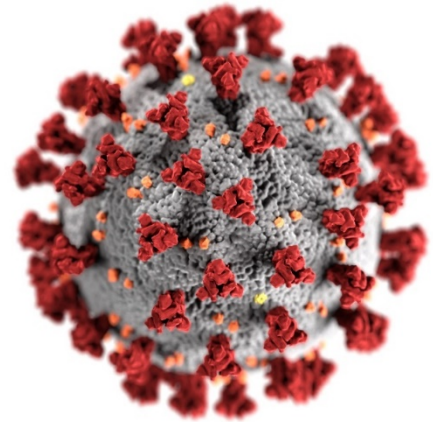


Building Confidence in COVID-19 Vaccines Among Your Patients and What HCP Need to Know

Tips for the Healthcare Team

Developed by:
CDC COVID-19 Response
Vaccine Task Force
December 2020
USF COVID Vaccine Taskforce



Vaccinate with **Confidence**

cdc.gov/coronavirus

Presentation Overview

- COVID-19 vaccines
- mRNA vaccine technology
- Vaccine safety monitoring
- Elements of vaccine confidence
- Strategies for building vaccine confidence
- Strategies for talking with patients about COVID-19 vaccine



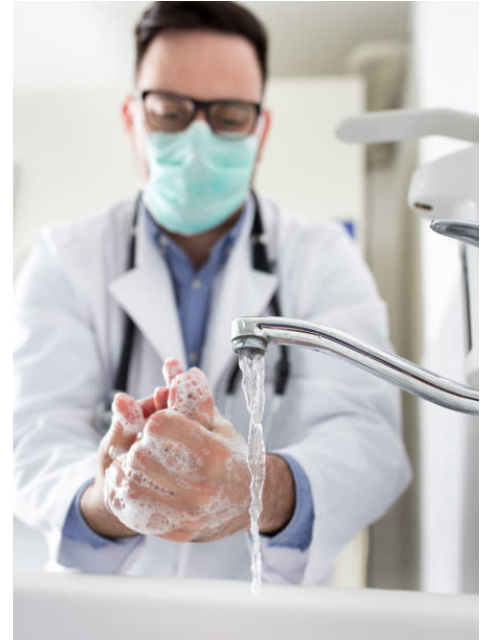
What we know about COVID-19

- Infection with SARS-CoV-2, the virus that causes COVID-19, can result in a range of illnesses, from mild symptoms to severe illness and death.
- We don't know how SARS-CoV-2 will affect each person.
- Some people are more likely than others to become severely ill, such as older adults (65+ years) or people with certain medical conditions.



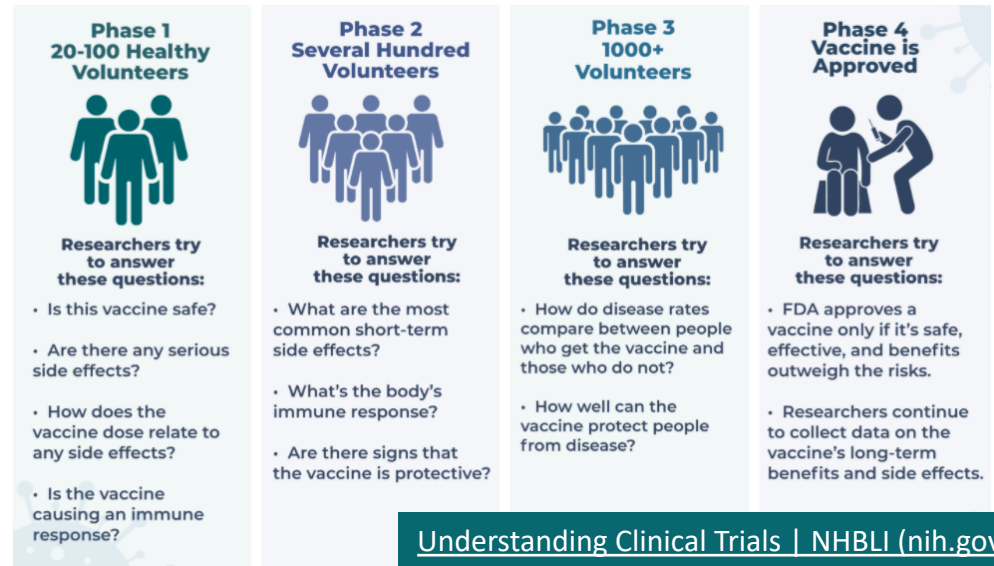
How to prevent COVID-19

- Wear a mask that covers your mouth and nose.
- Avoid close contact with others. Stay at least 6 feet (about 2 arms' length) from other people.
- Avoid touching your eyes, nose, and mouth with unwashed hands.
- Clean and disinfect frequently touched surfaces daily.
- Wash hands often with soap and water.
- Use an alcohol-based hand sanitizer with at least 60% alcohol if soap and water are not available.



