What is an Emergency Use Authorization (EUA)?
Emergency Use Authorization occurs when the FDA allows a drug or vaccine to be used during a public health emergency. The FDA may choose to grant EUA once studies have demonstrated the safety and effectiveness of a vaccine but before the manufacturer has submitted, or 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.

Which vaccines have been granted EUA?

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Ages included</th>
<th>Dosing</th>
<th>Date EUA granted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>16 and older</td>
<td>2 doses given intramuscularly 21 days apart</td>
<td>12/11/20</td>
</tr>
<tr>
<td>Moderna</td>
<td>18 and older</td>
<td>2 doses given intramuscularly 28 days apart</td>
<td>12/18/20</td>
</tr>
</tbody>
</table>

Are the COVID-19 vaccines safe?
In phase 3 clinical trials, COVID-19 vaccines are tested in tens of thousands of participants for safety and efficacy. To date, no serious safety concerns have been reported by an independent Data and Safety monitoring board overseeing the phase 3 clinical trials of the Pfizer and Moderna mRNA COVID-19 vaccines. Both vaccines met the safety and efficacy requirements outlined by the FDA to obtain EUA. In the safety analysis of the Pfizer and Moderna vaccines, patients were followed for at least 2 months after they received their second dose of the vaccine.

What side effects will the vaccine have?
In the Pfizer and Moderna vaccine clinical trials, the majority of side effects reported were mild to moderate, short lived, and happened within the first few days of receiving the vaccine. Examples of common mild to moderate side effects include pain at the injection site, headache, fatigue, fever, or chills. Side effect occurrence is typically higher after the second dose of vaccine. In Phase 3 clinical trials, the most common severe side effects reported were as follows:

<table>
<thead>
<tr>
<th>Side effect</th>
<th>Pfizer</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>3.8%</td>
<td>9.7%</td>
</tr>
<tr>
<td>Muscle pain</td>
<td></td>
<td>8.9%</td>
</tr>
<tr>
<td>Joint pain</td>
<td></td>
<td>5.2%</td>
</tr>
<tr>
<td>Headache</td>
<td>2%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Pain</td>
<td>4.1%</td>
<td></td>
</tr>
</tbody>
</table>

Percent reported
Are there going to be long term side effects from the vaccines?
Historically, long term side effects from vaccines have been rare. The vaccine advisory committee to the FDA has stated that historically, most side effects have been seen within the first 60 days of receiving vaccines.

How will side effects from the vaccines be treated?
Side effects from vaccines are typically short lived. You may take medications for pain or fever after you have been vaccinated. If you are concerned about your health after getting vaccinated, talk with your doctor. They will determine the appropriate treatment. You or your doctor can choose to report the side effect to the Vaccine Adverse Event Reporting System (VAERS). Information on how to submit a report to VAERS is available at: vaers.hhs.gov/index.html 1-800-822-7967

Should premedications be given prior to vaccination?
Taking medications as acetaminophen, ibuprofen, or antihistamines before receiving the vaccine to try to prevent side effects is not recommended at this time. This is because there is not enough information on how this will impact antibody responses, though, you can take these medications after receiving the vaccine if you develop side effects.

Are there any contraindications (factors that would be a reason to withhold vaccination due to harm) to receiving the vaccine?
The CDC considers the following to be contraindications to vaccination with the mRNA COVID-19 vaccines:
— Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
— Immediate allergic reaction of any severity to polyethylene glycol (PEG)*
— Immediate allergic reaction to polysorbate (potential cross-reactivity with PEG)*

An immediate allergic reaction means any hypersensitivity-related signs of symptoms such as hives, angioedema (throat swelling), respiratory distress (wheezing), or anaphylaxis within 4 hours following administration.

*These individuals should not receive the mRNA COVID-19 vaccines unless they have been evaluated by an allergist/immunologist and have been cleared to receive the vaccine.

Should I take the COVID-19 vaccine if I have a significant history of allergic reactions?
The CDC states severe allergic reaction (i.e. anaphylaxis) to any other vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) is a precaution, but not a contraindication to receiving the COVID-19 mRNA vaccines. Vaccine providers should observe these patients for 30 minutes after vaccination to monitor for the development of immediate adverse reactions. Deferral of vaccination and consultation with an allergist/immunologist may be considered.

