# COVID-19 Vaccine Resources for Colleagues

### When will the general public receive the vaccine?

It will take several months before the vaccine is available for the general public. Because of limited supply, some groups will be recommended to get a COVID-19 vaccine first. Healthcare personnel and long-term care facility residents should be offered COVID-19 vaccination in the initial phase of the U.S. COVID-19 vaccination program while there is limited vaccine supply. CDC officially made this recommendation on December 2, 2020, based on recommendations from the Advisory Committee on Immunization Practices (ACIP).

Expecting that a limited supply of COVID-19 vaccine was likely at first, experts began working during the summer on a strategy for distributing these limited vaccines in a fair, ethical, and transparent way. The National Academies of Sciences, Engineering, and Medicine gave to ACIP, who then set goals and ethical principles to guide their decision making.

### **Benefits of Getting a COVID-19 Vaccine**

Below is a summary of the benefits of COVID-19 vaccination based on what we currently know.

### COVID-19 vaccination will help keep you from getting COVID-19

- COVID-19 vaccines are being carefully evaluated in clinical trials and will be authorized or approved
  only if they make it substantially less likely you'll get COVID-19.
- Based on what we know about vaccines for other diseases, experts believe that getting a COVID-19
  vaccine may help keep you from getting seriously ill even if you do get COVID-19.
- Getting vaccinated yourself may also protect people around you, particularly people at increased risk for severe illness from COVID-19.
- Experts continue to conduct more studies about the effect of COVID-19 vaccination on severity of illness from COVID-19, as well as its ability to keep people from spreading the virus that causes COVID-19.

# COVID-19 vaccination will be a safer way to help build protection

- COVID-19 can have serious, life-threatening complications, and there is no way to know how COVID-19 will affect you. And if you get sick, you could spread the disease to friends, family, and others around you.
- Clinical trials of COVID-19 vaccines must first show they are safe and effective before any vaccine can
  be authorized or approved for use. The known and potential benefits of a COVID-19 vaccine must
  outweigh the known and potential risks of the vaccine for use under what is known as an Emergency Use
  Authorization (EUA). Watch a video on what an EUA is.
- Getting COVID-19 may offer some natural protection, known as immunity. But experts don't know how
  long this protection lasts, and 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 having to experience sickness.
- Both natural immunity and immunity produced by a vaccine are important aspects of COVID-19 that
  experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes
  available.

#### **Facts about COVID-19 Vaccines**

#### FACT: COVID-19 vaccines will not give you COVID-19

None of the COVID-19 vaccines currently in development in the United States use the live virus that causes COVID-19. There are several different types of vaccines in development. However, the goal for each of them is to teach our immune systems how to recognize and fight the virus that causes COVID-19. Sometimes this process can cause symptoms, such as fever. These symptoms are normal and are a sign that the body is building immunity. Learn more about how COVID-19 vaccines work.

It typically takes a few weeks for the body to build immunity after vaccination. That means it's possible 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.

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

Vaccines currently in clinical trials in the United States won't cause you to test positive on viral tests, which are used to see if you have a current infection.

If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some < a href="https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html" target="\_blank">antibody tests. Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.

# FACT: People who have gotten sick with COVID-19 may still benefit from getting vaccinated

Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible, people may be advised to get a COVID-19 vaccine even if they have been sick with COVID-19 before.

At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called natural immunity, varies from person to person. Some early evidence suggests natural immunity may not last very long.

We won't know how long immunity produced by vaccination lasts until we have a vaccine and more data on how well it works.

Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes available.

### FACT: Getting vaccinated can help prevent getting sick with COVID-19

While many people with COVID-19 have only a mild illness, others may get a severe illness or they may even die. There is no way to know how COVID-19 will affect you, even if you are not at increased risk of severe complications. If you get sick, you also may spread the disease to friends, family, and others around you while you are sick. COVID-19 vaccination helps protect you by creating an antibody response without having to experience sickness. Learn more about how COVID-19 vaccines work.

#### FACT: Receiving an mRNA vaccine will not alter your DNA

mRNA stands for messenger ribonucleic acid and can most easily be described as instructions for how to make a protein or even just a piece of a protein. mRNA is not able to alter or modify a person's genetic makeup (DNA). The mRNA from a COVID-19 vaccine never enter the nucleus of the cell, which is where our DNA are kept. This means the mRNA does not affect or interact with our DNA in any way. Instead, COVID-19 vaccines that use mRNA work with the body's natural defenses to safely develop protection (immunity) to disease. Learn more about how COVID-19 mRNA vaccines work.

