90 kg) or more</td>
<td>1.5 inches (38 mm)</td>
<td></td>
</tr>
</tbody>
</table>

² If the skin is stretched tightly and subcutaneous tissues are not bunched.
³ Preferred site
⁴ Some experts recommend a 5/8-inch needle for men and women weighing less than 60 kg. If used, skin must be stretched tightly and subcutaneous tissues must not be bunched.
⁵ The vastus lateralis muscle in the anterolateral thigh can also be used. Most adolescents and adults will require a 1-to-1.5-inch (25–38 mm) needle to ensure intramuscular administration.

https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf
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/vac-admin.html
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html
Observation after Immunization

• When planning for vaccination during the COVID-19 pandemic, it is important to select a space large enough to ensure a minimum distance of 6 feet between patients (where possible) in line or in waiting areas for vaccination, between vaccination stations and in the post monitoring area.

• Walk-Through clinics: Strongly consider observing patients for 15 minutes after vaccination to decrease the risk of injury should they faint or other adverse events.

• Curbside or drive-through clinics: Drivers should be directed to a waiting area for 15 minutes and checked before they leave. This is critical at a drive-through immunization clinic because of the potential for injury when the vaccinated person is driving a car. If possible, this should be done in the same space the vaccination occurs, or in a staff monitored parking area.

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html
https://www.cdc.gov/vaccines/pandemic-guidance/index.html
https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/during-clinic-activities.html
https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/curbside-vaccination-clinics.html
VACCINE SAFETY
Safety is a Priority

During all phases of vaccine development, authorization or approval, and use

active surveillance

DoD VAECs
VA ADERS
NHSN
active surveillance

CDC + FDA
VAERS
Vaccine Adverse Event Reporting System

passive surveillance

CDC
Clinical Immunization Safety Assessment (CISA) Project

individual case consults

start of vax

active surveillance, passive surveillance, case consults

large-linked database monitoring

safety monitoring timeline

DoD DMSS
Defense Medical Surveillance System

VA EHR & data warehouse

VSD
Vaccine Safety Datalink

VA
US Department of Veterans Affairs

VA
US Department of Veterans Affairs

12/1/2020 ACIP meeting
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/reportevent.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/resources/infoproviders.html](https://vaers.hhs.gov/resources/infoproviders.html)
[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 associated with an AE or not)

• serious AEs (even if they are not sure if the vaccination caused the event)

• multisystem inflammatory syndrome (MIS) in children or adults, and

• cases of COVID-19 that result in hospitalization or death

https://www2.cdc.gov/vaccines/ed/covid19/SHVA/40020.asp
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
Getting Started:

- CDC will create an electronic version of the v-safe enrollment sheet for printing
- Healthcare providers give a one-page enrollment sheet to patients at the time of vaccination
- Healthcare providers counsel patients on the importance of enrolling in v-safe
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)

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.

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 restart v-safe again by texting “RESTART.”

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'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.

Learn more about v-safe
www.cdc.gov/vsafe
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 and submit a report online
- For help: call 1-800-822-7967, email info@VAERS.org
- Video instructions https://www.youtube.com/watch?v=sbCWhcQADFE

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
VACCINATING DURING THE COVID-19 PANDEMIC
Interim Guidance for Immunization Services During the COVID-19 Pandemic

Purpose of Guidance

Importance of Immunization Services During the COVID-19 Pandemic

Vaccine Recommendations During the COVID-19 Pandemic

Considerations for Routine Vaccination

Additional Considerations for Influenza Vaccination

Deferring Routine Vaccination Visits for Persons with Suspected or Confirmed COVID-19 Who Are in Isolation or Persons with a Known COVID-19 Exposure Who Are in Quarantine

Vaccine Administration During the COVID-19 Pandemic

General Practices for the Safe Delivery of Vaccination Services

Additional Considerations for Alternative Vaccination Sites

Additional Considerations for Influenza Vaccination of Persons in Healthcare Facilities and Congregate Settings During the COVID-19 Pandemic*

Patients who are already in healthcare settings (e.g., outpatient settings, emergency departments, or inpatient acute care)