Those with allergies to food, pets, insects, latex, or oral medications do not fall under this precaution and are monitored similarly to all other vaccine recipients (15 minutes).

If you have a history of severe allergic reactions you should discuss this with your healthcare provider and notify the healthcare workers administering your vaccine.

Can I take the vaccine if I am pregnant?
Currently, there is no data on the safety and efficacy of COVID-19 vaccines in pregnant women as they were excluded from clinical trials. However, it is known that pregnant women can have an increased risk of severe illness or negative pregnancy outcomes, such as preterm birth, if they become infected with COVID-19. The CDC and ACIP have commented that the vaccine is unlikely to cause placental and fetal exposure and that there is minimal safety risk as the mRNA vaccine is not a live vaccine. Statements have also been made that the benefit of vaccination may outweigh the risk of severe COVID-19 disease. For this reason, if a pregnant woman is part of a group who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated. A discussion with her health care provider can help her make an informed decision. Pregnant women who develop a fever after vaccination should take acetaminophen as fever is associated with negative pregnancy outcomes.

Considerations for vaccination:
— Level of COVID-19 community transmission, (risk of acquisition)
— Her personal risk of contracting COVID-19, (by occupation or other activities)
— The risks of COVID-19 to her and potential risks to the fetus
— The efficacy of the vaccine
— The known side effects of the vaccine
— The lack of data about the vaccine during pregnancy

Can I take the vaccine if I am breastfeeding?
Currently, there is no data on the safety and efficacy of COVID-19 vaccines in breastfeeding women as they were excluded from clinical trials. The CDC has stated that since the mRNA vaccine does not contain live virus, it is not thought to be a risk to breastfeeding infants. For this reason, if a breastfeeding woman is part of a group who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated. A discussion with her health care provider can help her make an informed decision.
Will the vaccines cause infertility?
Currently, there is no evidence that any of the COVID-19 vaccines cause infertility. Claims circulating on social media is that antibodies formed after vaccination which target the COVID-19 spike protein may also target a protein found in placenta called syncytin-1. This has not been proven at this time. A Pfizer representative and virologists have stated the two proteins are not similar enough for this to happen. Additionally, if this were found to be true, then this would also suggest that people who become infected with COVID-19 and recover would carry a similar risk of infertility due to the formation of antibodies after natural infection. However, there is currently no definitive evidence that COVID-19 infection causes infertility.

Can I take the vaccine if I am immunocompromised?
Currently, there is no data on the safety and efficacy of COVID-19 vaccines in immunocompromised people as they were excluded from clinical trials. However, people with immunocompromised conditions or those on immunosuppressant medications might be at increased risk for severe disease if they get COVID-19. Therefore, the CDC recommends these individuals may still receive the COVID-19 vaccine. Immunocompromised individuals should discuss this with their healthcare provider. It is important to note that the mRNA vaccines do not contain live virus. Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the COVID-19 Vaccine.

Can I take the vaccine if I have an autoimmune condition?
The CDC states people with autoimmune conditions may still receive an mRNA COVID-19 vaccine.

Can I take the vaccine if I currently am infected with COVID-19?
No. You should wait until you have recovered and no longer in isolation. See the question below for more information.

Can I take the vaccine if I have already had COVID-19 and recovered? How long after can I take it?
People who have already had COVID-19 and recovered should still receive the vaccine. This is because it is unknown exactly how long immunity lasts after recovering from COVID-19. Early studies show that it is not long lasting, and cases of reinfection have been reported. The Pfizer trial did include a small percentage of individuals who previously had COVID-19 and recovered. The CDC states current evidence suggests reinfection is uncommon within 90 days after initial infection, so vaccination may be deferred until the end of this period; however, it is not known when another vaccination will be available to you.

Can I take the vaccine if I am in quarantine?
Persons who are in quarantine should wait until their quarantine period has ended to avoid exposing healthcare personnel during their vaccination visit.

