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

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- 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

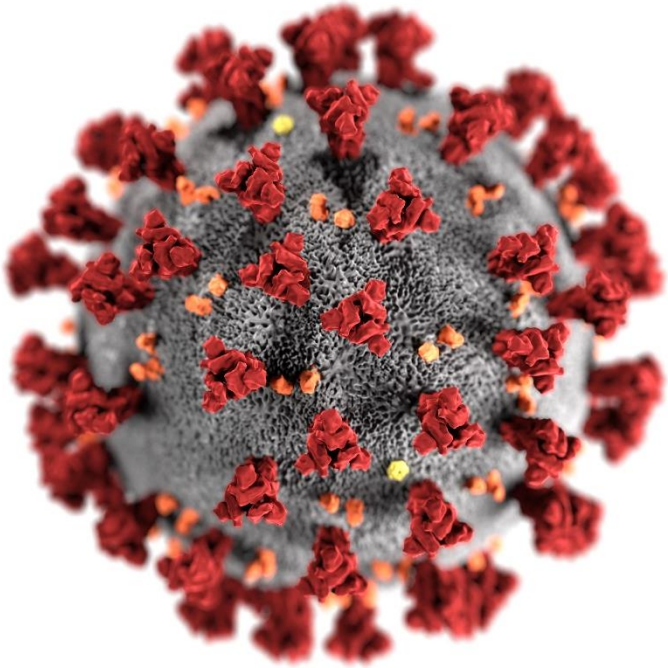
- **Amanda Cohn, MD**
  CAPT, U.S. Public Health Service
  Lead, Vaccine Planning Unit
  COVID-19 Response
  Centers for Disease Control and Prevention

