

COVID-19 VACCINE FAQ

CLINICAL FACILITATOR GUIDE

Updated on August 26, 2021

This document is intended to provide clinical facilitators with a series of FAQs regarding COVID-19 vaccines to guide conversations with community members. This information is based on currently available scientific evidence, reports, emergency use authorization details, and expert opinion, and is subject to change. This document will be frequently updated as evidence and information about COVID-19 vaccines becomes available.

How do I begin to address vaccine reluctance?

Vaccine reluctance represents a diverse range of perspectives and is not amenable to a “one size fits all” approach. It is important to elicit the specific concerns that communities and individuals have surrounding the vaccines and try to address them in a non-confrontational manner. Providing reliable, clear, multimodal information on known and unknown answers to common vaccine questions can help fill in gaps in understanding about the vaccines and COVID-19.

Is a COVID-19 vaccine necessary?

Getting the COVID-19 vaccine helps prevent you from getting sick with COVID-19. Even in young, healthy people, COVID-19 can lead to severe disease, hospitalization, long-term disability, or even death. Protection is key, particularly as the more transmissible and dangerous Delta variant spreads. Vaccination is an important step in helping to prevent this illness and its potentially devastating consequences for you and those around you.

Which COVID-19 vaccines are available in the U.S.?

Multiple COVID-19 vaccines have received Emergency Use Authorization (EUA) from the FDA. Two-dose mRNA vaccines developed by both Pfizer/BioNTech and Moderna received EUA in December 2020 and are currently available and being administered across the U.S. The Janssen/Johnson & Johnson (J&J) single-dose adenovirus vector vaccine received EUA in late February 2021. Several other COVID-19 vaccines are currently in development.

As of August 2021, the FDA granted full approval of the first COVID-19 vaccine formerly under EUA. The Pfizer/BioNTech vaccine will now be marketed as Comirnaty (koe-mir'-na-tee) for individuals 16+. The vaccine will continue to be available under EUA, including for individuals 12-15 and for the administration of a third dose in immunocompromised individuals.

What is the Delta variant? Do the COVID-19 vaccines work against it? I heard about breakthrough cases?

All viruses mutate and change naturally. When mutations fundamentally change the characteristics of a virus (its structure or behavior), we classify them as variants. The Delta variant is now the dominant COVID-19 variant in the U.S. It is spreading rapidly, especially in areas with low vaccination rates. The Delta variant is more transmissible than any other COVID-19 variant we've seen, meaning it can spread more easily from person to person. We're still learning about the Delta variant, but it may also be more deadly and dangerous to those who are infected than previous variants. It appears to be more likely to lead to hospitalization, oxygen requirements, and death compared to previously observed strains of the virus, especially among unvaccinated people.

COVID-19 vaccines are primarily intended to lower your risk of severe illness and death from the virus; they continue to do this very well. Despite vaccine's effectiveness, no vaccine is perfect and breakthrough cases (meaning positive cases among vaccinated people) are expected. The Delta variant is causing more breakthrough cases than other versions of the virus. However, the vast majority of these cases are either asymptomatic or mild. Unvaccinated

people continue to be at significant risk of serious illness or death. Breakthrough cases do not mean the vaccine is not working. Data show that the available vaccines are especially effective against symptomatic infection, hospitalization, and death. The best way to protect yourself and those around you from the Delta variant is to get vaccinated as soon as possible.

How do the Pfizer and Moderna mRNA vaccines work?

The Pfizer and Moderna vaccines contain synthetic messenger RNA (mRNA), which is genetic information used to mimic one of the SARS-CoV-2 spike proteins. 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 then later provide protection if a person comes into contact with the virus. Once injected, and the mRNA has instructed human cells to produce the spike protein, enzymes degrade the mRNA. No live virus is involved in these vaccines, and no genetic material is altered, or enters the nucleus of human cells.

How does the Johnson & Johnson vaccine work?

The Janssen/Johnson & Johnson (J&J) vaccine is a viral vector vaccine, which uses a harmless adenovirus to alert the body's immune system. Like mRNA, the harmless adenovirus delivers a blueprint, telling the body to produce SARS - CoV-2 spike proteins. The spike protein is the part of the virus that attaches to human cells. This causes the immune system to make antibodies against the virus, thereby creating an immune response. *The viruses are weakened and cannot cause COVID-19.* This viral vector technology has been used for many years in gene therapy and has been used in several vaccines before, including a J&J vaccine approved for use against Ebola.

