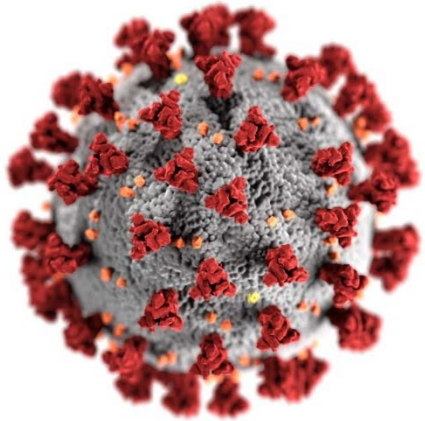
Building Confidence in COVID-19 Vaccines Among Your Patients

Tips for the Healthcare Team



Developed by:

CDC COVID-19 Response

Vaccine Task Force

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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

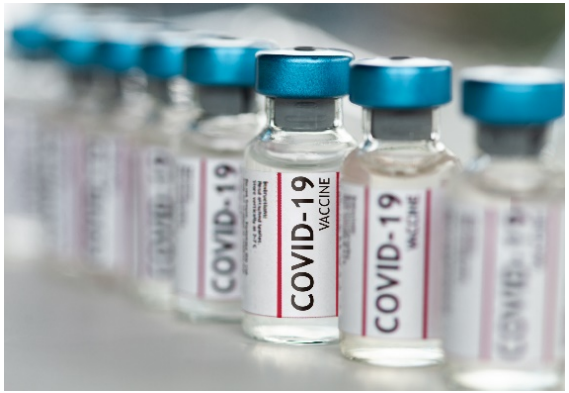
COVID-19 vaccines, mRNA Vaccine Technology, and Vaccine Safety Monitoring

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 and some of which have been authorized by the FDA.
- COVID-19 vaccines are being held to the **same safety standards** as all other vaccines.



Phases of clinical trials

Phase 1
20-100 Healthy Volunteers

Researchers try to answer these questions:

- Is this vaccine safe?
- Are there any serious side effects?
- How does the vaccine dose relate to any side effects?
- Is the vaccine causing an immune response?

Phase 2
Several Hundred Volunteers

Researchers try to answer these questions:

- What are the most common short-term side effects?
- What's the body's immune response?
- Are there signs that the vaccine is protective?

Phase 3
1000+ Volunteers

Researchers try to answer these questions:

- How do disease rates compare between people who get the vaccine and those who do not?
- How well can the vaccine protect people from disease?

Phase 4
Vaccine is Approved

Researchers try to answer these questions:

- FDA approves a vaccine only if it's safe, effective, and benefits outweigh the risks.
- Researchers continue to collect data on the vaccine's long-term benefits and side effects.

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

COVID-19 vaccines that have received FDA Emergency Use Authorizations

- Two vaccines have received 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. People being vaccinated should complete the two-dose series with the same vaccine product.
- Duration of protection is not yet known.
- 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 December 21, 2020

Pfizer/BioNTech

- **45,302** enrolled
  - **43,125** received 2nd dose
- **150** clinical sites
  - **39** U.S. states
- Racial/ethnic distribution
  - **13% -** Hispanic
  - **10% -** African American
  - **6% -** Asian
  - **1% -** Native American
- **40%** ages 56-85

Moderna

- **30,000** enrolled
  - **25,654** received 2nd dose
- **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

How COVID-19 mRNA vaccines work

- 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.
- mRNA vaccines do not affect our DNA; mRNA does not enter the cell nucleus.
- mRNA vaccines cannot give someone COVID-19.
- mRNA vaccines are new, but the technology is not. 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

- At least 8 weeks of safety data were gathered after participants received their 2nd dose in the trials. It is unusual for side effects to appear more than 8 weeks after vaccination.
- These mRNA vaccines produce common 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, although a small number of severe allergic reactions have been reported during the initial phases of rollout.

As with any vaccine, vaccination providers should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Providers should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction.

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

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 in large amounts than traditional vaccines.
- FDA and CDC are prioritizing review, authorization, and recommendation of COVID-19 vaccines.

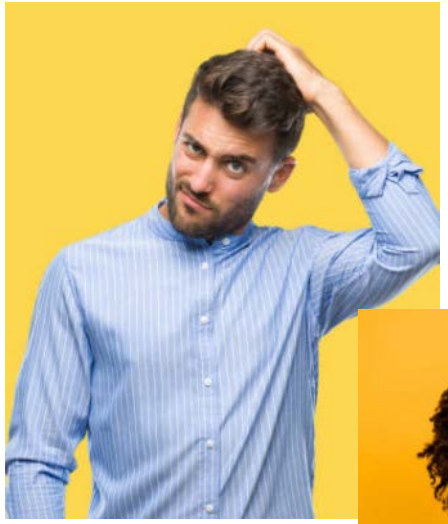
*For more information, visit the COVID-19 Prevention Network: www.coronaviruspreventionnetwork.org/about-covpn