- **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

COVID 19
CORONAVIRUS DISEASE

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

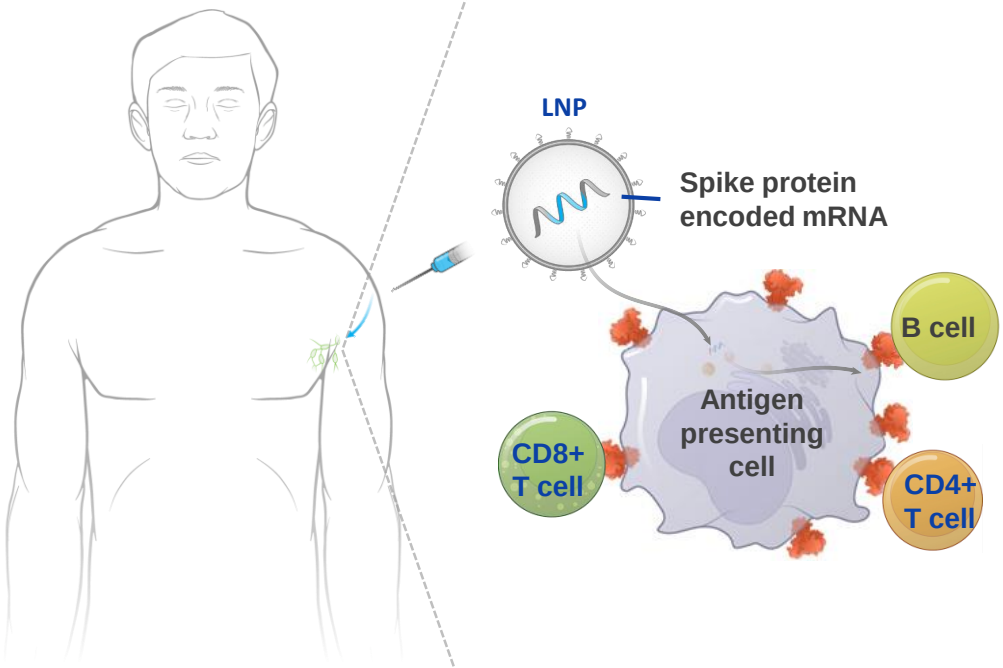
December 18, 2020

For more information: **www.cdc.gov/COVID19**

Pfizer-BioNTech and Moderna COVID-19 Vaccines

mRNA COVID-19 vaccines

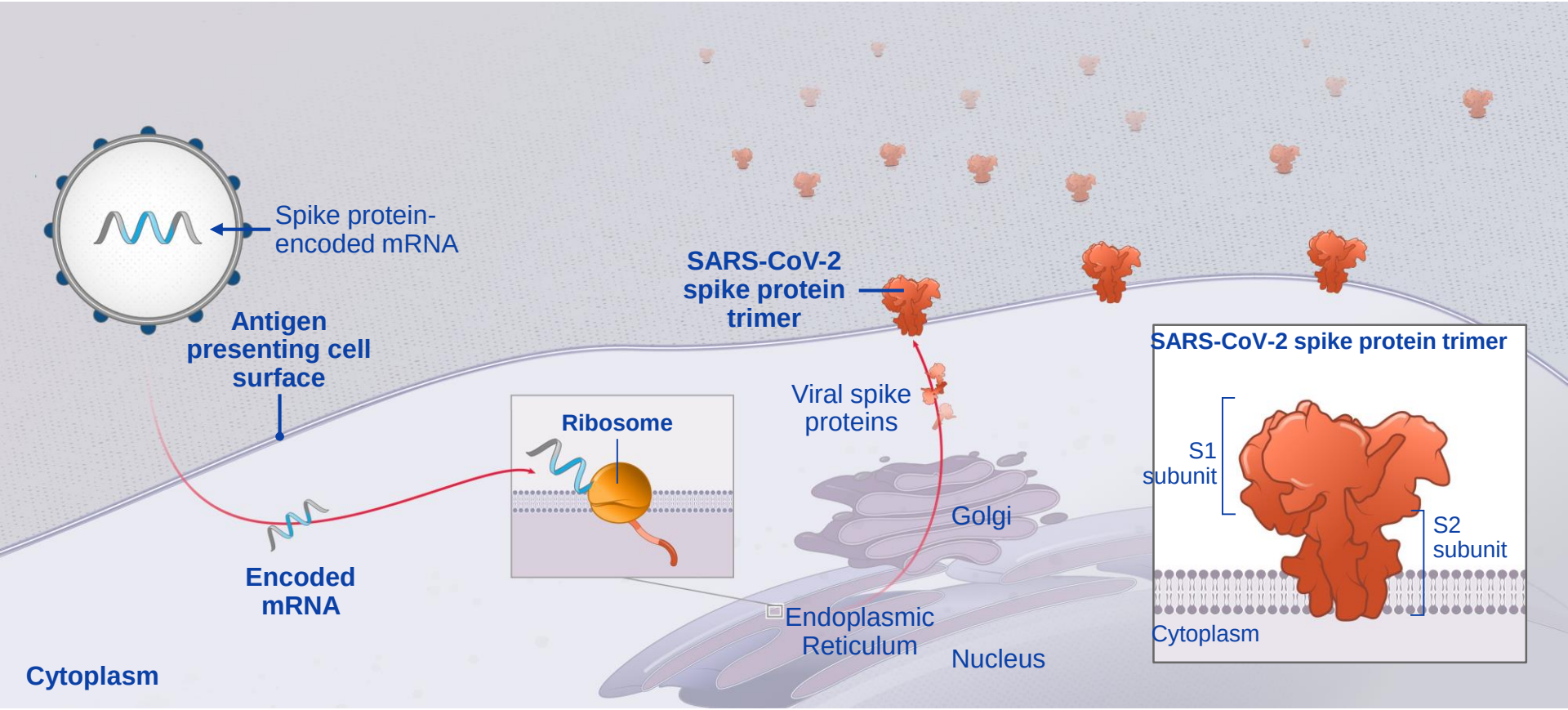
- Two mRNA COVID-19 vaccines likely to be available in next week
  - Pfizer-BioNTech vaccine authorized by FDA on December 11, 2020
  - VRPBAC voted to support authorization of Moderna vaccine on December 17, 2020
- Both products demonstrate vaccine effectiveness >90%
  - Effectiveness demonstrated across 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