Can I get COVID-19 from a vaccine? Are these vaccines safe?

The vaccines do not contain the full live SARS-CoV-2 virus and therefore cannot cause COVID-19. The vaccines currently in use and/or being researched contain either mRNA (non-infectious genetic material), viral vectors (modified versions of live viruses), or protein subunits (parts of viral proteins). *None of these vaccine types can cause infection.* Some minor side effects have been reported, which are typical of all vaccines, such as pain at the site of injection, fatigue, headaches, chills, fever, and nausea. The FDA continues to monitor the safety of the vaccines closely.

What about the Johnson & Johnson vaccine? I heard the vaccine was paused for safety reasons?

In April, use of the Janssen/Johnson & Johnson (J&J) vaccine was briefly paused so that experts could better understand an extremely rare blood clotting disorder, Thrombosis with Thrombocytopenia Syndrome (TTS) occurring in a small number of recipients. In these patients with TTS, a cerebral venous sinus thrombosis (a type of blood clot in the brain) occurred alongside low platelet counts, a combination of serious blood clotting and potential for abnormal bleeding. These are important details because TSS treatment is different than treatment for most other blood clots, and clinicians must be aware of the potential for such rare events in recipients. See [CDC guidance](#) for additional clinical considerations.

After weighing the risk of complications with the risk of getting COVID-19 and developing serious illness, regulators and medical experts determined that the benefits of the J&J vaccine outweigh potential risks. After 10 days, the pause ended and states have resumed use of the vaccine. Of the 7.9 million doses of the J&J vaccine administered as of late April, there were 15 cases of the disorder. This pause is an example of the public health regulatory system working as it should to prioritize patient safety and transparency.

If you receive the J&J vaccine, your risk of experiencing this adverse event is very, very small, and it decreases with time, with known cases happening between 6-14 days following vaccination. Be aware of symptoms of the disorder, including severe headache, abdominal or leg pain, and shortness of breath, and contact your medical provider if you

experience these symptoms or have concerns. The J&J vaccine now contains a new warning for rare clotting events among women aged 18-49 years. The vaccines approved under the EUA, including the J&J vaccine, are all highly effective against COVID-19, and experts recommend that you continue to get the vaccine available to you to protect yourself and your family.

Why were the vaccines developed so fast? I'm concerned that these vaccines did not undergo enough testing.

The speed of COVID-19 vaccine development is not a result of compromised safety or quality. The vaccine process is happening faster because research and development, clinical trials, manufacturing, and plans for distribution are occurring at the same time, with unprecedented levels of government spending. This method removes delays that occur when these processes are carried out sequentially. No standards in the safety evaluations have been changed during this process.

How will the vaccine affect older people or those with underlying medical conditions?

There is no maximum age restriction, though more evidence is needed to determine vaccine efficacy among advanced ages and those who are not ambulatory or clinically stable. The vaccines are safe and effective in people with preexisting conditions like diabetes and obesity—many of the participants in the vaccine trials had underlying medical conditions. Individuals who have underlying medical conditions or have concerns are encouraged to speak with a health care provider to help make an informed decision.

Can individuals who are immunocompromised receive the vaccine?

Individuals who are immunocompromised are eligible to receive the vaccine. On August 12, 2021 the FDA amended the EUAs for both the Pfizer and Moderna vaccines to allow for the use of a third dose in certain immunocompromised individuals. This specifically includes solid organ transplant recipients or those diagnosed with conditions with similar levels of immunocompromise. Individuals who are immunocompromised or have concerns are encouraged to speak with a health care provider to discuss their eligibility for an additional dose.

Can children get the COVID-19 vaccine?

At this time, individuals above 12 years old are eligible to receive the Pfizer vaccine, and individuals over 18 years old can receive the Moderna or J&J vaccines. Trials are underway for younger children, with the results of trials for ages 5-11 from Pfizer expected early fall 2021 and from Moderna several months later. Results and eligibility determinations for younger children will follow this initial group.

Is it safe for my child to receive a COVID-19 vaccine?

