GENERAL VACCINE INFORMATION

1. Will there be enough vaccine for everyone?

When the Food and Drug Administration (FDA) approves the use of one or more COVID-19 vaccines in the United States, there will be a limited supply. This means that not everyone will be able to be vaccinated right away. The supply will be limited at first, and doses will be given to high-risk exposure groups initially. Your timeline for vaccination depends on recommendations that will be provided by the state and the Advisory Committee on Immunization Practices (ACIP), as well as how much of the vaccine is available.

That is why, early in the response, the <u>federal government began investing in select vaccine</u> <u>manufacturers</u> to help them increase their ability to quickly make and distribute a large amount of COVID-19 vaccine. This will allow the United States to start with as much vaccine as possible and continually increase the supply in the weeks and months to follow. The goal is for everyone to be able to easily get a COVID-19 vaccine as soon as large quantities are available. There will be several thousand vaccination providers, including hospitals, doctors' offices, retail pharmacies, and federally qualified health centers.

2. I'm a patient. When can I get a vaccine?

We are not currently offering Covid vaccines to patients. This is because there is a limited supply of COVID-19 vaccine available, and the CDC and the Alabama Department of Public Health (ADPH) has issued guidance that the first vaccines should go to health care teams, emergency service workers, and long-term care facilities. We are carefully monitoring this situation as it evolves and will make sure that our UAB Medicine patients are notified and are given the opportunity to receive a vaccine once the vaccine is made available to the public, consistent with CDC and ADPH guidance. Please note that it could be early spring before the vaccine is more widely available to the public. We do not have additional information on when the vaccine will be available to you but will continue to communicate as we learn new information.

3. How many COVID-19 vaccines are under development?

Multiple COVID-19 vaccines are under development. Currently, four large-scale (Phase 3) clinical trials are in progress in the United States, and a fifth is expected to start soon.

4. How are the Pfizer and Moderna vaccines different than other vaccines?

These two vaccines contain synthetic mRNA, which is genetic information used to make the SARS-CoV-2 (COVID-19) spike protein. Because mRNA is highly unstable, these vaccines are made with a lipid nanoparticle that protects it from being destroyed prior to injection. The spike protein is the part of the virus that attaches to human cells. The spike protein alone cannot cause COVID-19. Once the spike protein is created, it causes the immune system to make antibodies against the virus. These antibodies can then provide protection if a person comes into contact with the virus. mRNA vaccines are non-infectious and do not enter the human cell nucleus, so the mRNA cannot be inserted into human DNA. Additionally, once the mRNA is injected into the arm, it is broken down rapidly, and this theoretically reduces the chances for long-term side effects. mRNA vaccines do not have the ability to cause cancer.

5. How is the COVID-19 vaccine administered?

All but one of the vaccines under development require a series of two intramuscular injections in the upper arm 21-28 days apart to be effective. The first two vaccine types we expect, from Pfizer and Moderna, both require two shots.



6. What happens if I only get the first shot and not the second?

The second dose of the COVID-19 vaccine functions as a booster, triggering the immune system to produce long-lasting memory cells that stick around to protect against the virus in the future. Even if the first dose offers some protection in the short term, the second dose is critical.

7. Can I get COVID-19 between the first and second shot?

According to the FDA, the Pfizer and BioNTech COVID-19 vaccine starts working within about two weeks of the first dose. While potential vaccines have very high protection rates against infection from COVID-19, it is possible that the vaccine will be ineffective for you. You will still need to wear a mask and practice good hand hygiene and social distancing following a vaccination.

8. If I take the vaccine, will I expose my family to COVID-19?

Information currently available about the Pfizer and Moderna vaccines indicates that these vaccines would not affect a person who is a close contact of a person taking the vaccine. It typically takes a few weeks for the body to build immunity after vaccination. That means it is possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick and infect others. This is because the vaccine has not had enough time to provide protection. If you have COVID-19 symptoms after getting the vaccine or at any time, you should contact your health care provider and consider getting tested for COVID-19.

9. Do I have to get tested before getting the vaccine?

No, you do not need a test before receiving the COVID-19 vaccine. You should not sign up to receive the vaccine if you have had COVID-19 within the last 90 days.

10. Do I need the vaccine if I've already had COVID-19?

At this time, vaccinations are not being given to people who have had COVID-19 in the last 90 days. Those who have had COVID-19 within the last 90 days should have natural immunity, and since there is limited supply of vaccine available, they should not receive the vaccine until they are beyond the 90-day window. Those who had COVID-19 more than 90 days ago should receive the vaccine.