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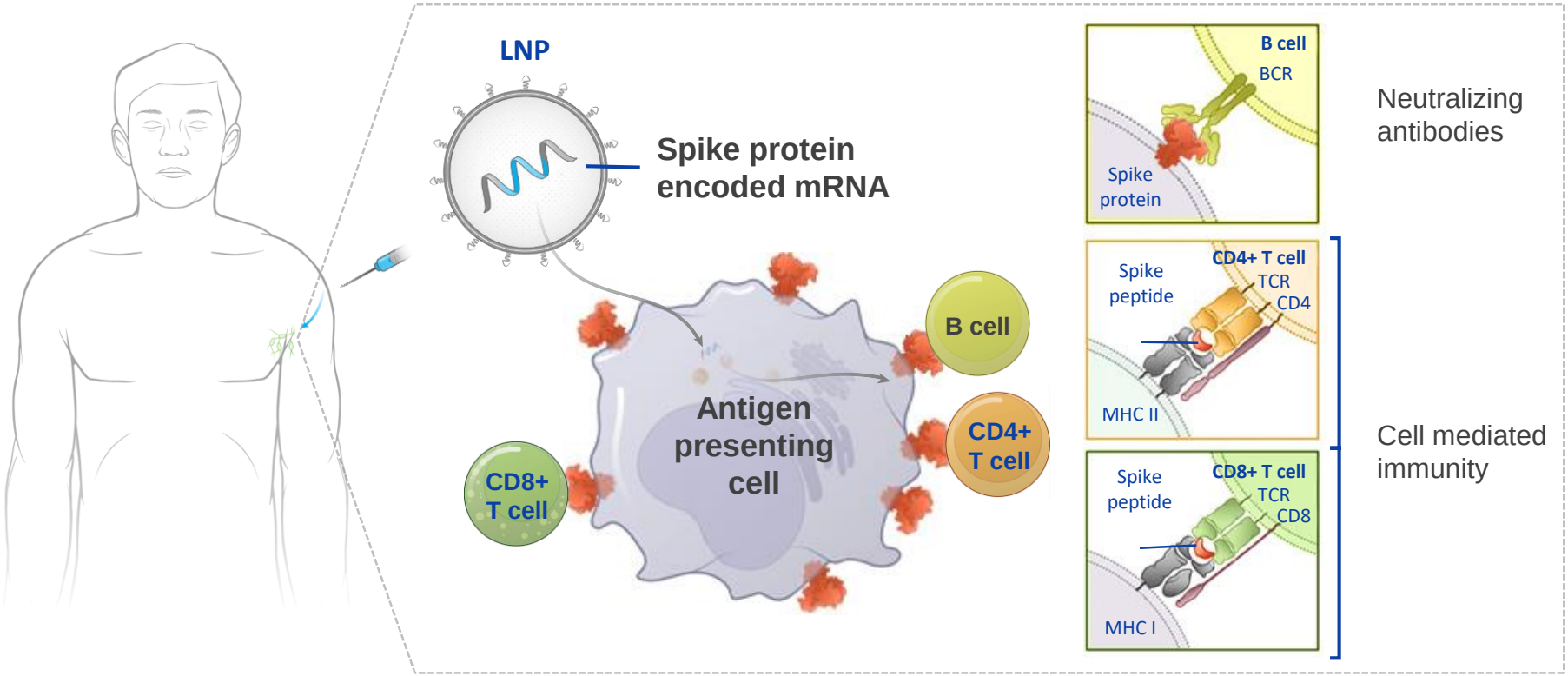


Source: https://www.fda.gov/media/144583/download

Ingredients* included in mRNA COVID-19 vaccines

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	1 monomethoxypolyethyleneglycol-2,3-dimyristylglycerol with polyethylene glycol of average molecular weight 2000 (PEG2000-DMG)
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	cholesterol	cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102 (proprietary to Moderna)
Salts and Sugars	potassium chloride	Tris buffer containing sucrose and sodium acetate
	monobasic potassium phosphate	
	sodium chloride	
	dibasic sodium phosphate dihydrate	
	sucrose	

*As reported in the prescribing information

Advisory Committee on Immunization Practices (ACIP) Recommendations

ACIP recommendations for use of COVID-19 vaccines

- 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

Reactogenicity

- 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

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-manufacturer%2Fpfizer%2Freactogenicity.html

