COVID-19 Vaccines and People with HIV

Frequently Asked Questions

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The HIV Medicine Association and Infectious Diseases Society of America developed this document to respond to questions from HIV clinicians, and as a resource for HIV clinicians to respond to patient questions regarding the three COVID-19 vaccines authorized for use in the U.S. by the Food and Drug Administration. The two mRNA vaccines are referred to by the manufacturer’s names – Moderna and Pfizer/BioNTech, and the Johnson and Johnson/Janssen adenoviral-vector vaccine is referred to as J&J/Janssen. Unless otherwise specified, the information provided is applicable to all three vaccines. This resource does not cover COVID-19 vaccines that have not been authorized for use in the U.S. The World Health Organization is a resource for information on other COVID-19 vaccines.

Except when otherwise referenced, the information provided is based on the IDSA COVID-19 Real-Time Learning Network’s Vaccine Information and FAQs and the following Centers for Disease Control and Prevention resources: Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, Facts About COVID-19 Vaccines, Frequently Asked Questions About COVID-19 Vaccination, COVID-19 ACIP Vaccine Recommendations, Interim Public Health Recommendations for Fully Vaccinated People, and Vaccine Considerations for People with Underlying Medical Conditions. Please email us with questions not covered.

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SAFETY

Are the COVID-19 vaccines safe for people with HIV?

- In clinical trials, COVID-19 vaccines were found to be safe and effective. Given these data and extensive experience following vaccine authorization, people with HIV should receive the COVID-19 vaccine. There are no data to suggest that the vaccines are not safe and effective for people with HIV, including adolescents between 12 and 15 years.
- There have been no links between HIV or other types of immunosuppression with any of the rare serious adverse events for the COVID-19 vaccines. Data compiled by the WHO from 37 countries indicate that people with HIV are likely at increased risk for severe illness due to COVID-19. For that reason, it is important that people with HIV receive the COVID-19 vaccine.
- The CDC guidance advises that people with HIV may receive the vaccine as long as they do not have other conditions that would exclude them, such as a known severe allergic reaction or immediate allergic reaction of any severity after a previous dose or to a component of the COVID-19 vaccine. The vaccines authorized for use in the United States do not contain infectious virus so they are expected to be safe in people with low CD4 cell counts.
- People with stable HIV have been included in the COVID-19 vaccine clinical trials, so information specific to people with HIV should become available in the future.

Is the Pfizer-BioNTech vaccine safe for adolescents with HIV between the ages of 12 and 15?

- The CDC recommends COVID-19 vaccination for all people 12 and older in the U.S.
- The Pfizer-BioNTech vaccine is the only COVID-19 vaccine currently authorized for vaccination for adolescents between the ages of 12 and 15, including for adolescents with HIV.

Are the Pfizer/BioNTech and Moderna (mRNA) vaccines safe?

- The safety monitoring data for the Pfizer/BioNTech and Moderna vaccines confirm that they are safe.
- Rare, serious allergic reactions have occurred with the Moderna and the Pfizer/BioNTech vaccines and this issue is being monitored by the CDC. The CDC also recommends that everyone who receives a COVID-19 vaccine is monitored onsite for at least 15 minutes, and for at least 30 minutes if they have had a reaction to a vaccine or other prior history of significant allergic reactions.

Is the J&J/Janssen (adenoviral-vector) COVID-19 vaccine safe?

- During the clinical trial, the most common reactions in people who received the J&J/Janssen vaccine were pain at the injection site, headache, fatigue, muscle pain, nausea and fever. The side effects were more common in patients younger than 60 years of age. Overall, these rates were lower than those reported for both mRNA vaccines.
- The safety data available so far for the J&J/Janssen vaccine is similar to what was reported during the clinical trial and 97% of the events reported have not been serious events. Rare but serious blood clotting disorders have occurred in less than two in one million individuals who have received the J&J/Janssen vaccine. The CDC and FDA reviewed the data on the blood clotting cases and, after a temporary pause, recommended that the use of the J&J/Janssen vaccine resume. The FDA has added a warning to the authorization label for clotting events with low platelets, primarily occurring among women aged 18 to 49 years.
- The blood clotting cases were identified through the CDC’s vaccine adverse event reporting system (VAERS). There have been no reported cases of blood clotting events in people with HIV and there’s no reason to believe people with HIV are a greater risk for blood clots based on their HIV status.
- CDC advises people who receive the J&J/Janssen vaccine to seek medical care right away if within three weeks of getting vaccinated, they have a severe or persistent headache or blurred vision, shortness of breath, chest pain leg swelling, persistent abdominal pain or easy bruising.