11. Does the vaccine make me immune to the virus or just reduce the symptoms?

COVID-19 vaccines are being carefully evaluated in clinical trials and are authorized or approved by the FDA only if they make it substantially less likely that you'll get COVID-19. The Pfizer and Moderna vaccines were shown to prevent COVID-19 in people compared to those who received a placebo.

Experts believe that getting a COVID-19 vaccine may help keep you from getting seriously ill even if you are exposed to COVID-19 by boosting your immune response should you be exposed to COVID-19 in the future.

Getting vaccinated 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 the severity of illness from COVID-19, as well as its ability to keep people from spreading the virus that causes COVID-19.



12. Is the COVID-19 vaccine safe?

COVID-19 can have serious, life-threatening complications, and there is no way to know how COVID-19 will affect you. Additionally, 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 approved by the FDA 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 continuing to study.

13. If the vaccine runs out, will more be available soon?

The goal is for everyone to be able to easily get a COVID-19 vaccination as soon as large quantities are available. Several thousand vaccination providers will be available, including hospitals, doctors' offices, retail pharmacies, and federally qualified health centers.

Learn about how the <u>federal government began investing in select vaccine manufacturers</u> to help them increase their ability to quickly make and distribute a large amount of COVID-19 vaccine.

14. Can I get the flu vaccine and the COVID-19 vaccine at the same time?

At this time, a COVID-19 vaccine will be administered separately from the flu vaccine. The ACIP will be making recommendations on how long after the flu shot one should wait before receiving the COVID-19 vaccine.

15. Can I still be a carrier of the virus (asymptomatic) after the vaccine?

Yes, it is possible. However, experts believe that getting a COVID-19 vaccine may help keep you from getting seriously ill even if you do get COVID-19, and it also may protect people around you – particularly people who are at increased risk for severe illness from COVID-19.

Experts continue to conduct more studies about the effect of COVID-19 vaccination on the severity of illness from COVID-19, as well as its ability to keep people from spreading the virus that causes COVID-19.



16. What percent of the population needs to get the vaccine for it to be effective and give us "herd immunity"?

Experts do not know what percentage of people would need to get vaccinated to achieve herd immunity to COVID-19. Herd immunity is a term used to describe when enough people have protection — either from previous infection or vaccination — that it is unlikely a virus or bacteria can spread and cause disease.

As a result, everyone within the community is protected, even if some people don't have any protection themselves. The percentage of people who need to have protection in order to achieve herd immunity varies by disease.

17. Will I still need to wear a mask if I have received both doses of the vaccine?

Yes. Wearing a mask and practicing social distancing is still important after receiving the vaccine. There will be limited doses available initially, and because people will be vaccinated in waves, it will take time to vaccinate enough of the population to stop the spread of COVID-19. Additionally, it is not known how long immunity will last. Furthermore, infection after a receiving a vaccine may still be possible, although it is likely that it would be less severe, such as a mild or asymptomatic infection. Others can still be infected in this scenario, necessitating the continued use of masks.

18. Can I receive the vaccine if I have had convalescent plasma or monoclonal antibodies?

Currently there is no data on the safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. The ACIP recommends that vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.

19. What guidance is there for women who are pregnant or planning to become pregnant? What is the timeline for resuming pregnancy planning after receiving the vaccine? And what about breastfeeding?

At this time, we have insufficient data to inform individuals about vaccine-associated risks in pregnancy or breastfeeding. These decisions should be considered in conjunction with the woman's health care provider, so that she can make an informed decision about whether or not to receive the vaccine. Considerations for vaccination include the level of COVID-19 community transmission, the woman's personal risk of contracting COVID-19, the risks of COVID-19 to her and potential risks to the baby, the efficacy of the vaccine, the known side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

20. Will women be required to take a pregnancy test prior to receiving a COVID-19 vaccine?

At this time, the CDC does not recommend routine testing for pregnancy prior to receiving a COVID-19 vaccine.



VACCINE SAFETY

1. How do I know it is safe?

The coronavirus that causes COVID-19 is a new virus, so entirely new vaccines must be developed and tested to ensure that they work and are safe. There are many steps in the <u>vaccine testing and approval process</u>. <u>Multiple agencies and groups in the United States</u> are working together to make sure that safe and effective COVID-19 vaccines are available as quickly as possible.

The U.S. vaccine safety system ensures that all vaccines are as safe as possible. Learn how federal partners are working together to ensure the safety of COVID-19 vaccines.

To date, no serious safety concerns have been reported by an independent data and safety monitoring board overseeing Phase 3 trials of the Pfizer and Moderna mRNA COVID-19 vaccines. Both vaccines met the safety requirements outlined by the FDA to seek an EUA. In the safety analysis, patients were followed for two months after they received their second dose of the vaccine.

