What Clinicians Need to Know About the Pfizer-BioNTech and Moderna COVID-19 Vaccines

Clinician Outreach and Communication Activity (COCA) Webinar

Friday, December 18, 2020
Continuing Education Disclaimer

- Continuing education will not be offered for this webinar.
Additional Information

- All participants joining us today are in listen-only mode.
- The video recording of this COCA Call will be posted at https://emergency.cdc.gov/coca/calls/2020/callinfo_121820.asp and available to view on-demand a few hours after the call ends.
- If you are a patient, please refer your questions to your healthcare provider.
- For media questions, please contact CDC Media Relations at 404-639-3286, or send an email to media@cdc.gov.
Today’s Presenters

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  CAPT, U.S. Public Health Service  
  Lead, Vaccine Planning Unit  
  COVID-19 Response  
  Centers for Disease Control and Prevention

- Sarah Mbaeyi, MD, MPH  
  CDR, U.S. Public Health Service  
  Medical Officer  
  National Center for Immunization and Respiratory Diseases  
  Centers for Disease Control and Prevention

- Sara Oliver, MD  
  LCDR, U.S. Public Health Service  
  Co-lead, Advisory Committee for Immunization Practices COVID-19 Vaccines WG  
  COVID-19 Response  
  Centers for Disease Control and Prevention
What Clinicians Need to Know About the Pfizer-BioNTech and Moderna COVID-19 Vaccines

CAPT Amanda Cohn, MD
CDR Sarah Mbaeyi, MD, MPH
LCDR Sara Oliver, MD

December 18, 2020

For more information: www.cdc.gov/COVID19
Pfizer-BioNTech and Moderna COVID-19 Vaccines
mRNA COVID-19 vaccines

- Two mRNA COVID-19 vaccines likely to be available in next week
  - Pfizer-BioNTech vaccine authorized by FDA on December 11, 2020
  - VRPBAC voted to support authorization of Moderna vaccine on December 17, 2020

- Both products demonstrate vaccine effectiveness >90%
  - Effectiveness demonstrated across age groups, racial and ethnic groups

- Vaccine safety profile of both products acceptable
  - Imbalance of Bell’s Palsy but still within expected range
  - Local and systemic reactogenicity, particularly after second dose
Messenger RNA vaccines

- Provides instruction directly to the immune system (Spike protein)
- Efficiently creates specific immune memory in a natural context (*in situ*)
- mRNA can neither interact with nor integrate into DNA

Source: https://www.fda.gov/media/144583/download
Spike protein-encoded mRNA

SARS-CoV-2 spike protein trimer

Encoded mRNA

Ribosome

Viral spike proteins

Golgi

S1 subunit

S2 subunit

Endoplasmic Reticulum

Nucleus

Cytoplasm

Source: https://www.fda.gov/media/144583/download
CD4+ T cell

CD8+ T cell

B cell

Antigen presenting cell

Spike protein encoded mRNA

LNP

Neutralizing antibodies

Cell mediated immunity

Source: https://www.fda.gov/media/144583/download
### Ingredients* included in mRNA COVID-19 vaccines

<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech COVID-19 vaccine</th>
<th>Moderna COVID-19 vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>mRNA</strong></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><strong>Lipids</strong></td>
<td>2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide</td>
<td>1 monomethoxypolyethyleneglycol-2,3-dimyristylglycerol with polyethylene glycol of average molecular weight 2000 (PEG2000-DMG)</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)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)</td>
<td>SM-102 (proprietary to Moderna)</td>
</tr>
<tr>
<td><strong>Salts and Sugars</strong></td>
<td>potassium chloride</td>
<td>Tris buffer containing sucrose and sodium acetate</td>
</tr>
<tr>
<td></td>
<td>monobasic potassium phosphate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>sodium chloride</td>
<td></td>
</tr>
<tr>
<td></td>
<td>dibasic sodium phosphate dihydrate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>sucrose</td>
<td></td>
</tr>
</tbody>
</table>

*As reported in the prescribing information*
Advisory Committee on Immunization Practices (ACIP) Recommendations
On December 12, 2020, ACIP recommended use of the Pfizer-BioNTech COVID-19 vaccine in persons 16 years of age and older under the FDA’s Emergency Use Authorization.

On December 19, 2020, ACIP will consider use of Moderna COVID-19 vaccine in persons 18 years of age and older if authorized by FDA.

ACIP recommends that when a COVID-19 vaccine is authorized by FDA and recommended by ACIP, that 1) health care personnel and 2) residents of long-term care facilities be offered vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a).