### **COVID-19 Vaccine Myths Debunked**

### Myth #1: Vaccines were rushed and shortcuts were taken

Facts: mRNA Vaccines (Pfizer and Moderna) development:

- mRNA technology is new in vaccine development but has been studied for other uses for more than a
  decade.
- Previously used to develop vaccines against Zika, CMV, influenza and rabies, all of which went through human trials and were found to be safe (CDC1).
- Went through same rigorous safety procedures as ALL FDA approved vaccines- NO SHORTCUTS!
- Had over 70,000 (Moderna and Pfizer) individuals safely participate in the trials before receiving Emergency Use Authorization (EUA) by the FDA.

### Myth #2: mRNA will somehow rearrange my DNA

#### **Facts**

- mRNA is injected into your muscle, usually the upper arm and enters into the cytoplasm (the water part)
  of your muscle cells, where it triggers your body to produce protective antibodies to the COVID "spike
  protein."
- It does not (and cannot) enter into the nucleus, where our DNA is housed (CDC1).

#### Myth #3: Vaccines could induce sterility in women

#### Facts

- Infertility is not identified as an adverse outcome in any of the mRNA vaccine trials performed to date (CDC2).
- ACOG recommends vaccination of individuals who are actively trying to become pregnant or are contemplating pregnancy and meet the criteria for vaccination based on ACIP prioritization

- recommendations. Additionally, it is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine (ACOG).
- COVID-19 mRNA vaccines are not thought to cause an increased risk of infertility (ACOG). Concerns related to "the spike protein" found in popular media have not been established in research (CDC1).

### Myth #4: Pregnant (or trying) and the vaccines could be harmful for my unborn child

Facts: Pregnant women

- Are NOT usually included in initial trials for vaccines or medications including the COVID-19 Vaccine.
- Are at an increased risk of severe illness from COVID-19 including respiratory failure, need for mechanical ventilation (or ECMO), and death. There may also be an increased incidence of adverse outcomes of pregnancy, including preterm births and stillbirths (CDC2).
- Are encouraged to speak with their healthcare provider if they are pregnant or are considering pregnancy.
- Routinely and safely receive vaccines that are not live viruses, e.g. annual flu and Tdap. The mRNA COVID vaccines are NOT live vaccines.

#### References

- 1. Centers for Disease Control and Prevention. Understanding and Explaining mRNA COVID-19 Vaccines.
- Centers for Disease Control and Prevention. Vaccination Considerations for People who are Pregnant or Breastfeeding.
- American College of Obstetricians and Gynecologists. Vaccinating Pregnant and Lactating Patients
  Against COVID-19.

#### **HOW mRNA Vaccines Work**

#### A Closer Look at How COVID-19 mRNA Vaccines Work

COVID-19 mRNA vaccines give instructions for our cells to make a harmless piece of what is called the "spike protein." The spike protein is found on the surface of the virus that causes COVID-19.

COVID-19 mRNA vaccines are given in the upper arm muscle. Once the instructions (mRNA) are inside the muscle cells, the cells use them to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them.

Next, the cell displays the protein piece on its surface. Our immune systems recognize that the protein doesn't belong there and begin building an immune response and making antibodies, like what happens in natural infection against COVID-19.

At the end of the process, our bodies have learned how to protect against future infection. The benefit of mRNA vaccines, like all vaccines, is those vaccinated gain this protection without ever having to risk the serious consequences of getting sick with COVID-19.

# COVID-19 mRNA Vaccines Will Be Rigorously Evaluated for Safety

mRNA vaccines are being held to the same rigorous safety and effectiveness standards as all other types of vaccines in the United States. The only COVID-19 vaccines the Food and Drug Administration (FDA) will make available for use in the United States (by approval or emergency use authorization) are those that meet these standards.

#### mRNA Vaccines Are New, But Not Unknown

There are currently no licensed mRNA vaccines in the United States. However, researchers have been studying and working with them for decades. Interest has grown in these vaccines because they can be developed in a laboratory using readily available materials. This means the process can be standardized and scaled up, making vaccine development faster than traditional methods of making vaccines.

mRNA vaccines have been studied before for flu, Zika, rabies, and cytomegalovirus (CMV). As soon as the necessary information about the virus that causes COVID-19 was available, scientists began designing the mRNA instructions for cells to build the unique spike protein into an mRNA vaccine.

Future mRNA vaccine technology may allow for one vaccine to provide protection for multiple diseases, thus decreasing the number of shots needed for protection against common vaccine-preventable diseases.

Beyond vaccines, cancer research has used mRNA to trigger the immune system to target specific cancer cells.

# **Ensuring the Safety of COVID-19 Vaccines in the United States**

The U.S. vaccine safety system ensures that all vaccines are as safe as possible. Safety is a top priority while federal partners work to make a coronavirus disease 2019 (COVID-19) vaccine(s) available.