2. How was the vaccine approved by the FDA?

The FDA authorized the vaccine under an Emergency Use Authorization (EUA) based on two months of safety data. According to the FDA, Pfizer must collect six months of safety data to apply for full approval. The EUA process has been deliberative, and the authorization wasn't rushed to meet any artificial deadlines. Plus, because the new coronavirus has surged so severely in recent weeks, we've seen a growing number of COVID-19 cases among placebo recipients — even as those who received the vaccine enjoyed robust protection. In that sense, the worsening of the pandemic has actually increased confidence that the vaccines are effective.

3. Will there be ongoing monitoring to ensure the vaccine is safe in the long term?

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.

The FDA's June 2020 guidance document includes important recommendations for ongoing safety evaluation after any COVID-19 vaccine is made available in the United States. The **CDC** is working to expand safety surveillance through new systems such as V-SAFE and additional information sources, as well as by scaling up existing safety monitoring systems.



4. Is the vaccine effective for members of all major U.S. demographic groups(by age, gender, race, etc.)?

Trial data were reported by age, gender, race, ethnicity, and more, and the conclusions were that the vaccine shows good efficacy in every group. The limitations of the study are that there were small numbers of people studied in some minority groups and that children under age 16 and pregnant women were excluded from the study.

Based on what we know, this vaccine works well across a wide range of populations, but data will continue to be collected to re-examine these questions as the vaccine becomes more widely available.

5. Were clinical trial data on the vaccine released to the public?

Data on the Pfizer-BioNTech vaccine has been released to the public here. https://www.fda.gov/media/144245/download

6. Is the vaccine made from a live virus or is it attenuated?

The vaccines do not contain the full live SARS-CoV-2 virus and therefore cannot cause COVID-19. The only part of the virus they contain or make is spike protein. As such, there is NO risk of becoming infected with COVID because of the vaccine. The first vaccines that will be available will either contain mRNA (non-infectious genetic material), viral vectors, (modified versions of live viruses), or protein subunits (parts of viral proteins) which cannot cause infection.

7. What are the side effects of the shot?

In Phase 3 clinical trials, the most common side effects were mild and included soreness at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever.

Side effects have been reported to be short-lived (most resolving in a day), mild, and to happen within the first few days of receiving the vaccine. Side effect occurrence typically is higher after the second dose of vaccine. Historically, long-term side effects from vaccines have been rare.

8. Will certain allergies/medications impact the effectiveness of the vaccine?

Individuals who take immunosuppressive medications may still receive COVID-19 vaccine, but it is unknown if the vaccine will be as effective in such cases.

9. Who (if anyone) should avoid getting the vaccine?

Individuals who have had a severe allergic reaction to any component of the Pfizer-BioNTech COVID-19 vaccine should not receive the vaccine.

Because of reports of anaphylactic reactions in people vaccinated outside of clinical trials, the CDC recommends that people who have had a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) should not receive the Pfizer-BioNTech vaccine at this time. The ACIP will be making more recommendations in the future on who should and should not receive the vaccines.



10. How effective will the vaccines be?

In Phase 3 trials, the Pfizer vaccine showed a 95% efficacy rate seven days after the second dose. The vaccine was 94% effective in adults over the age of 65. The Moderna vaccine showed a 94% efficacy rate 14 days after the second dose. These results were consistent across gender, age, race, and ethnicity.

11. How long will immunity last after I get vaccinated? Will I need to be vaccinated every year?

The length of immunity following vaccination is not yet known for COVID-19. Given the novel nature of this virus and vaccine development, long-term data are not yet available to guide future vaccine protocols.

12. Is there any known ingredient in the vaccine that someone could be allergic to (like eggs with the flu shot)?

The Pfizer BioNTech COVID-19 vaccine includes the following ingredients: mRNA, lipids, potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

13. What is an EUA, and what does it mean about the safety of a COVID-19 vaccine?

Learn more about Emergency Use Authorization and watch a video on what an EUA is.

The FDA issues an EUA when it allows a drug or vaccine to be used during a public health emergency. The FDA may choose to grant an EUA once studies have demonstrated the safety and effectiveness of a vaccine but before the manufacturer has submitted, or before the FDA has completed, its formal review of the license application. EUAs provide timely access to critical medical products during a medical emergency when there are no sufficient treatments or vaccines available.



VACCINE FOR NON-EMPLOYEES

1. Are children recommended to receive the vaccine?

The vaccine is approved for people age 16 and up.

2. Does insurance cover the vaccine?

Yes. Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. However, vaccination providers will be able to charge an administration fee for giving the shot to someone. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund.

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