Medical and public health experts trust the very serious and thorough FDA trial and approval process for the vaccines, as well as the public health regulatory system that constantly monitors ongoing vaccine safety and effectiveness. Trials for children under 12 have expanded to include more children and acquire more data on safety and effectiveness against the virus—ensuring experts know as much as possible. Speak to your pediatrician to learn more.

Can pregnant women get the COVID-19 vaccine? What about those trying to become pregnant now or in the future?

The CDC recommends that pregnant women become vaccinated against COVID-19. No individuals who were pregnant were enrolled in the original clinical trials; however, vaccine surveillance systems have not showed any major safety concerns for pregnant women or their babies. In fact, if you get vaccinated during late pregnancy, it is likely that the antibodies you develop from vaccination will be passed to your baby and may provide some protection against COVID-19. Pregnant women who get COVID-19 have been shown to become more sick than non-

pregnant women, so preventing COVID-19 with vaccination is especially important in pregnancy. If you are pregnant and/or lactating, please speak with a health provider to learn more. If you are trying to become pregnant now or in the future, experts recommend you should receive a COVID-19 vaccine.

There is no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems and data has shown no increased risk of miscarriage. Like with all vaccines, medical experts will continue to study side effects; we will update you with any new findings as they become available.

What side effects will the vaccine have? Are there going to be long-term side effects?

Side effects can include pain at the injection site, fatigue, headache, chills, muscle pain, fever, nausea, and joint pain. These side effects are usually mild and last 1-3 days. Generally, side effects are more common in younger vs. older patients, and the 2nd dose associated with more side effects than the 1st. Talk to your doctor or vaccine provider about taking over-the-counter medicines for managing any discomfort you may experience after getting vaccinated. Vaccine recipients can sign up with [v-safe](#) to report any adverse events or reactions, and provide feedback on side effects. Historically, long-term side effects from vaccines have been rare.

Where can I get vaccinated?

Anyone eligible for vaccination (12+), will be able to get their vaccine at a variety of locations, including pharmacies, mobile clinics, or other types of sites. You can search online for locations in your area here: <https://www.vaccines.gov/search/>. Refer to your local health department or doctor for more details, as there may be opportunities not listed on this website.

Will I pay to get the vaccine?

No! All vaccines are provided through the U.S. government and will be free of charge to all individuals, including those without insurance. For those who have insurance, your information may be collected so the vaccine provider can bill the insurance company for administrative costs, but there will be no out-of-pocket cost to the individual.

What should I do to protect myself until I receive the COVID-19 vaccine?

You should continue to wear a mask when around others, avoid contact with people who are sick, get regularly tested, practice social distancing, and wash your hands often.

How long will immunity last after vaccination? Will I need to be vaccinated every year? What about booster shots?

It is still unclear how long vaccination immunity lasts, and this is in large part because new variants are emerging. Evidence is mounting that vaccine protection against infection—but not against hospitalization and death—waned after a few months in the groups vaccinated earliest, although it is not yet fully understood how much is due to age, variants, or the waning effectiveness of the vaccines. The Biden administration has called for booster shots to begin in September, pending FDA and Advisory Committee on Immunization Practices (ACIP) approval. If that happens, it is not yet known whether this will be the final booster, or whether boosters will be required at regular intervals to maximize protection.

If I had COVID-19 and recovered, or if I tested positive for COVID-19 antibodies, do I still need to get vaccinated?

At this time, it is recommended that everyone is vaccinated, even if they have had COVID-19 before and recovered, or tested positive for antibodies. Early evidence suggests natural immunity from COVID-19 may not last forever, and reinfection with new variants is common, particularly among the unvaccinated. There is no minimum recommended period between infection and vaccination; individuals are advised to become vaccinated after symptoms resolve (if

symptomatic) and after completing requirements for isolation. Refer to the [CDC website](#) for current requirements for isolation.

Do I still need to wear a mask and follow social distancing protocols after I take the vaccine?

Mostly, yes. We must recommit to proven mitigation measures—including masking and social distancing—amidst a changing pandemic, the emergence of the more dangerous and transmissible Delta variant, and insufficient vaccination rates. The CDC has recently updated its guidance to reflect that reality and better protect people, recommending masking regardless of vaccination status. The CDC now recommends masking indoors for anyone—regardless of vaccination status—living in areas of substantial or high spread, which currently describes the vast majority of the country. Country transmission levels can be found [here](#). Those older than 65, with a compromised immune system or a chronic disease, or living with people who fit into one of these categories, may also want to consider masking indoors, regardless of local transmission. Getting COVID-19 while outdoors is very unlikely in most scenarios, but if in crowded spaces, people may want to consider wearing a mask.