Public health recommendations for vaccinated persons

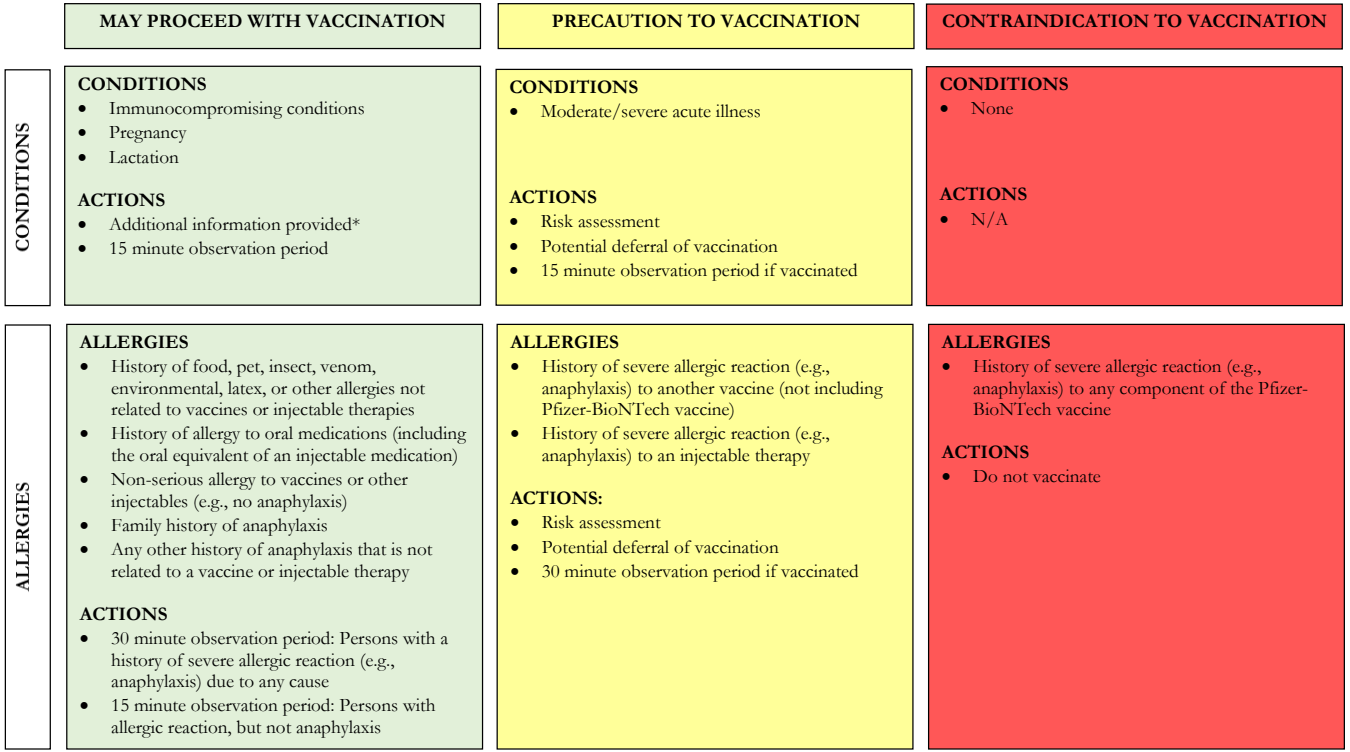
- Protection from vaccine is not immediate; vaccine is a 2-dose series and will take 1 to 2 weeks following the second dose to be considered fully vaccinated

- No vaccine is 100% effective

- Given the currently limited information on how well the vaccine works in the general population; how much it may reduce disease, severity, or transmission; and how long protection lasts, vaccinated persons should continue to follow all current guidance to protect themselves and others, including:
  - Wearing a mask
  - Staying at least 6 feet away from others
  - Avoiding crowds
  - Washing hands often
  - Following CDC travel guidance
  - Following quarantine guidance after an exposure to someone with COVID-19
  - Following any applicable workplace or school guidance

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

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

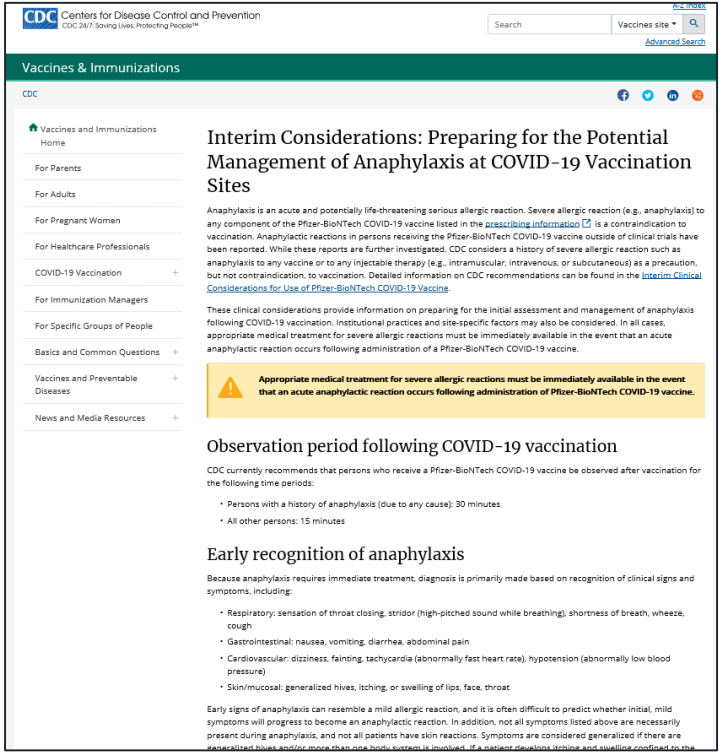


	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15 minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**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	**ALLERGIES** • 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	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine **ACTIONS** • Do not vaccinate