Adding new measures for prevention: COVID-19 vaccines

- Multiple COVID-19 vaccines are in development, several of which are in large scale (Phase 3) trials.
- FDA's Emergency Use Authorization is a process that helps facilitate the availability and use of medicines and vaccines during public health emergencies, such as the current COVID-19 pandemic.
- COVID-19 vaccines are being held to the **same safety standards** as all vaccines.



Healthcare personnel are first in line for COVID-19 vaccine



COVID-19 vaccines, mRNA Vaccine Technology, and Vaccine Safety Monitoring

Healthcare personnel: A priority for COVID-19 vaccination

- On the front lines and at risk of exposure
- Can potentially transmit the virus that causes COVID-19 to patients, their families, and their communities
- Can positively influence vaccination decisions of peers, patients, friends, and family
- *Healthcare personnel* = paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials – not exclusive to medical personnel, includes administration, support staff, etc.



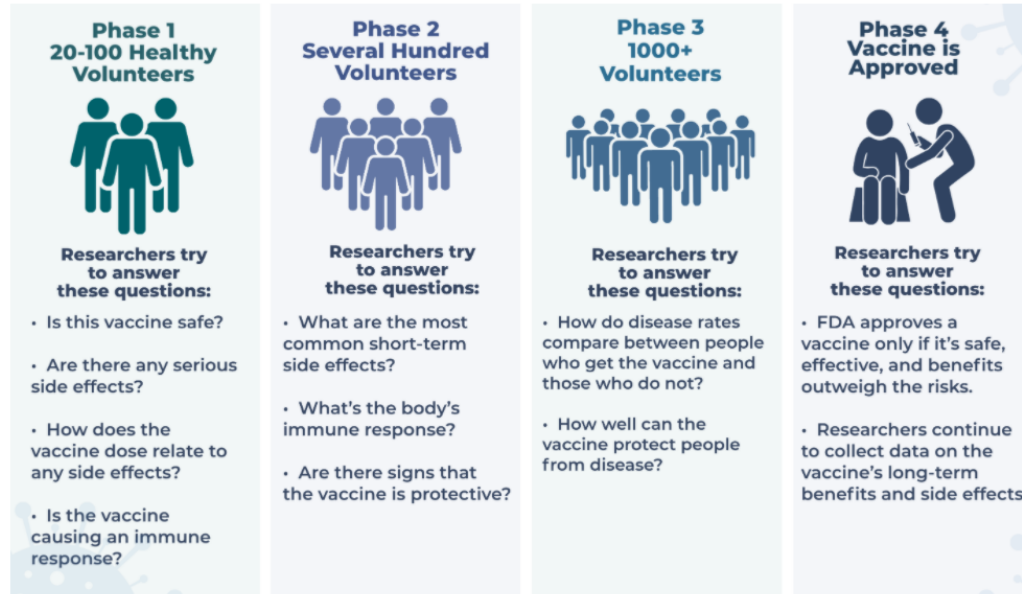
COVID-19 vaccines under development

- The federal government is funding and coordinating the development of multiple vaccine candidates, several of which are in large-scale (Phase 3) trials.
- COVID-19 vaccines are being held to the **same safety standards** as all other vaccines.



Phases of clinical trials

- There are four phases of clinical trials



Source: <https://covid19community.nih.gov/resources/understanding-clinical-trials>



COVID-19 vaccines expected to receive FDA Emergency Use Authorizations

- Two vaccines are expected to receive FDA Emergency Use Authorizations (EUAs):
 - **Pfizer/BioNTech (BNT162b2)** – 95% effective (manufacturer data)
 - **Moderna (mRNA-1273)** – 94.5% effective (manufacturer data)
- Both are mRNA vaccines with a 2-dose schedule.
- Duration of protection is not yet known.
- Both vaccines were tested in diverse adult populations, including older adults and communities of color.
- For the latest information about authorized vaccines, visit www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.