For Pfizer or Moderna: When will I receive my 2nd dose? Can doses be delayed?

For the mRNA vaccines, a person is considered fully vaccinated 14 days after the 2nd of two doses; doses are administered 21 days apart (Pfizer) or 28 days apart (Moderna). The 2nd dose may be given early (within four days of the intended date) only if the recipient is unable to return or be available on the exact date of administration. The 2nd dose may be delayed up to six weeks after the 1st dose. For the J&J vaccine, a person is considered fully vaccinated 14 days after receiving a single dose. Vaccinations should be delayed in individuals experiencing acute symptoms, until they have recovered. Those with chronic conditions and stable symptoms from such underlying medical issues can be vaccinated safely. While there is insufficient evidence around delaying 2nd doses for COVID-19 vaccines and the resulting level and duration of protection, delays within the window should still result in protection. If delay is necessary, the 2nd dose should be given as soon as possible after the missed scheduled dose.

For Pfizer or Moderna: Can I receive different vaccines for each dose?

The underlying way the mRNA vaccines work is the same, but they are not identical, and should not be used interchangeably (i.e. the 2nd dose should be from the same vaccine as the 1st). There is no evidence to indicate that receiving a different vaccine as a 2nd dose would be unsafe or less effective, but the vaccines have not been fully studied this way. This guidance is especially salient if/when new vaccines, utilizing different mechanisms enter the market.

Does the COVID-19 vaccine take the place of the pneumonia vaccine or the flu vaccine?

No, the COVID-19 vaccine does not take the place of the pneumonia vaccine or the flu vaccine. It is recommended to remain up to date on pneumonia and flu vaccines in addition to COVID-19. Please consult with your health care provider regarding which vaccines and vaccine schedule are recommended for you.

Is the vaccine being targeted to communities of color?

No, the vaccines are not being targeted at people of color. Communities of color have experienced higher rates of infection and hospitalization from COVID-19 than their white counterparts. Failure to reach the groups that are most vulnerable will be a tragedy stretching well beyond the pandemic. This is why health experts are encouraging everyone to take the vaccine when it becomes available.

Did people of all backgrounds participate in the clinical trials? Were the vaccines effective for people of all races and ethnicities?

In the Pfizer trial, 26% of participants identified as Hispanic or Latinx, 10% of participants identified as Black, 4% as Asian, and 1% as Native American or Pacific Islander. In the Moderna vaccine trial, 20% of participants identified as Hispanic or Latinx, 10% of participants identified as Black, 5% as Asian, and 1% as Native American or Pacific Islander. In the Johnson & Johnson trial, 45% of participants identified as Hispanic or Latinx, 17% of participants identified as Black, 4% as Asian, and 9% as Native American or Pacific Islander. The participants enrolled in the studies reflected the race, ethnicity, age, and sex distributions we see within the US. Final trial results from all vaccines revealed that their COVID-19 vaccines are equally effective at preventing COVID-19 illness across all racial and ethnic groups.

Why is there a vaccine already for COVID-19 and not a vaccine or cure for other diseases we've known for longer, like AIDS and cancer?

Some diseases may not be able to be prevented by current vaccine technology, such as cancers and AIDS, although research is ongoing. COVID-19 is caused by a coronavirus. Prior to the current COVID-19 outbreak, research was underway across the world on other coronavirus vaccines, for diseases such as SARS and MERS. When the pandemic hit, scientists were able to call upon this research and use some of these previous lessons learned to develop the current vaccine candidates.

The ideas presented in this document reflect the latest public health thinking and scientific evidence as of August 2021. You are advised that the COVID-19 vaccine landscape remains highly fluid, and it is your responsibility to ensure that decisions are made based on the most up-to-date information available. Partners In Health does not provide medical advice, diagnosis or treatment in the United States. Always seek the advice of a physician or other qualified health care provider with any questions regarding a medical condition. The information, including but not limited to, text, graphics, images and other material contained in this document, are intended for informational purposes only.