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

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

- 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

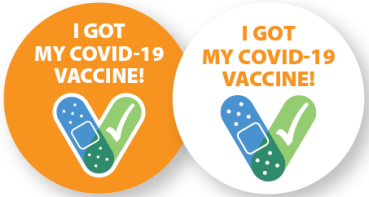
Should be available at all sites	Include at sites where feasible
Epinephrine prefilled syringe or autoinjector*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine)†	Oxygen
Blood pressure cuff	Bronchodilator (e.g., albuterol)
Stethoscope	H2 antihistamine (e.g., famotidine, cimetidine)
Timing device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

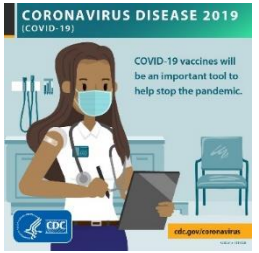
*COVID-19 vaccination sites should have at least 5 doses of epinephrine on hand at any given time.

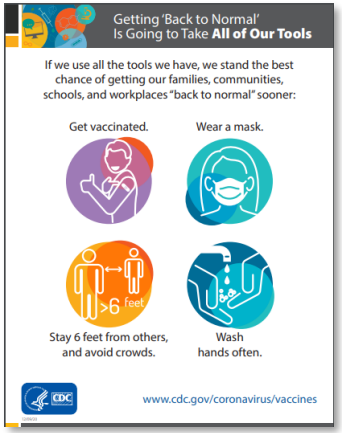
†Antihistamines may be given as adjunctive treatment and should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to persons with impending airway obstruction.

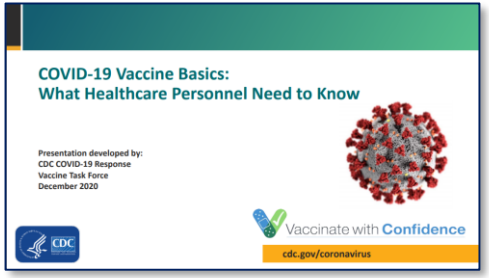
COVID-19 vaccine communication resources

- 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



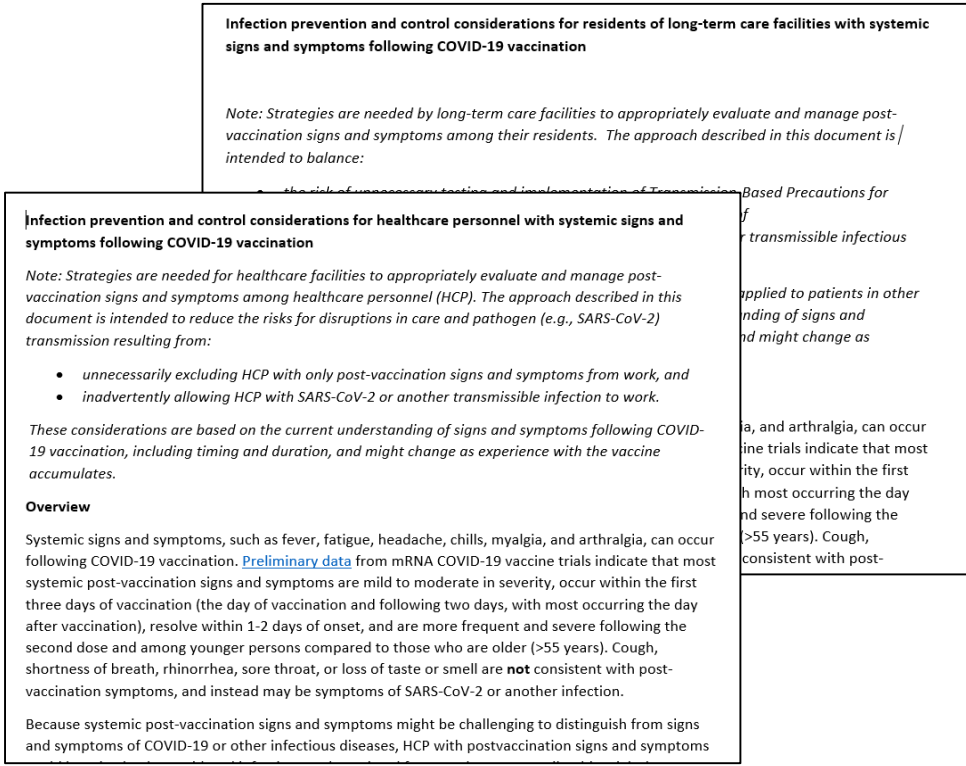






Infection prevention and control recommendations for persons with post-vaccination symptoms