Sources: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine>
<https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy>

COVID-19 vaccine trials by the numbers

As of November 30, 2020

Pfizer/BioNTech

- **43,931** enrolled
- **150** clinical sites
 - 39 U.S. states
- Racial/ethnic distribution
 - **13%** - Hispanic
 - **10%** - African American
 - **6%** - Asian
 - **1%** - Native American
- **45%** ages 56-85

Moderna

- **30,000** enrolled
- **89** clinical sites
 - 32 U.S. states
- Racial/ethnic distribution
 - **63%** - White
 - **20%** - Hispanic
 - **10%** - African American/Black
 - **4%** - Asian
 - **3%** - All others
- **64%** ages 45 and older
 - 39% ages 45-64
 - 25% ages 65+

Sources: <https://www.pfizer.com/science/coronavirus/vaccine>;
<https://www.modernatx.com/cove-study>
For more information, visit www.clinicaltrials.gov



What are messenger RNA (mRNA) vaccines?

- Carry genetic material that teaches our cells how to make a harmless piece of “spike protein,” which is found on the surface of the SARS-CoV-2 virus.
 - Genetic material from the vaccine is destroyed by our cells once copies of the spike protein are made and it is no longer needed.
- Cells display this piece of spike protein on their surface, and an immune response is triggered inside our bodies. This produces antibodies to protect us from getting infected if the SARS-CoV-2 virus enters our bodies.
- Do not affect our DNA; mRNA does not enter the cell nucleus.
- Cannot give someone COVID-19.
- Use technology that is new but not unknown. mRNA vaccines have been studied for influenza, Zika, rabies, and cytomegalovirus (CMV).



Sources: College of Physicians of Philadelphia. What is an mRNA vaccine? <https://historyofvaccines.blog/2020/07/29/what-is-an-mrna-vaccine/>
JAMA. COVID-19 and mRNA Vaccines—First Large Test for a New Approach. <https://jamanetwork.com/journals/jama/fullarticle/2770485>

About these COVID-19 mRNA vaccines

- These mRNA vaccines are expected to produce side effects after vaccination, especially after the 2nd dose.
 - Side effects may include:
 - Fever
 - Headache
 - Muscle aches
- No significant safety concerns were identified in the clinical trials.
- At least 8 weeks of safety data were gathered in the trials. It is unusual for side effects to appear more than 8 weeks after vaccination.



Safety of COVID-19 vaccines is a top priority

- COVID-19 vaccines are being held to the same safety standards as all vaccines.
- FDA's [Vaccines and Related Biological Products Advisory Committee \(VRBPAC\)](#) reviews applications for EUAs.
- The [Advisory Committee on Immunization Practices \(ACIP\)](#) considers safety and efficacy data before recommending use.
- VRBPAC and ACIP are independent committees composed of scientific and clinical experts.
- FDA and CDC monitor vaccine safety and side effects once vaccines are in use.



Robust vaccine safety monitoring systems exist

- **Existing** systems and data sources are used to monitor safety of vaccines post-authorization and post-licensure, such as:
 - [Vaccine Adverse Event Reporting System \(VAERS\)](#)
 - [Vaccine Safety Datalink \(VSD\)](#)
 - [Clinical Immunization Safety Assessment \(CISA\)](#)
 - [Biologics Effectiveness and Safety System \(BEST\)](#)
- **New** systems have been developed to monitor COVID-19 vaccine safety, such as **v-safe**:
 - Active surveillance that uses text messaging to initiate web-based survey monitoring.
 - Will provide telephone follow up to anyone who reports medically significant adverse events.



How was the vaccine development timeline accelerated while ensuring safety?

- Researchers used existing clinical trial networks to begin conducting COVID-19 vaccine trials.
- Manufacturing was started while the clinical trials were still underway. Normally, manufacturing doesn't begin until after completion of the trials.
- mRNA vaccines are faster to produce than traditional vaccines.
- FDA and CDC are prioritizing review, authorization, and recommendation of COVID-19 vaccines.

*For more information, visit the COVID-19 Prevention Network:
www.coronaviruspreventionnetwork.org/about-covpn



Elements of Vaccine Confidence

The Problem: Patients may be hesitant to receive COVID-19 Vaccine

- Only **58%** of the general public said they would receive a COVID-19 vaccine

Factors weighing on acceptance




Are there side effects?

