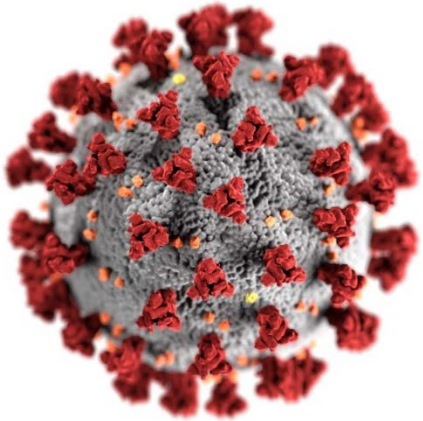
ARCHIVED DOCUMENT
(COVID-19)

The following document is for historical purposes and is no longer being updated. Please go to the COVID-19 Vaccination Clinical & Professional Resources for more recent information.

U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

COVID-19 Vaccine Basics: What Healthcare Personnel Need to Know



Presentation developed by:
CDC COVID-19 Response
Vaccine Task Force
January 2021

Vaccinate with Confidence

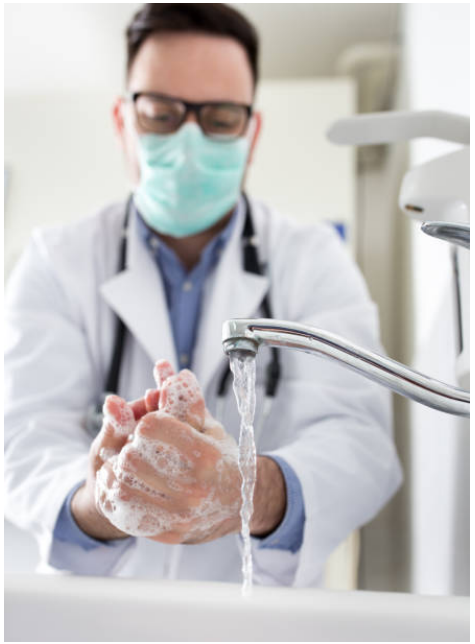
cdc.gov/coronavirus

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

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.

Understanding Clinical Trials | NHBLI (nih.gov)

COVID-19 vaccines have received FDA Emergency Use Authorizations (EUAs)

- Two vaccines have received FDA Emergency Use Authorizations (EUAs):
  - **Pfizer/BioNTech (BNT162b2):** 2 doses given at least 21 days apart
  - **Moderna (mRNA-1273)**: 2 doses given at least 28 days apart
- 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.

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
  - **20%** - Hispanic
  - **10%** - African American/Black
  - **4%** - Asian
  - **3%** - All others
- **64%** ages 45 and older
  - 39% ages 45-64
  - 25% ages 65+

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

Healthcare personnel are first in line for COVID-19 vaccine

How COVID-19 mRNA vaccines work

- mRNA vaccines teach our cells how to make a harmless piece of the “spike protein” for SARS-CoV-2.
  - After the protein piece is made, the cell breaks down the instructions (the mRNA) and gets rid of them.
- 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 use the live virus that causes COVID-19. They **CANNOT** give someone COVID-19.
- mRNA vaccines **DO NOT** affect or interact with our DNA in any way.
- mRNA vaccines are new, but the technology is not. mRNA vaccines have been studied for other infections.

Source: Understanding and Explaining mRNA COVID-19 Vaccines | CDC

About these COVID-19 mRNA vaccines

- Two shots are needed to provide the best protection against COVID-19 for both mRNA vaccines.
  - First shot primes the immune system, helping it recognize the virus.
  - Second shot strengthens the immune response.
- Side effects are commonly seen in these mRNA vaccines, especially after the 2nd dose.
- Side effects may include:
  - fever
  - headache
  - muscle aches

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

About safety of 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.
- No significant safety concerns were identified in the clinical trials, although a small number of severe allergic reactions have been reported.
  - Recommendations for observation after vaccination include monitoring for 15 or 30 minutes.
  - If you get a COVID-19 vaccine and you think you might be having a severe allergic reaction after leaving the vaccination site, call 911 to seek immediate medical care.
  - Learn more about COVID-19 vaccines and rare severe allergic reactions.

Fast-tracking COVID-19 vaccines while ensuring safety

- Researchers used existing vaccine clinical trial networks to conduct the COVID-19 vaccine trials.
- Manufacturing began while 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 and authorization of COVID-19 vaccines.

*For more information, visit the COVID-19 Prevention Network: www.coronaviruspreventionnetwork.org/about-covpn
**For more information, visit FDA's Emergency Use Authorization for Vaccines Explained: https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

Safety of COVID-19 vaccines is a top priority.

- COVID-19 vaccines are being held to the **same safety standards** as all vaccines.

Before authorization

- **FDA** carefully reviews all safety data from clinical trials.
- **ACIP** reviews all safety data before recommending use.

After vaccine authorization

- **FDA** and **CDC** closely monitor vaccine safety and side effects.