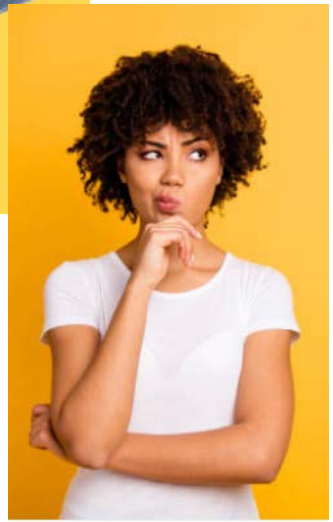
Elements of Vaccine Confidence

The Challenge: Need to instill vaccine confidence

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

  (Data from October 2020 Harris poll)
- Factors weighing on acceptance
  - Are there side effects?
  - Does it work?
  - Is it safe?
  - How much does it cost?





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/

The Challenge: Increasing acceptability

- COVID-19 vaccine would 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

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.

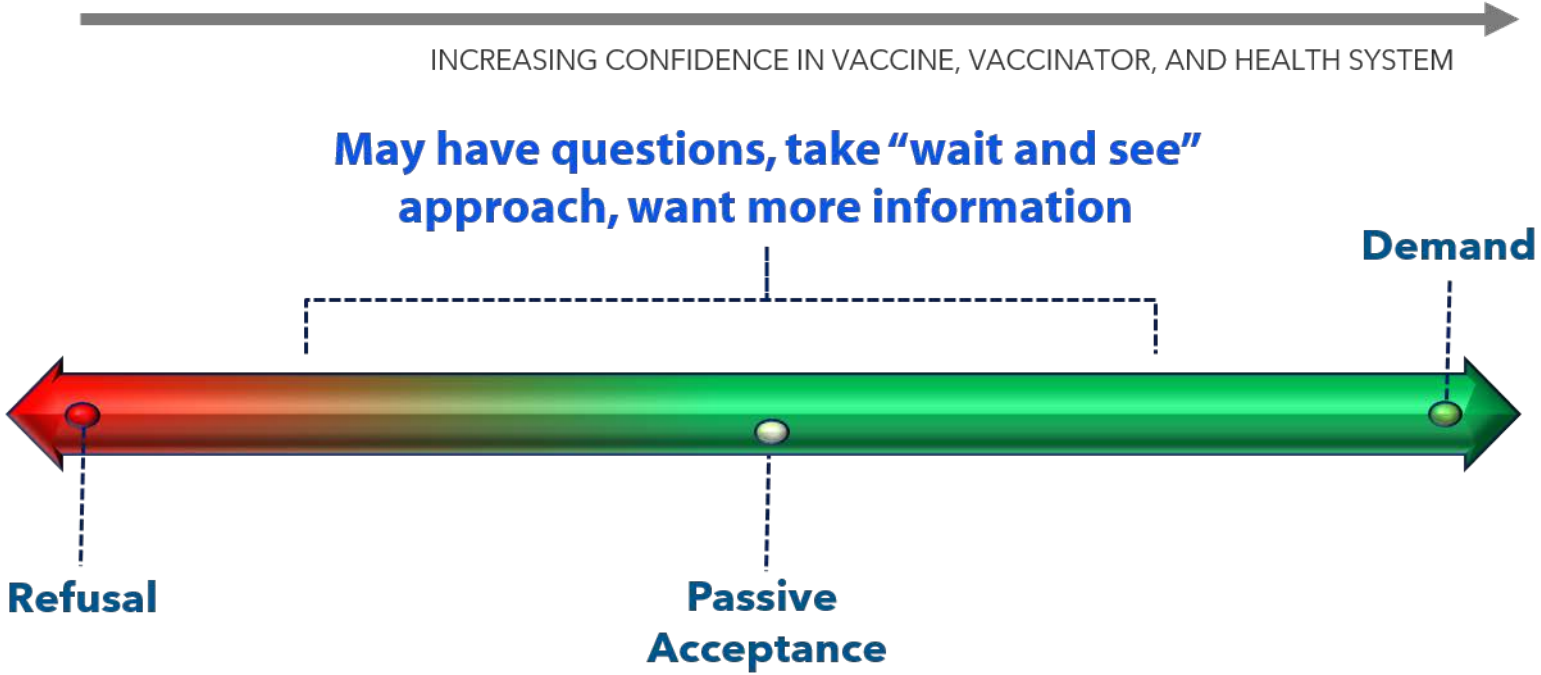
Sources:

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 local and 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!