Does it work?

Is it safe?

How much does it cost?

COVID-19 vaccine more acceptable if:



Healthcare team said it was safe

No costs to the individual

It would help get back to school and work

They could get it easily



Tyson, A, Johnson, C, & Funk, C. (2020, September 17). *U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine*. Pew Research Center. <https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/>

Jackson, C., & Newall, M. (2020, September 29). *Despite COVID-19 spike, few individual behaviors are changing*. Ipsos. <https://www.ipsos.com/en-us/news-polls/axios-ipsos-coronavirus-index>

Vaccine hesitancy among healthcare providers

- American Nursing Foundation Survey (Oct 2020)
 - 63% were somewhat or very confident that the vaccine will be safe and effective.
 - 34% would voluntarily receive COVID-19 vaccine.
 - 57% are comfortable discussing COVID-19 vaccines with patients.
- CDC web survey of healthcare providers (Sept-Oct 2020)
 - 63% said they would get a COVID-19 vaccine.

Sources:

1. American Nurses Foundation, Pulse on the Nation's Nurses COVID-19 Survey Series: COVID-19 Vaccine, October 2020.
<https://www.nursingworld.org/practice-policy/work-environment/health-safety/disaster-preparedness/coronavirus/what-you-need-to-know/covid-19-vaccine-survey>
2. Lindley, et al. CDC COVID-19 Response Team. Report in progress.