Monitoring vaccine safety is a regular, ongoing part of vaccine development.

- **Existing** systems and data sources are used to monitor safety of vaccines after they are authorized or licensed, 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 are being developed to monitor vaccine safety, such as **v-safe**:
  - Active surveillance that uses text messaging to initiate web-based survey monitoring
  - Any clinically important events reported by a participant would be sent to VAERS for follow-up

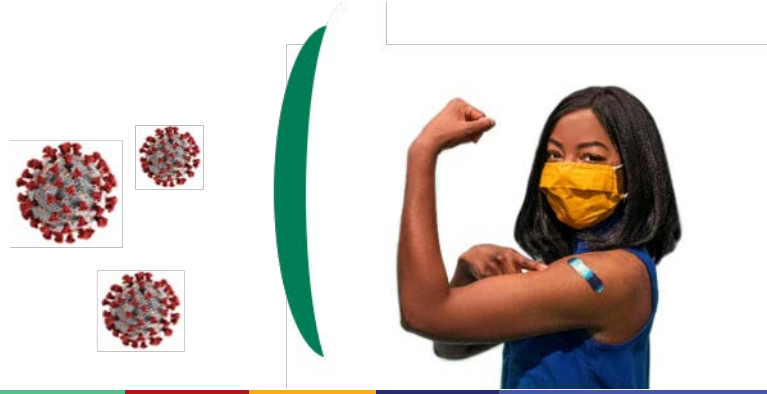
COVID-19 vaccination will help protect you from COVID-19.

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.
- May 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. However, 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.
- Both natural immunity and immunity produced by a vaccine are important parts of COVID-19 disease that experts are trying to learn more about.



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.
- The two vaccines currently authorized require two doses for best protection. Receiving only one dose will not provide optimal protection.
- 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 triggered an immune response in your body and that you may have some level of protection against the virus.

The facts:

People previously diagnosed with COVID-19 should still get vaccinated with a COVID-19 vaccine.

- Due to the severe health risks associated with COVID-19 and the fact that a person can become infected with the virus more than once, vaccine should be offered regardless of whether you already had COVID-19 infection.
- At this time, experts do not know how long someone is protected from getting sick again after recovering.

What to expect before, during, and after your COVID-19 vaccine appointment

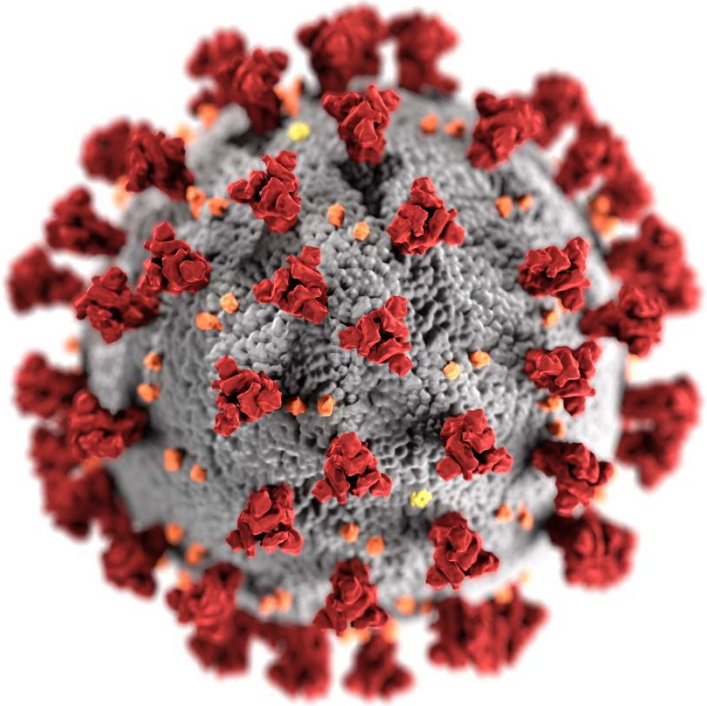
- **Before**
  - Learn about COVID-19 vaccines.
  - See if COVID-19 vaccination is recommended for you.
- **During**
  - Read the fact sheet that tells you about the specific COVID-19 vaccine you receive.
  - Tell your provider about your medical conditions.
  - Receive a vaccination record card.
  - Stay on-site for monitoring after vaccination.
- **After**
  - With most COVID-19 vaccines, you will need two shots.
  - Expect some side effects.
  - Enroll in v-safe.
  - Continue using all the measures to protect yourself (mask + 6ft social distance + handwashing).

Protect yourself from serious illness. Get vaccinated.

- Get vaccinated when it is available to you.
- Participate in **v-safe** and help CDC monitor for any health effects after vaccination.
- Share your experience with coworkers, friends, and family.
- Know the basics about the COVID-19 vaccine. Help answer questions from your family and friends.
- Visibly show you received a vaccine, such as by wearing a sticker or button.

Learn more!

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