COVID-19 Vaccine and Treatment Therapies

Since the beginning of the COVID-19 pandemic, scientists, physicians and health officials across the world have been working towards developing a vaccine for the virus. After months of extraordinary efforts, there have been significant developments regarding these vaccines and drug-therapies.

As more information becomes available, we want to ensure our patients, communities, physicians, clinical staff and employees are informed of these updates regarding the vaccines and drug-therapies.

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Additional Vaccine Information

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- Should I be vaccinated if I have been exposed to COVID-19?
- Should I be vaccinated if I am pregnant or breastfeeding?
- Should I vaccinate my children?
- Should I be vaccinated if I am immunocompromised?

Treatments and COVID-19

- Can I be vaccinated if I have received monoclonal antibody or convalescent plasma treatment?
- Can I receive a COVID-19 vaccine if I received another vaccine within 14 days?
- Can I take over-the-counter medication prior to getting vaccinated?

Post-Vaccination

- Will people still need to wear a mask, social distance and wash their hands after being vaccinated?
- Once I have received both doses of the COVID-19 vaccine, can I return to normal activities?
- How long does it take for the body to build immunity after vaccination?

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Definitions

Q. What is an Emergency Use Authorization (EUA)?

- Food & Drug Administration (FDA) authorization of an unapproved product or unapproved uses of an approved product for emergency use
- Emergency Use Authorization is NOT the same as FDA approval or licensure
- EUA is still considered an investigational state

Q. What are the requirements for a COVID-19 vaccine to get an EUA?

- Vaccines must be at least 50% effective in protecting against SARS-CoV2 infections
- For safety monitoring, study participants must be followed for at least two months following completion of the vaccination clinical trial regimen
- Participants will continue to be monitored for an additional two years to confirm long-term safety and protection

Q. What is an mRNA vaccine?

- These vaccines contain material from the COVID-19 virus to help cells make a harmless protein which can teach immune systems how to destroy the genetic material of the virus - therefore protecting from future infections
- Pfizer and Moderna vaccine are mRNA vaccines

Current Vaccine Candidate Information

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

- Large-scale (Phase 3) clinical trials are in progress or have been completed for five COVID-19 vaccines in the United States

Q. Information about the Pfizer vaccine

- The Pfizer vaccine has received the Federal Food and Drug Administration for Emergency Use Authorization in individuals 16 years or older
- Click here for the FDA Pfizer Fact Sheet
- The Pfizer vaccine is a two-dose series mRNA vaccine
- This vaccine is administered in two doses, 21 days apart. The ACIP recommends a +/- 4 day grace period for the second dose.
- If the second shot is not given by day 21, it should be given as soon as possible; it is not necessary to restart the series
- Do not mix doses of different vaccine brands (i.e., do not use Pfizer for dose 1 and Moderna for dose 2)
- People receiving the vaccine are considered fully vaccinated 1-2 weeks after the second dose but should continue following safety measures of mask wearing, physical distancing and hand washing until the general population has been vaccinated
- Early data shows that after the second dose, the vaccine is over 95% effective

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Q. Information about the Moderna vaccine

- The Moderna vaccine has received the Federal Food and Drug Administration for Emergency Use Authorization in individuals 18 years or older
- Click here for the FDA Moderna Fact Sheets
- The Moderna vaccine is a two-dose series mRNA vaccine
- This vaccine is administered in two doses: one dose, then 28 days later, a second dose. The ACIP recommends a +/- 4 day grace period for the second dose.
- Do not mix doses of different vaccine brands (i.e., do not use Pfizer for dose 1 and Moderna for dose 2)
- Early data shows that after the second dose, the vaccine is 94.5% effective

Q. Will I have to receive a COVID-19 vaccine every year, like the flu?

- The coronavirus is still so new that researchers will have to monitor people for an extended period of time to determine how long protection from the vaccine will last. Some vaccinations last a lifetime and some require an annual booster, such as the flu vaccine.