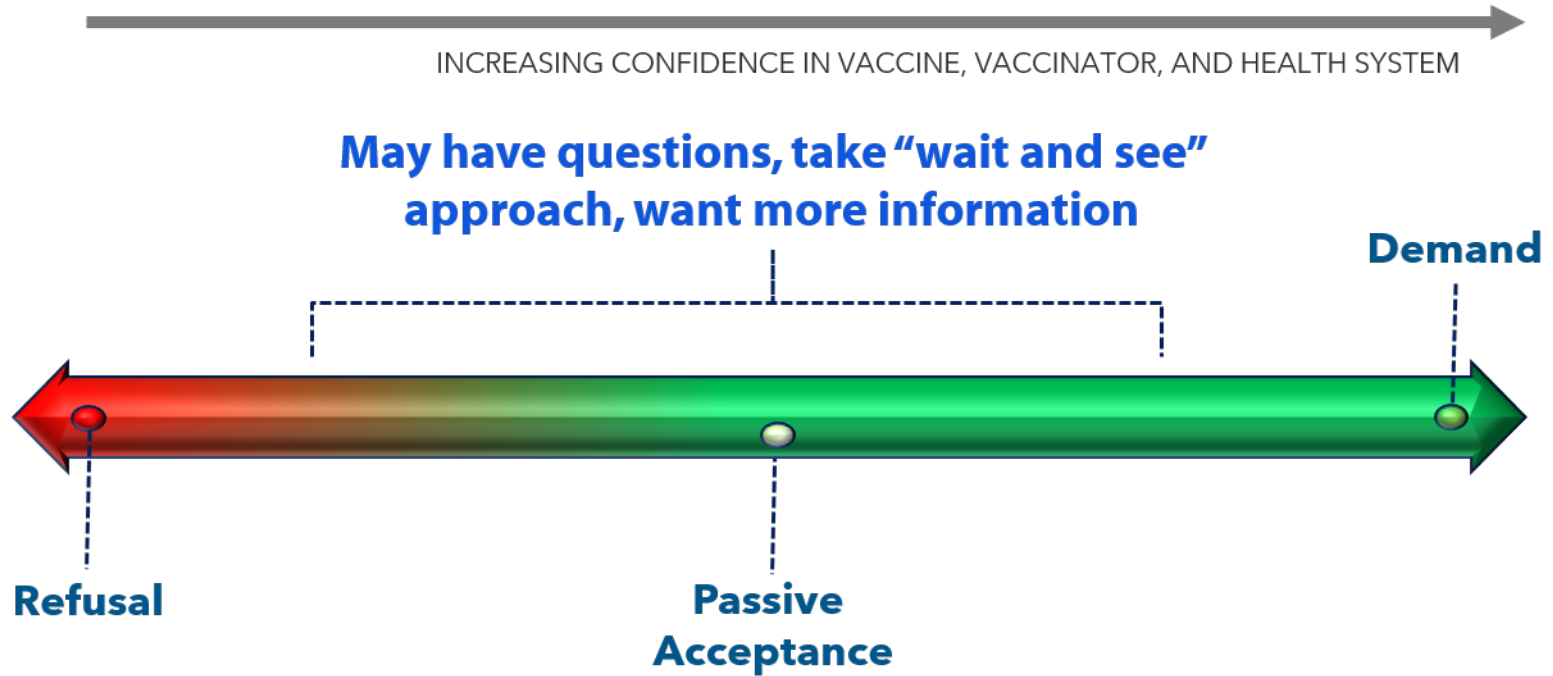


Defining vaccine confidence

- *Vaccine confidence* is the trust that patients, parents, or providers have in:
 - recommended vaccines;
 - providers who administer vaccines; and
 - processes and policies that lead to vaccine development, licensure, manufacturing, and recommendations for use.



Willingness to accept a vaccine falls on a continuum



Strategies for Building Vaccine Confidence



Vaccinate with **Confidence**

A National Strategy to Reinforce Confidence in COVID-19 vaccines

Build Trust

Objective: Share clear, complete, and accurate messages about COVID-19 vaccines and take visible actions to build trust in the vaccine, the vaccinator, and the system in coordination with federal, state, and local agencies and partners.

Empower Healthcare Personnel

Objective: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.

Engage Communities & Individuals

Objective: Engage communities in a sustainable, equitable, and inclusive way—using two-way communication to listen, build trust, and increase collaboration.



Vaccinate with **Confidence**

A component of the National Strategy to Reinforce Confidence in COVID-19 vaccines

Empower Healthcare Personnel

Objective: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.

- Tactics**
- ✓ Engage national professional associations, health systems, and healthcare personnel often and early to ensure a clear understanding of the vaccine development and approval process, new vaccine technologies, and the benefits of vaccination.
 - ✓ Ensure healthcare systems and medical practices are equipped to create a culture that builds confidence in COVID-19 vaccination.
 - ✓ Strengthen the capacity of healthcare professionals to have empathetic vaccine conversations, address myths and common questions, provide tailored vaccine information to patients, and use motivational interviewing techniques when needed.



Vaccine confidence starts with you!

- As part of the healthcare team, **you** will likely be in the first phase to receive a COVID-19 vaccine.
- **Get a COVID-19 vaccine**, when it is available to you.
- **Share** your experience and your personal reasons for getting vaccinated with your patients, family, and friends.
- **Visibly show** you received the vaccine, by wearing a sticker, button, or lanyard and sharing on social media or other communication channels.



COVID-19 vaccination will help protect you from COVID-19.

Getting a COVID-19 vaccine...



- Will help create an immune response in your body against the virus.
- May help keep you from getting severely ill, even if you do get COVID-19.



- Can protect your family, your coworkers, and patients.

COVID-19 vaccination is a safer way to build protection.

- Getting the virus that causes COVID-19 may offer some natural protection, known as immunity. But experts don't know how long this protection lasts.
- The risk of severe illness and death from COVID-19 far outweighs any benefits of natural immunity.
- COVID-19 vaccination will help protect you by creating an antibody response without the risk of severe illness.



Vaccination is one measure to help stop the pandemic.

- While COVID-19 mRNA vaccines appear to be highly effective, additional preventive tools remain important to limit the spread of COVID-19.
- The combination of getting vaccinated and following CDC recommendations to protect yourself and others offers the best protection from COVID-19.
 - Cover your nose and mouth with a mask.
 - Avoid close contact. Maintain social distancing.
 - Clean and disinfect.
 - Wash your hands.



The facts:

COVID-19 mRNA vaccines will not give you COVID-19.

- **None** of the COVID-19 vaccines in use or under development use the live virus that causes COVID-19.
- People can experience normal side effects, such as fever, after vaccination. These side effects are signs that the body is building immunity.
- It takes a few weeks for the body to build immunity after vaccination. A person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection.

The facts:

COVID-19 mRNA vaccines will not cause you to test positive on COVID-19 viral tests.

- Vaccines currently authorized for use or in development won't cause you to test positive on viral tests, which are used to see if you have a **current infection**.
- There is a possibility you may test positive on some antibody tests, which show **previous infection**. This would indicate that the vaccine likely triggered an immune response in your body and that you may have some level of protection against the virus.



The facts:

People who have gotten sick with SARS-CoV-2, the virus that causes COVID-19, may still benefit from vaccination.