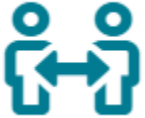
- As part of the healthcare team, **you** will likely be in the first phase to receive a COVID-19 vaccine.
- **Get a COVID-19 vaccine**, when it is available to you.
- **Share** your experience and your personal reasons for getting vaccinated with your patients, family, and friends.
- **Visibly show**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

Talking with Patients about COVID-19 Vaccination

Prepare for COVID-19 vaccine conversations

Choose to get vaccinated

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]."

Address misinformation about COVID-19 vaccination by sharing key facts

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/vaccines/facts.html

*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: Is it safe to get a COVID-19 vaccine if I have allergies?

- Ask what kind of allergies they are concerned about.
- Explain that people should not get vaccinated if they are allergic to any ingredient in COVID-19 vaccines.
- Explain that people with other types of allergies may still be vaccinated, and that you can help determine if it is safe for them.

If you have ever had a severe allergic reaction to any ingredient in a COVID-19 vaccine, you should not get that the vaccine. If you have had an immediate allergic reaction of any severity to other vaccines or injectable therapies, I will help you decide if it is safe for you to get vaccinated. You may still get vaccinated if you have severe allergies to oral medications, food, pets, insect stings, latex, or environmental irritants like pollen or dust.

Q: Is it safe to get a COVID-19 vaccine if I am pregnant or breastfeeding?

- Explain that there is limited data about the safety of COVID-19 vaccines during pregnancy and breastfeeding, but that experts do not believe it poses a risk.
- Clarify that patients may choose to get vaccinated if they are part of a recommended group.
- Emphasize that vaccination is a personal decision and offer to discuss it in more depth.

There is limited information about the safety of COVID-19 vaccines during pregnancy. However, based on what we know about how these vaccines work, experts believe they are unlikely to pose a risk for pregnant patients. You may choose to get vaccinated if you are part of a group that is recommended for COVID-19 vaccine. We can talk through this decision together.

Q: Have these vaccines been tested in all populations?

- Explain that the clinical trials recruited a diverse mix of participants.
- Be specific and provide 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 the shingles vaccine 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. However, your arm may be sore or swollen. 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."

Q: Do I have to continue to wear a mask and avoid close contact with others after I have been vaccinated?

- Explain that there is not enough information currently available to say if or when CDC will stop recommending that people wear masks and avoid close contact with others. Factors that are being considered include how many people get vaccinated and how the virus is spreading in communities.
- Explain that we don't yet know if the vaccine reduces transmission of SARS-CoV-2.
- Emphasize that these precautions will need to be observed until the vaccine is in widespread use and disease rates start to decline.

Right now, experts don't know how long the vaccine will protect you, so it is important to keep covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others after getting each dose of the vaccine. We also know not everyone will be able to get vaccinated right away, so it's still important to protect yourself and others. Everyone who gets vaccinated should continue taking these precautions until the vaccine is in widespread use and COVID-19 rates have declined.

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/vaccines
  - 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

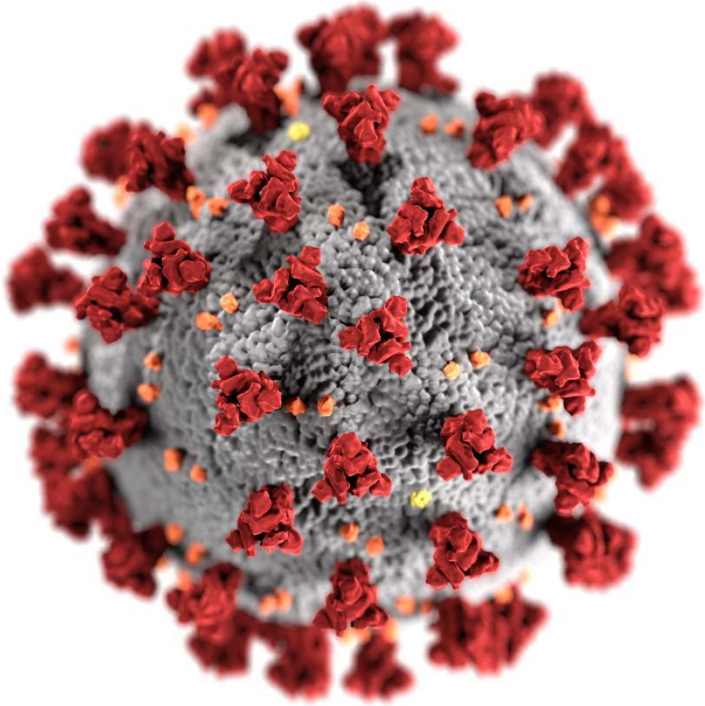
- Preparing to Provide COVID-19 Vaccines
- Talking to Patients about COVID-19 Vaccines
- Understanding and Explaining mRNA COVID-19 Vaccines
- Making a Strong Recommendation for COVID-19 Vaccination
- Answering Patients' Questions
- *More tools coming soon!*

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
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TTY: 1-888-232-6348 www.cdc.gov

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