Residents in congregate healthcare settings (e.g., post-acute and long-term care facilities, group homes, mental health inpatient facilities, and inpatient substance use disorder treatment centers)

Persons in correctional or detention facilities

https://www.cdc.gov/vaccines/pandemic-guidance/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)

- **Recommended**: All health care providers (N95 masks not recommended)
- **Recommended**: Areas of moderate/substantial community transmission
- **Optional**: Areas of minimal/no community transmission
- **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
Protective Measures for Vaccinating During the Pandemic

Minimize Chances for Patient Exposure

Share information with patients. Communicate with your patients in advance about measures that have been put in place to ensure their safety.

Screen for COVID-19. Screen patients for COVID-19 risk (e.g., possible exposure, pending test results, underlying medical conditions) and COVID-19 symptoms before and at the visit. Promptly isolate anyone exhibiting symptoms.

Separate well and sick patients. Plan vaccination services for well patients at different times and in different areas from the times and areas in which you provide sick patient care.

Ensure All Staff Follow Infection Control Guidance

Adhere to standard infection control precautions. Follow standard infection control precautions, including washing hands and/or using hand sanitizer and thoroughly cleaning the vaccination area between patients.

Wear PPE. Use appropriate personal protective equipment.

Face masks: Recommended for all healthcare providers (N95 masks not required for vaccination services).

Gloves: Recommended for intranasal or oral vaccines (FluMist or rotavirus); optional for intramuscular or subcutaneous injections. Change gloves and practice hand hygiene between patients.

Control Patient Flow. Limit and monitor facility points of entry, control direction of patient flow, and install barriers to limit physical contact between staff and patients at triage. Limit entry of non-essential visitors.

Maintain distance. Ensure physical distancing of at least 6 feet between patients and staff where feasible, except during vaccination.

Consider all needed vaccines. When possible, screen for and provide all vaccines due or overdue at the visit. If feasible, assess vaccine needs prior to the patient’s arrival to reduce in-person visit time.

Post signage. Prominently display reminders about face coverings (masks), physical distancing, and hygiene in patient areas.

Require masks. Require appropriate face covering for people age 2 years and older, if tolerated.

Ensure proper hygiene. Ensure respiratory hygiene, cough etiquette, and hand hygiene. Make hygiene supplies accessible, including hand sanitizer or soap and water, tissues, and waste receptacles.

Disinfect surfaces. Frequently decontaminate high touch surfaces in both patient and staff areas.

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

**VACCINES**

**Refrigerated vaccines**
- Select the vaccine(s) that will be offered at the clinic.
- Measles, mumps, and rubella (MMR)
- Meningococcal ACWY (MensACWY)
- Men/Influenza A2 (H3N2)
- Rabies vaccine
- Hepatitis B (HepB)
- Hepatitis B (HepB 20)
- Hepatitis A (HepA)
- Influenza vaccine
- Flu vaccine (TIV in season)
- Influenza, live attenuated intranasal (LAIV) (in season)

**Frozen vaccines**
(Frozen vaccines may only be administered at satellite, temporary, and off-site clinics if they can be safely shipped and monitored at the site. They should never be transported from their location to another site.)
- Measles, mumps, rubella, varicella (MMR, MMRv, Varicella)
- Varicella

**CLINICAL SUPPLIES**

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

**Additional supplies needed during the COVID-19 pandemic**
- Additional hand sanitizer with at least 60% alcohol for hand hygiene
- Additional cleaning equipment for more frequent cleanings, using EPA Registered Antimicrobial Products for Use Against 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

**Office supplies**
- Clipboards
- Notepads
- Pens
- Printer paper
- Printer, if applicable

**Additional supplies needed during the COVID-19 pandemic**
- Adhesive bandages
- Sterile alcohol prep pads
- Appropriate needles (length, gauge) for the route of administration (Subcut, IM) and the expected patient population
- Syringes (1 or 3 cc)