#### **Clinical Trials**

Currently, clinical trials are evaluating investigational COVID-19 vaccines in many thousands of study participants to generate scientific data and other information for the Food and Drug Administration (FDA) to determine their safety and effectiveness. These clinical trials are being conducted according to the rigorous standards set forth by FDA in their June 2020 guidance document, Development and Licensure of Vaccines to Prevent COVID-19. If FDA determines that a vaccine meets its safety and effectiveness standards, it can make these vaccines available for use in the United States by approval or emergency use authorization.

After FDA makes its determination, the Advisory Committee on Immunization Practices (ACIP) will review available data before making vaccine recommendations to CDC. Learn more about how CDC is making COVID-19 vaccine recommendations.

### Vaccine Safety Monitoring

After a vaccine is authorized or approved for use, many vaccine safety monitoring systems watch for adverse events (possible side effects). This continued monitoring can pick up on adverse events that may not have been seen in clinical trials. If an unexpected adverse event is seen, experts quickly study it further to assess whether it is a true safety concern. Experts then decide whether changes are needed in U.S. vaccine recommendations. This monitoring is critical to help ensure that the benefits continue to outweigh the risks for people who receive vaccines.

FDA's June 2020 guidance document also includes important recommendations for ongoing safety evaluation after any COVID-19 vaccine is made available in the United States.

**CDC** is working to expand safety surveillance through new systems and additional information sources, as well as by scaling up existing safety monitoring systems.

#### **Expanded Safety Monitoring Systems**

The following systems and information sources add an additional layer of safety monitoring, giving CDC and FDA the ability to evaluate COVID-19 vaccine safety in real time and make sure COVID-19 vaccines are as safe as possible:

CDC: V-SAFE — A new smartphone-based, after-vaccination health checker for people who receive
COVID-19 vaccines. V-SAFE will use text messaging and web surveys from CDC to check in with
vaccine recipients for health problems following COVID-19 vaccination. The system also will provide
telephone follow up to anyone who reports medically significant (important) adverse events.

- CDC: National Healthcare Safety Network (NHSN) An acute care and long-term care facility
  monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS
- **FDA:** Other large insurer/payer databases A system of administrative and claims-based data for surveillance and research

### **Getting Vaccinated**

### How many shots of COVID-19 vaccine will be needed?

All but one of the COVID-19 vaccines currently in Phase 3 clinical trials in the United States need two shots to be effective. The other COVID-19 vaccine uses one shot.

#### Are there side effects from the vaccine?

Initial information comes from the clinical trials for the Pfizer and Moderna vaccines. More information may be available after Emergency Use Authorization approval. Side effects may begin to present the day the vaccine is received, or may present in the days following. Side effects have been seen in about 10 to 15% of those who took the vaccine.

Pfizer vaccine reported side effects: Fever, chills, headache, myalgia (muscle aches), nausea.

Moderna vaccine reported side effects: Chills, headache, myalgia (muscle aches), fatigue.

### If I have already had COVID-19 and recovered, do I still need to get vaccinated with a COVID-19 vaccine when it's available?

There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. Until we have a vaccine available and the Advisory Committee on Immunization Practices makes recommendations to CDC on how to best use COVID-19 vaccines, CDC cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine.

Why would a vaccine be needed if we can do other things like social distancing and wearing masks, to prevent the virus that causes COVID-19 from spreading?

Stopping a pandemic requires using all the tools available. Vaccines work with your immune system so your body will be ready to fight the virus if you are exposed. Other steps, like covering your mouth and nose with a mask and staying at least 6 feet away from others, help reduce your chance of being exposed to the virus or spreading it to others. Together, COVID-19 vaccination and following CDC's recommendations to protect yourself and others will offer the best protection from COVID-19.

### Do I need to wear a mask and avoid close contact with others if I have received two doses of the vaccine?

Yes. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using all the tools available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others. Together, COVID-19 vaccination and following CDC's recommendations for how to protect yourself and others will offer the best protection from getting and spreading COVID-19.

Experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on steps everyone should take to slow the spread of the virus that causes COVID-19. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

### When can I stop wearing a mask and avoiding close contact with others after I have been vaccinated?

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 to help prevent the spread of the virus that causes COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before making that decision. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

## Does immunity after getting COVID-19 last longer than protection from COVID-19 vaccines?

The protection someone gains from having an infection (called natural immunity) varies depending on the disease, and it varies from person to person. Since this virus is new, we don't know how long natural immunity might last. Some early evidence—based on some people— seems to suggest that natural immunity may not last very long.

Regarding vaccination, we won't know how long immunity lasts until we have a vaccine and more data on how well it works.

Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes available.



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