- People may be advised to get a COVID-19 vaccine even if they have already had the virus. This is because a person can become infected with the virus more than once.
- At this time, experts do not know how long someone is protected from getting sick again after recovering.



Talking with Patients about COVID-19 Vaccination

Prepare for COVID-19 vaccine conversations



Choose to get vaccinated yourself



Start conversations early



Engage in effective conversations



Be prepared for questions

Know the elements of effective vaccine conversations

- Start from a place of empathy and understanding.
- Assume patients will want to be vaccinated but be prepared for questions.
- Give your strong recommendation.
- Address misinformation by sharing key facts.
- Listen to and respond to patient questions.
- Proactively explain side effects.

“I strongly recommend you get a COVID-19 vaccine once it is widely available...”

“...This shot is especially important for you because of your [job or underlying health condition].”

“...I believe in this vaccine so strongly that I plan to get it as soon as it is available.”



Address misinformation about COVID-19 vaccination by sharing key facts



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

COVID-19 vaccines can not give you COVID-19

People who have already gotten sick with COVID-19 may still benefit from getting vaccinated

Getting vaccinated can help prevent getting sick with COVID-19

COVID-19 vaccines will not cause you to test positive on COVID-19 **viral** tests*



*<https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

Answering Common Patient Questions about COVID-19 Vaccination

Q: How do we know if COVID-19 vaccines are safe?

- Explain:
 - FDA carefully reviews all safety data from clinical trials.
 - FDA authorizes emergency vaccine use only when the expected benefits outweigh potential risks.
 - ACIP reviews safety data before recommending any vaccine for use.
 - FDA and CDC will continue to monitor the safety of COVID-19 vaccines to make sure even very rare side effects are identified.

“COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offer protection to people of different ages, races, and ethnicities, as well as those with different medical conditions.”



Q: Have these vaccines been tested in people like me?

- Probe what they mean by “people like me.”
- Explain that the clinical trials recruited a diverse mix of participants.
- Share any data you have about the percentages of people from communities of color, people with underlying health conditions, and older adults included in the trials.
- Reiterate that no serious safety concerns were identified.

“The first two mRNA vaccines in line for FDA authorization were tested in a diverse group of people. About 30% of U.S. participants were Hispanic, African American, Asian or Native American. About half were older adults. There were no significant safety concerns identified in these or any other groups.”



Q: Is it better to get natural immunity rather than immunity from vaccines?

- Explain the potential serious risk COVID-19 poses to them and their loved ones if they get the illness or spread it to others, adding that the disease can be serious even if they are not in a high-risk group.
- Explain that scientists are still learning more about the virus that causes COVID-19. It is not known whether getting COVID-19 disease will protect everyone against getting it again or, if it does, how long that protection might last.

“Both this disease and the vaccine are new. We don’t know how long protection lasts for those who get infected or those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death for a lot of people. If you get COVID-19, you also risk giving it to loved ones who may get sick. Getting a COVID-19 vaccine is a safer choice.”



Q: Will the shot hurt? Will it make me sick? What about the side effects?

- Explain that they cannot get COVID-19 from the vaccine.
- Explain what the most common side effects from vaccination are, how severe they may be, and that they typically go away on their own within a week.
 - Make sure patients know that a fever is a potential side effect.
- Provide a comparison if it is appropriate for the patient (for example, pain after receiving *Shingrix* for older adults who have received it).

“These side effects are signs that your immune system is doing exactly what it is supposed to do. It is working and building up protection to disease.”

“Most people do not have serious problems after getting a vaccine. We will understand more about mild side effects of the COVID-19 vaccine before we start to use it. However, your arm may be sore, red, or warm to the touch. These symptoms usually go away on their own within a week. Some people report getting a headache, fever, fatigue, or body aches after getting a vaccine. “



Q: How do we know these vaccines are safe when they are so new? What about long-term side effects?

- Explain how FDA and CDC are continuing to monitor safety.
- Let patients know that ACIP will take action to address any potential safety problems detected.
- Compare the potential serious risk of COVID-19 illness with what is currently known about the safety of COVID-19 vaccines.

“COVID-19 vaccines are being tested in large clinical trials to learn more about their safety and effectiveness. However, it does take time and more people getting vaccinated before we can learn about very rare or long-term side effects. That is why safety monitoring will continue. CDC has an independent group of experts that reviews all the safety data as they come in and provides regular safety updates. Any possible problems will be quickly investigated to find out if the issue is related to the COVID-19 vaccine and determine the best course of action.”