**MEASURING SUPPLIES**
- Blood pressure measuring device

**MEDICAL EMERGENCY SUPPLIES**

- Epinephrine in prefilled autoinjector or prefilled syringe (needle donors), prepackaged syringes, vials, or ampules (Epipens)
- Face mask
- First aid kit
- Additional supplies may include:
  - Blood pressure measuring device
  - Oxygen
  - Stethoscope
  - Fax machine
  - Blood pressure measuring device
  - Thermometer

**Additional supplies needed during the COVID-19 pandemic**
- Additional hand sanitizer with at least 60% alcohol for hand hygiene
- Additional cleaning equipment for more frequent cleanings, using EPA Registered Antimicrobial Products for Use Against 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

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

- Partitions
- Paper towels
- Sanitizing products for vaccination and preparation surfaces
- Sharps containers
- Tablets and bars for patient and vaccination provider at each vaccination station
- Vaccine storage units (passes or pass-through windows in pass-through) to maintain the appropriate vaccine cold chain
- Mailboxes

- Laptops, computers, tablets, or smartphones, as well as printers and 20 inkjet or color printers
- Including multiple plug outlet strips and extension cords
- Screening checklist to confirm vaccine for children, teens, and adults
- Vaccination standing orders and protocols, as necessary
- Patient information statement, (VIS) 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 (fridge or freezer)

Best Practices for Holding Safe Vaccination Clinics

CDC has also posted Resources for Hosting a Vaccination Clinic, where you can find a checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations, and other useful material.

- Best Practices Checklist
- Pledge for Organizations Holding Clinics
- Ten Principles for Holding Safe Clinics
- FAQs about checklist and pledge

https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/
Resources for Curbside/Drive-Through Vaccination Clinics

Also available from CDC is Considerations for Planning Curbside/Drive-Through Vaccination Clinics, which outlines some things to take into consideration when planning a curbside or drive-through clinic.

https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/curbside-vaccination-clinics.html
RESOURCES
HEALTHCARE PROVIDERS /PUBLIC HEALTH:
COVID-19 Vaccination
https://www.cdc.gov/vaccines/covid-19/index.html

Healthcare Professional: Preparing for COVID-19 Vaccination
https://www.cdc.gov/vaccines/covid-19/hcp/index.html

Preparing to Provide COVID-19 Vaccines to Your Patients
https://www.cdc.gov/vaccines/covid-19/hcp/prepare.html

Understanding and Explaining mRNA COVID-19 Vaccines
https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html

Talking to Patients about Covid-19 Vaccines
https://www.cdc.gov/vaccines/covid-19/hcp/talking-to-patients.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

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

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

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
COVID-19 Vaccine Resources

**CDC**
Pfizer-BioNTech COVID-19 Vaccine

**US FDA**
Covid-19 Vaccines website:

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

**TRAINING & RESOURCES:**
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

**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

Pfizer-BioNTech COVID-19 Vaccine Website:
https://www.cvdvaccine.com/
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
Vaccine Administration

Proper vaccine administration is critical to ensure that vaccination is safe and effective for the patient. This page offers comprehensive information for health care providers, including guidelines for vaccine administration.

**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**

It is important to screen for contraindications and precautions before administering vaccines.

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**Resource Library**

- **Vaccine Administration**
  - Updated: November 2020
  - Jittikan Chalal, PhD, RN, and Elaine Miller, MD, RN, MPH
  - This chapter summarizes best practices related to vaccine administration. It includes a series of articles covering patient status and determining needed vaccines, screening for contraindications, educating patients, preparing and administering vaccines, and documenting the vaccination administration. Proven standards for medication administration, manufacturer’s instructions, and organizational policies and procedures should always be followed.

- **Staff Training and Education**
  - Policies should be in place to validate health care professionals’ and staff’s vaccine administration. All health care professionals should be familiar with the vaccine administration guidelines.

**Web-based Training Courses**

- **Vaccine Administration e-Learn**
  - A self-paced vaccine administration course that provides comprehensive training using videos, job aids, and interactive modules.

- **You Call the Shots**
  - An interactive, web-based immunization training course that includes the latest guidelines and reconfirms vaccine practice.

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**CDC Vaccine Administration Resources**

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

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

• Describes the ACIPs recommendations and guidelines on vaccination practice

• Updated as needed online
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
- 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!