- 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:

Infection prevention and control considerations for healthcare personnel with systemic signs and symptoms following COVID-19 vaccination

Note: Strategies are needed for healthcare facilities to appropriately evaluate and manage post-vaccination signs and symptoms among healthcare personnel (HCP). The approach described in this document is intended to reduce the risks for disruptions in care and pathogen (e.g., SARS-CoV-2) transmission resulting from:

- *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

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

Answers to Your Questions

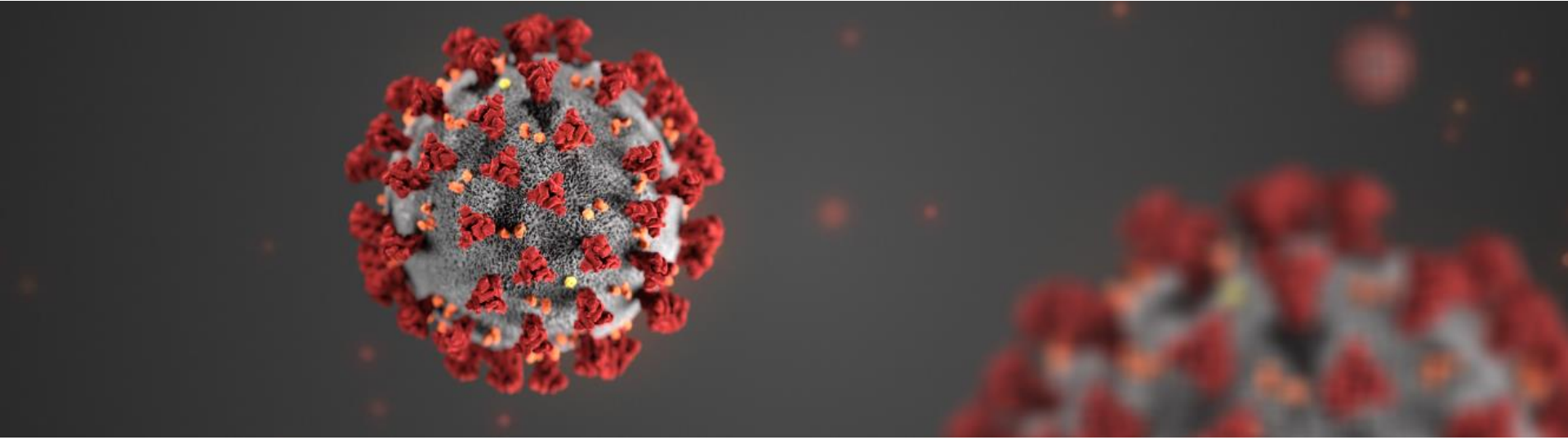
Resources

FDA EUA resources

- FDA COVID-19 EUA
  - https://www.fda.gov/media/144412/download

- FDA COVID-19 Information
  - https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

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



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you

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

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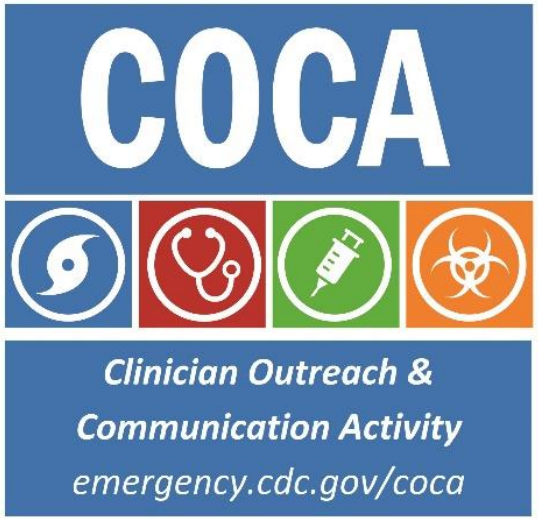

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