Q. What are the storage and handling considerations for the leading vaccine candidates?

- Due to their formulations, the two leading vaccine candidates in the U.S. must be stored at extremely low temperatures. The other vaccine candidates appear to be stable at normal refrigerated temperatures (2-8°C). The Pfizer/BioNTech vaccine must be stored at -70°C and will last for up to 5 days at refrigerated temperatures (2-8°C). Thermal shippers can be room temperature for 10 days (some sources indicate 15 days) if they are replenished with dry ice. Prior to administration, the vaccine must be thawed (thawed vaccine must be used within 5 days) and then reconstituted with diluent (reconstituted vaccine must be used within 6 hours). The Moderna vaccine must be stored at -20°C and can be stored for up to 6 months. The vaccine will be stable at refrigerated temperatures of 2-8°C for 30 days. All doses in a vial must be administered within 6 hours after vial puncture.[14]

Vaccine Evaluation/Distribution

Q. When will a COVID-19 vaccine be available in the United States?

- The FDA issued an Emergency Use Authorization (EUA) on Friday, December 11, 2020, approving the Pfizer vaccine for use in the United States. Shipment of the vaccines has begun across the country and hospitals should have doses for healthcare workers.
- The FDA issued an EUA on Friday, December 18, 2020, approving the Moderna vaccine for use in the United States. Shipment of the vaccines has begun across the country and hospitals should have doses for healthcare workers.
- The CDC has recommended that the highest priority groups to receive vaccinations are those at highest risk including healthcare workers and residents and staff of nursing homes
- The ACIP advising the CDC has recommended that people 75 and older and essential frontline workers be the next in line for limited supplies of COVID-19 vaccines.
- When a vaccine is authorized or approved in the United States, there may not be enough doses available for all adults right away. Supplies will increase over time, and all adults should be able to get vaccinated later in 2021.

Q. Who gets a vaccine?

- The Advisory Committee on Immunization Practices (ACIP) has recommended to the Center for Disease Control and Prevention (CDC) that health care workers and staff and residents of long-term care facilities should receive top priority for COVID-19 vaccines, although states have final approval of vaccine distribution in their state

Q. Is there a cost to receive the vaccination?

- Vaccines subsidized by United States taxpayer dollars will be available to citizens at no cost
- Vaccine providers can charge insurance providers or the Health Resources and Services Administration's Provider Relief Fund for the administration of the vaccine

Vaccine Safety, Research and Development

Q. Are these vaccines safe?

- Yes, both the Pfizer and Moderna vaccines have been studied in rigorous clinical trials and demonstrate safe outcomes in study participants

Q. Should I be concerned that development of the vaccine was rushed?

- No. Vaccine development has been led by the world's best scientists. One reason this came about so quickly is because the mRNA approach to creating a vaccine is highly precise. With new techniques, this sequence was developed in a matter of days. Stage 3 clinical trials testing the vaccines on tens of thousands of people have occurred. These all provide confidence in the safety and effectiveness of the vaccine. [12]

Q. How are scientists able to confirm so quickly that the COVID-19 vaccines available will indeed create antibodies to fight the new strains of COVID-19?

- In an alert sent to all health care providers on January 8, the U.S. Food and Drug Administration indicated that clinical studies have shown antibodies produced by the BioNTech/Pfizer vaccine are effective in neutralizing both the British and South African variant strains of COVID-19. Both Moderna and Pfizer are actively studying their efficacy against the newer strains of the SARS-CoV-2 virus.
- The Centers for Disease Control and Prevention (CDC) is enlisting private laboratories to help sequence the genomes of coronavirus samples from 50 states to track emerging variants.
- National Institute of Allergy and Infectious Diseases (NIAID) scientists also believe that both the Moderna and Pfizer SARS-CoV-2 vaccine will provide protection against COVID-19 variants: "As part of a person's immune response to the vaccines, they produce many antibodies that bind to different locations on the spike protein on the surface of the SARS-CoV-2 virus. Even if a SARS-CoV-2 variant has a few mutations that prevent binding of some antibodies, scientists expect that other antibodies with different binding properties will neutralize the virus," said a spokesperson at NIAID.