Q: How many doses are needed and why?

- Explain that two shots are needed to provide the best protection against COVID-19 for both mRNA vaccines. The first shot primes the immune system, helping it recognize the virus, and the second shot strengthens the immune response.
- Explain that COVID-19 vaccines may differ in the number of doses needed and the spacing between doses.
- When applicable, explain the dosing options available in your office and encourage the patient to set up an appointment before they leave to come back for a second dose.

“Nearly all COVID-19 vaccines being studied in the United States require two shots. The first shot starts building protection, but everyone has to come back a few weeks later for the second one to get the most protection the vaccine can offer.”



Proactively explain side effects

- Extremely important because:
 - New COVID-19 vaccines are reactogenic. They are likely to cause side effects, especially after the 2nd dose.
 - Patients may confuse these side effects with COVID-19 or flu symptoms.
 - Patients may worry that the vaccine gave them COVID-19.
- Things to emphasize:
 - Side effects indicate a good immune response.
 - Side effects are generally short-lived.
 - It is important to return for second dose, even if the first dose has unpleasant side effects.



Wrapping up the conversation

- Encourage patients to take at least one action. For example:
 - Schedule the second-dose appointment (if they got vaccinated that day).
 - Read additional information you provide them (if they declined vaccination).
- If they decline, continue to remind them about the importance of getting a COVID-19 vaccine during future routine visits.
- Wrap up the conversation by letting your patient know that you are open to continuing the discussion and answering any additional questions they may have.



Know where to go for the latest information about COVID-19 vaccines

- CDC and FDA websites:
 - www.cdc.gov/covid-19
 - www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
- Your professional association
- Your state or local health department
- Your facility's immunization coordinator



Provider resources for COVID-19 vaccine conversations with patients

- Preparing to Provide COVID-19 Vaccines
- Talking to Patients about COVID-19 Vaccines
- Understanding and Explaining mRNA COVID-19 Vaccines
- Making a Strong Recommendation for COVID-19 Vaccination
- Answering Patients' Questions
- *More tools coming soon!*



www.cdc.gov/vaccines/hcp/covid-conversations

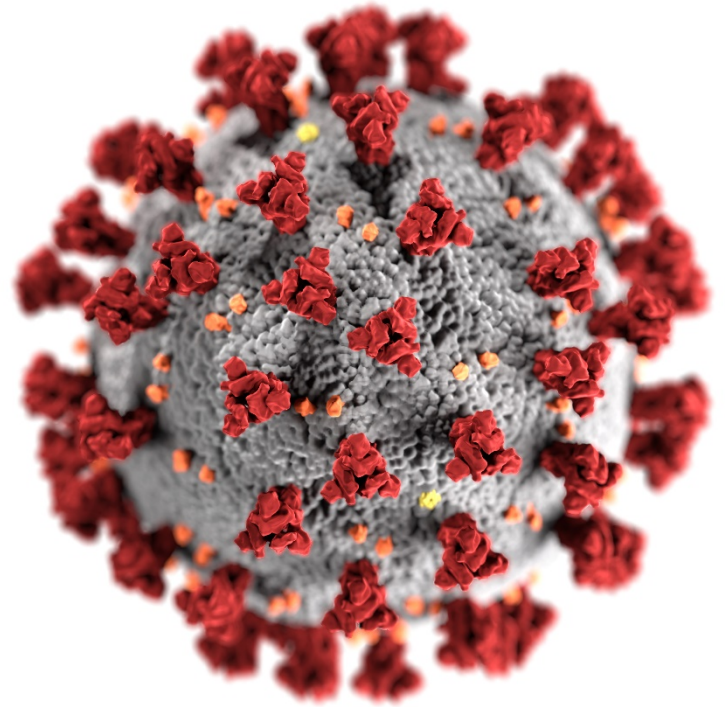


COVID-19 vaccine clinical training resources

- *COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Professionals*
- Webinars about ACIP recommendations and vaccine products
- Clinical forms, trackers, and FAQs
- Educational materials about each authorized vaccine:
 - Online training module
 - Vaccine preparation and administration summary
 - Storage and handling summary
 - Temperature log for freezer units
 - Beyond use date tracker labels for refrigerator storage
 - Standing orders template



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



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

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.