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• Rare cases of the neurological disorder Guillain-Barré syndrome (GBS) have been reported through VAERS in individuals receiving the J&J/Janssen vaccine. In July 2021, FDA added a warning for GBS to the EUA for symptoms occurring within 42 days of vaccination with the J&J vaccine. Common symptoms are weakness or tingling sensations in legs or arms; difficulty walking, difficulty with speaking, chewing or swallowing; double vision or inability to move eyes; and difficulty with bladder control or bowel function.

REPORTING SIDE EFFECTS OR ADVERSE EVENTS

How do I report side effects or adverse events?
• Side effects should be reported through the CDC’s vaccine adverse event reporting system (VAERS) either online or by calling 1-800-822-7967 for more information. CDC also has an app called y-safe that can be used to report side effects.
• If you are experiencing a medical emergency, contact your health care provider or call 911.

EFFICACY

Are the mRNA (Pfizer/BioNTech and Moderna) vaccines more efficacious than the adenoviral-vector (J&J/Janssen) vaccine? How does the single dose of the J&J/Janssen vaccine compare to two doses of Pfizer/Biontech or Moderna in terms of efficacy?
• The estimates of vaccine efficacy for the Pfizer/BioNTech and Moderna and the J&J/Janssen vaccine cannot be compared directly. The clinical trials for these vaccines were conducted at different times during the pandemic and in different populations. In addition, the outcomes used to determine the efficacy was not the same in the studies. The J&J/Janssen study looked at moderate to severe illness due to COVID-19 at 14 and 28 days after vaccination. The Moderna study evaluated incidence of symptomatic COVID-19 at least 14 days after the second dose of the vaccine while the Pfizer/BioNTech study assessed incidence of symptomatic COVID-19 at least 7 days after the second dose. All of the vaccines available in the U.S. met and exceeded the criteria set for efficacy by the FDA for emergency use authorization.
• Data from a small study comparing the antibody responses to the Pfizer-BioNTech vaccine for people with HIV to people without HIV found a similar response in both groups suggesting that the mRNA vaccines are protective for people with HIV.

Do the vaccines protect against the Delta variant?
• The COVID-19 vaccines authorized for use in the U.S. are highly effective at preventing serious illness from COVID-19, and all individuals with HIV should be encouraged to get vaccinated to protect their health and their family and friends.
• According to CDC, the Delta variant is more than twice as transmissible as other variants and is now the dominant variant in the U.S. COVID-19 infections in fully vaccinated individuals are rare. A small number of fully vaccinated individuals may become infected with the Delta variant and may be able to transmit the virus to others. The Moderna and Pfizer-BioNTech vaccines are strongly protective against serious illness and hospitalization from the Delta variant. Data on the effectiveness of the J&J/Janssen vaccine against the Delta variant are still being evaluated, but this vaccine protects against severe disease caused by other variants.

Is a third shot or a “booster” shot recommended for people who are immunocompromised?
• FDA’s EUA for the COVID-19 vaccines does not currently authorize the use of a third vaccination shot.
• CDC’s Advisory Committee on Immunization Practices has not made a recommendation regarding a third vaccination shot for people who are immunocompromised.
GETTING VACCINATED

What are the eligibility requirements for vaccination?
• States are no longer limiting vaccinations to certain groups. In every state and the District of Columbia, anyone over 16 years of age is eligible to be vaccinated, including people with HIV.
• The Department of Health and Human Services developed the following resources to facilitate finding vaccination sites:
  o Visit vaccines.gov (English) or vacunas.gov (Spanish) to search by zip code;
  o Text GETVAX to 438829 (English) or VACUNA to 822862 (Spanish) to receive three vaccine sites on your phone;
  o Call the National COVID-19 Vaccination Assistance Hotline at 1-800-232-0233.
• Also check your local or state health department for the latest information specific to your community.