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

- Scientists are still learning more about the virus that causes COVID-19 and 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

Q. Does getting vaccinated help prevent me from getting sick with COVID-19?

- COVID-19 vaccination helps protect you by creating an antibody response without having to experience sickness

Q. Was fetal tissue used in the development or production of the vaccines?

- Neither the Pfizer nor the Moderna vaccine involved the use of fetal cell lines that originated in fetal tissue at any level of design, development or production

Q. Will the vaccine protect us from the mutant strain of COVID-19 we are hearing about?

- There isn't enough data yet to be certain, but the fundamental properties of the spike protein have not changed so we expect that the vaccines will offer protection against this mutation.
- Since viruses are expected to mutate frequently, the medical community has been looking at these variations under the microscope since the pandemic began. [12]

Q. Will a COVID-19 vaccine give me COVID-19?

- None of the COVID-19 vaccines currently in development in the United States use the live virus that causes COVID-19
- The goal for each of the vaccines is to teach our immune systems how to recognize and fight the virus that causes COVID-19
- Sometimes a vaccination can cause side effects but these symptoms are normal and are a sign that the body is building immunity. These symptoms should go away on their own in a week[4]

Vaccine Side Effects

Q. What are possible initial reactions from the COVID-19 vaccine?

- Some minor effects are expected as your body responds to the COVID vaccine. Common reported symptoms include pain at the injection site, fever, fatigue, and headaches, and are worse after the second dose. Other symptoms can include muscle and joint pain, cough, lethargy, and shortness of breath.[13]

Q. What are the long-term side effects of the vaccine?

- Recipients of the vaccines in clinical trials will be monitored for a two-year period to determine any long-term side effects of the vaccines
- For the Pfizer vaccine, the most commonly reported side effects, which typically lasted several days, were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever
    - Of note, more people experienced these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose
- Potential side effects will be reviewed with those receiving the vaccine

Q. Should I be vaccinated if I have a history of severe allergic reactions?

- The main side effect of the Pfizer vaccine is a reaction among some people with a history of anaphylaxis. Those people can receive the vaccine if anaphylaxis medication is readily available at the time of vaccination.
- CDC currently recommends that persons who receive a Pfizer-BioNTech COVID-19 vaccine be observed after vaccination for the following time periods:
    - Persons with a history of anaphylaxis (due to any cause): 30 minutes
    - All other persons: 15 minutes
- Patients who experience anaphylaxis after the first dose of COVID-19 vaccination should be instructed not to receive additional doses. In addition, patients should be referred to an allergist-immunologist for appropriate work-up and additional counseling.

Q. Do the COVID-19 vaccines affect male or female fertility?

- Thomas Bader, M.D., vice president of medical quality at Hackensack Meridian *Health* noted that "The FDA has determined that these new vaccines are safe and effective, based on rigorous clinical trials, and no evidence has suggested that problems with fertility is even a consideration." [10]

- Some people may be unsure about the safety of the COVID-19 vaccines because they contain a new type of technology, known as messenger RNA (mRNA). The new vaccines are the first to be released with this technology, but researchers have studied mRNA vaccines for years. This type of vaccine provides an immune response in a different way than other vaccines do, but it causes the same result, protecting you from disease. Other types of vaccines also don't impact fertility. In fact, doctors routinely recommend vaccinations to women who are trying to conceive, as well as pregnant women, because pregnant women and newborns may be more susceptible to illness. [10]
- Research suggests that COVID-19 itself – the virus, not the vaccine – may impact sperm quality, which could contribute to problems with infertility in some people. The University of Miami Miller School of Medicine is studying the impact of COVID-19 on sperm and have found the virus itself impacts sperm quality: "Our group and others have confirmed that the COVID-19 virus can affect sperm production inside the testes. We have shown that long after the infection is gone and when men who have had the virus become asymptomatic, the virus can continue to linger inside the testes," confirmed Ranjith Ramasamy, M.D., associate professor and director of reproductive urology said. [9]
- Vaccination against COVID-19 may actually help to protect male fertility and the Miller School is the first institution studying the effects on sperm of men who receive the vaccine. "Based on the mechanism by which mRNA acts, we do not expect the COVID-19 vaccines will have an impact on male fertility. But obviously we want data to confirm that hypothesis," Dr. Ramasamy said. [9]

Q. Will receiving an mRNA vaccine alter my DNA?

- 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

Treatments and COVID-19

Q. Can I be vaccinated if I have received monoclonal antibody or convalescent plasma treatment?

- Those who have received monoclonal antibodies are recommended to delay receiving the vaccine for 90 days to avoid interference with antibody treatment

Q. Can I receive a COVID-19 vaccine if I received another vaccine within 14 days?

- A minimum interval of 14 days should be maintained before or after administration of this COVID-19 vaccine with any other type of vaccine.