Can I take the vaccine if I have had convalescent plasma or a COVID-19 monoclonal antibody (bamlanivimab or casirivimab/imdevimab)?
Currently, there is no data on the safety and efficacy of COVID-19 vaccines in people who received convalescent plasma or one of these monoclonal antibodies. Vaccination should be deferred until 90 days after receiving convalescent plasma or monoclonal antibodies. This is to avoid interference of these treatments with vaccine induced immune responses.

Can I take the COVID-19 vaccine with other vaccines?
The CDC recommends the COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration with any other vaccine. However, mRNA COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination outweigh the unknown risks of vaccine co-administration (e.g., tetanus toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to mRNA COVID-19 vaccination.

How effective will the vaccines be?
In Phase 3 trials, the Pfizer vaccine showed a 95% efficacy rate 7 days after the second dose. The vaccine was 94% effective in adults >65 years old. The Moderna vaccine showed a 94% efficacy rate 14 days after the second dose. These results were consistent across gender, age, race and ethnicity.

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 is not yet available to guide future vaccine protocols.

How many people need to get the vaccine for “herd immunity”?
The number or percentage of population that need to be vaccinated in order to reach “herd immunity” is not yet known. This number is impacted by the pathogen itself (in this case a novel virus with still unknown aspects), how efficacious these new vaccines will be (preliminary data shows both Moderna and Pfizer to be >90%), and how long immunity would last with these vaccines. This is an unknown at the moment as we do not know how long immunity lasts either from vaccination or from natural infection.
For 2 dose vaccines, what happens if I only receive one dose of the vaccine and not both?
It is recommended to receive both doses of the vaccine. Both doses of the vaccine are necessary for protection. Efficacy of a single dose of the Moderna or Pfizer/BNT vaccine has not been studied.

For the 2-dose series vaccines, when do I take the second dose?
The Pfizer product is a 2-dose vaccination series given 21 days apart. If more than 21 days have passed since the first dose, the second dose should be given at the earliest opportunity. You do not have to repeat any doses. The Moderna product is a 2-dose vaccination series given 28 days apart. If more than 28 days have passed since the first dose, the second dose should be given at the earliest opportunity.

Do not factor in the 4-day “grace period” when scheduling your second dose (i.e. receiving the second dose on days 17-20 for Pfizer vaccine and days 24-27 for the Moderna vaccine). The CDC has stated although giving the vaccine within the grace period is possible, it should be an exception and not standard practice.

How do the Pfizer and Moderna mRNA vaccines work?
The vaccines contain synthetic mRNA, which is genetic information used to make the SARS-CoV-2 spike protein. 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 the provide protection if a person comes into contact with the virus. The mRNA vaccines are non-infectious and do not enter the human cell nucleus so it cannot be inserted into human DNA. Additionally, mRNA is rapidly broken down, and this theoretically reduces chances for long term side effects. The mRNA vaccines do not have the ability to cause cancer.

Can I get COVID-19 from a vaccine?
No. None of the COVID-19 vaccines currently authorized for use or in development in the United States use the live virus that causes COVID-19. The vaccines 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. The CDC states that protection from the vaccine is not immediate, and it will take 1-2 weeks following the second dose of a 2-dose series vaccine to be considered fully vaccinated. That means it is possible you could catch the virus from the community just before or after vaccination and get sick. The vaccine does not cause infection.

Will taking the vaccine cause a false positive COVID test?
No. The COVID-19 vaccines will not cause a false positive result on COVID-19 viral tests that test for a current infection. There is a possibility that you will test positive on some antibody tests that detect antibodies to the spike protein. A positive antibody test means you may have previously been infected with COVID-19, or it may result from vaccination.

Do I still need to wear a mask after I take 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, we don’t know how long immunity will last. Furthermore, infection after a receiving a vaccine may still be possible, although it may be less severe, such as a mild or asymptomatic infection. Others can still be infected in this scenario, necessitating the continued use of masks.

Why is vaccine development happening so fast?
The vaccine process is happening faster because vaccine research and development, clinical trials, manufacturing, and plans for distribution are occurring at the same time. This method removes delays that occur when these processes are carried out separately. Steps for development are not being eliminated.

Disclaimer: This FAQ is based on the current available literature and is subject to change.


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