ACIP will consider next prioritization groups (Phase 1b and 1c) on December 20, 2020.
Clinical considerations for use of mRNA COVID-19 vaccines

- CDC clinical considerations for use of Pfizer-BioNTech COVID-19 vaccine presented to ACIP on December 12, 2020
  - Final considerations published to CDC website: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html

- Clinical considerations will be updated to include information on both authorized mRNA vaccine products

- Informed by data submitted to the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the vaccine, other data sources, general best practice guidelines for immunization, and expert opinion
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

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

# Algorithm for the triage of persons presenting for mRNA COVID-19 vaccine

## Conditions

<table>
<thead>
<tr>
<th>Conditions</th>
<th>May Proceed with Vaccination</th>
<th>Precaution to Vaccination</th>
<th>Contraindication to Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Allergies</strong></td>
<td>History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies</td>
<td>History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine)</td>
<td>History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine</td>
</tr>
<tr>
<td><strong>Actions</strong></td>
<td>Additional information provided*</td>
<td>Risk assessment</td>
<td>Do not vaccinate</td>
</tr>
<tr>
<td></td>
<td>30 minute observation period</td>
<td>Potential deferral of vaccination</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15 minute observation period</td>
<td>30 minute observation period if vaccinated</td>
<td></td>
</tr>
</tbody>
</table>

*See Special Populations section for information on patient counseling in these groups.

## Conditions

- Immunocompromising conditions
- Pregnancy
- Lactation

**Actions:**
- 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause
- 15 minute observation period: Persons with allergic reaction, but not anaphylaxis

- Moderate/severe acute illness

**Actions:**
- Risk assessment
- Potential deferral of vaccination
- 15 minute observation period if vaccinated

- None

**Actions:**
- N/A

- Immunocompromising conditions
- Pregnancy
- Lactation

**Actions:**
- Risk assessment
- Potential deferral of vaccination
- 15 minute observation period if vaccinated

- Moderate/severe acute illness

**Actions:**
- Risk assessment
- Potential deferral of vaccination
- 15 minute observation period if vaccinated

- None

**Actions:**
- N/A

- Immunocompromising conditions
- Pregnancy
- Lactation

**Actions:**
- Risk assessment
- Potential deferral of vaccination
- 15 minute observation period if vaccinated

- Moderate/severe acute illness

**Actions:**
- Risk assessment
- Potential deferral of vaccination
- 15 minute observation period if vaccinated

- None

**Actions:**
- N/A

## Allergies

- History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies
- History of allergy to oral medications (including the oral equivalent of an injectable medication)
- Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis)
- Family history of anaphylaxis
- Any other history of anaphylaxis that is not related to a vaccine or injectable therapy

**Actions:**
- 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause
- 15 minute observation period: Persons with allergic reaction, but not anaphylaxis

- History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine)
- History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy

**Actions:**
- Risk assessment
- Potential deferral of vaccination
- 30 minute observation period if vaccinated

- History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine

**Actions:**
- Do not vaccinate

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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

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html
Recommended medications and supplies for the management of anaphylaxis at COVID-19 vaccination sties

<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 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.
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
Infection prevention and control recommendations for persons with post-vaccination symptoms

- Healthcare personnel
- Long-term care facility residents

Infection prevention and control considerations for residents of long-term care facilities with systemic signs and symptoms following COVID-19 vaccination

Note: Strategies are needed by long-term care facilities to appropriately evaluate and manage post-vaccination signs and symptoms among their residents. The approach described in this document is intended to balance:

- Unnecessarily excluding HCP with only post-vaccination signs and symptoms from work, and
- Inadvertently allowing HCP with SARS-CoV-2 or another transmissible infection to work.

These considerations are based on the current understanding of signs and symptoms following COVID-19 vaccination, including timing and duration, and might change as experience with the vaccine accumulates.

Overview

Systemic signs and symptoms, such as fever, fatigue, headache, chills, myalgia, and arthralgia, can occur following COVID-19 vaccination. Preliminary data from mRNA COVID-19 vaccine trials indicate that most systemic post-vaccination signs and symptoms are mild to moderate in severity, occur within the first three days of vaccination (the day of vaccination and following two days, with most occurring the day after vaccination), resolve within 1-2 days of onset, and are more frequent and severe following the second dose and among younger persons compared to those who are older (>55 years). Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms, and instead may be symptoms of SARS-CoV-2 or another infection.

Because systemic post-vaccination signs and symptoms might be challenging to distinguish from signs and symptoms of COVID-19 or other infectious diseases, HCP with postvaccination signs and symptoms should be closely monitored. Additional recommendations for healthcare personnel with systemic signs and symptoms following COVID-19 vaccination:

Based Precautions for healthcare personnel with systemic signs and symptoms

- Apply mask to reduce transmission of respiratory viruses
- Wash hands
- Avoid touching eyes, nose, and mouth
- Use a face shield
- Wear disposable gloves
- After clinical encounter, wash hands

Extensive asymptomatic transmission can occur for SARS-CoV-2. When caring for patients in other settings, such as long-term care facilities, these restrictions may vary and might change as the situation evolves.
Answers to Your Questions
Resources
FDA EUA resources

- **FDA COVID-19 EUA**
  - [https://www.fda.gov/media/144412/download](https://www.fda.gov/media/144412/download)

- **FDA COVID-19 Information**

- **FDA EUA Guidance**
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Today’s COCA Call Will Be Available On-Demand

- **When:** A few hours after the live call
- **What:** Video recording
- **Where:** On the COCA Call webpage at [https://emergency.cdc.gov/coca/calls/2020/callinfo_121820.asp](https://emergency.cdc.gov/coca/calls/2020/callinfo_121820.asp)
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October 31 at 1:18pm

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