Q. Can I take over-the-counter medication prior to getting vaccinated?

- The CDC recommends not to take an over-the-counter pain medication to prevent symptoms until after your vaccination.

Additional Vaccine Information

Q. Will the COVID-19 vaccine cause me 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 antibody tests
- Antibody tests indicate you had a previous infection **and** that you may have some level of protection against the virus

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Q. If I have already had COVID-19 and recovered, should I still get vaccinated when a vaccine is available?

- The vaccine has been proven safe and effective in people previously infected with COVID-19. There is no need to test for antibodies prior to vaccination.

Q. If I currently have COVID-19, can I receive a vaccination?

- It is recommended that the vaccine occur within the 90-day period, however, the CDC has said it can be delayed towards the end of the 90 days.

Q. Should I be vaccinated if I have been exposed to COVID-19?

- Those who have been exposed to COVID-19 should defer being vaccinated until their quarantine period is over

Q. Should I be vaccinated if I am pregnant or breastfeeding?

- Pregnant people with COVID-19 are at high risk for severe disease, including pre-term delivery. Those who are pregnant or breastfeeding are allowed to receive the vaccine, but should speak with their provider to make their choice, considering local prevalence, personal risk of exposure, general safety of the vaccine and lack of data from the trial.

Q. Should I vaccinate my children?

- The FDA has provided Emergency Use Authorization to administer the Pfizer vaccine to people aged 16 and above. Researchers will need to conduct additional studies on how the vaccine affects younger children. This process could take several months, according to pediatric infectious disease experts. Children might not see a vaccine until the summer or fall of 2021.
- Vaccines are typically first tested in adults before they're evaluated in children. Then, drugs are usually first examined in older kids before being tested in younger children. Pfizer recently began testing its vaccine in children ages 12 and older. The other leading manufacturers, AstraZeneca and Moderna, have not yet started testing their vaccines in children. Once vaccine safety is displayed in older kids, the trials could slowly and carefully incorporate younger children.
- The studies will likely need to look at the dosage, the number of doses, and the interval between the doses to determine if these elements need to be adjusted for children.

Q. Should I be vaccinated if I am immunocompromised?

- There is no clinical data on the safety or efficacy of the vaccine in immunocompromised people but they can be vaccinated unless otherwise contraindicated. They should speak with their provider to make their choice.

Post-Vaccination

Q. Will people still need to wear a mask, social distance and wash their hands after being vaccinated?

- Yes, it is recommended to wear a mask, social distance and wash your hands per state and federal guidance until the guidance changes.

Q. Once I have received both doses of the COVID-19 vaccine, can I return to normal activities?

- No. Until at least 70% of the U.S. population has been vaccinated, you will need to maintain safety precautions of wearing masks, maintaining physical distancing and frequent handwashing. Even if people have received the vaccine, they still may be able to spread the novel coronavirus to others who haven't yet been vaccinated, particularly those who have not been vaccinated for health reasons.

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- Once a majority of Americans have been vaccinated against the new coronavirus, it will be safer for people to once again eat at restaurants indoors, attend parties, ride a bus, and gather for the holidays, scientists say.
- Many experts believe that these activities will be relatively safe to resume once at least 70% of Americans are vaccinated or have recovered from a coronavirus infection, at which point many scientists say that the United States will have reached herd immunity and the coronavirus will no longer spread easily, However, it's too early to tell when the United States will reach that threshold, because scientists are still unsure how the newly authorized vaccines will affect the coronavirus's contagiousness.
- In addition, scientists say it's unclear when the United States will have the vaccine doses needed to vaccinate the hundreds of millions of Americans it could take to meet the heard immunity threshold. Federal officials estimate they'll be able to do so by the summer of 2021. [11]

Q. How long does it take for the body to build immunity after vaccination?

- It typically takes a few weeks for the body to build immunity after vaccination

Resources

- The Food and Drug Administration posted a webpage: Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions. Questions cover specifics, such as what data did the FDA use to make the decision to authorize the vaccine for emergency use, to more general questions, such as how does a vaccine go from emergency use authorization to licensure.
- Find a suite of information and materials that are needed for each specific COVID-19 vaccine that cover administration, storage and handling, safety, and reporting.
    - https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
- Additional information about the COVID-19 vaccines is available on the CDC website:
    - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html
    - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html#:~:text=If%20I%20have%20already%20had,this%20is%20called%20natural%20immunity
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