When am I considered fully vaccinated?
• According to the CDC, people (whether they have HIV, or do not) are considered fully vaccinated:
  o For the Moderna and Pfizer/BioNTech vaccine, two weeks after the 2nd dose of the two-dose series; and
  o For the J&J/Janssen vaccine, two weeks after receiving the one-dose vaccine.

What can I do when I am fully vaccinated?
• The COVID-19 vaccines authorized for use in the U.S. are highly effective at preventing serious illness from COVID-19, and individuals with HIV should be encouraged to get vaccinated to protect their health and their family and friends.
• In response to new data on the transmissibility of the Delta variant including among fully vaccinated individuals, CDC updated its guidance to recommend that unvaccinated and fully vaccinated individuals wear masks in indoor public spaces in areas with substantial and high transmission to stop community spread of the virus. To prevent widespread community transmission, IDSA urges that in communities with moderate transmission rates, all individuals, even those who are vaccinated, wear masks in public indoor spaces.
• Data considered by CDC’s Advisory Committee on Immunization Practices indicate that people who are immunocompromised are at higher risk for serious illness due to COVID-19 and more likely to have breakthrough infections when fully vaccinated. Individuals with HIV who are untreated or who may not be virally suppressed should be encouraged to take extra precautions, including wearing a mask in public indoor spaces and maintaining a safe physical distance from others.

What if I am not fully vaccinated?
• If you are not fully vaccinated, it is important to get vaccinated as soon as possible to protect yourself and your family and friends, and to wear face coverings in public places and maintain a safe physical distance from others to protect yourself from getting COVID-19.

SIDE EFFECTS

Will I have more side effects because I have HIV?
• The effects of the vaccines on people with HIV are still being studied, so we do not yet know if any of them will affect people with HIV differently. So far, no data suggest that people with HIV have more side effects than the general population.
• Side effects common among all study participants included pain and swelling at the injection site, fatigue and headache. A smaller number reported having a fever. These side effects did not last longer than a few
days at most.

**Have there been any serious side effects with the J&J/Janssen vaccine?**

- A rare, clotting disorder has occurred in less than two in a million individuals receiving the J&J/Janssen vaccine. The FDA has added a warning to the authorization for clotting events with low platelets, primarily occurring among women under 50 years of age. None of the women affected were living with HIV and there are no data to suggest that people with HIV are at higher risk of that occurring due to their HIV status.

- Rare cases of the neurological disorder Guillain-Barré syndrome (GBS) have been reported through the Vaccine Adverse Event Reporting System (VAERS) in individuals receiving the J&J/Janssen vaccine. In July 2021, the FDA added a warning for GBS to the EUA for symptoms occurring within 42 days of vaccination with the J&J vaccine. Common symptoms are weakness or tingling sensations in legs or arms; difficulty walking, difficulty with speaking, chewing or swallowing; double vision or inability to move eyes, and difficulty with bladder control or bowel function.

**Have there been any serious side effects with the Moderna and the Pfizer/BioNTech vaccines?**

- Rare, serious allergic reactions have occurred with the Moderna and the Pfizer/BioNTech vaccines and this issue is being monitored by the CDC. The CDC also recommends that everyone who receives a COVID-19 vaccine is monitored onsite for at least 15 minutes, and for at least 30 minutes if they have had a reaction to a vaccine or other prior history of significant allergic reactions.

**Should I wait for another COVID-19 vaccine since I have HIV? Have any of the other vaccines been found to be safer or more effective for people with HIV?**

- Based on the current data available, the vaccines authorized for the U.S. are safe and effective.
- A serious blood clotting disorder has occurred in less than two in a million individuals receiving the J&J/Janssen vaccine. The events have occurred primarily in women under 50 years.
- Data specific to people with HIV are not yet available, but the vaccine trials included people with treated HIV so additional data should become available in the future.
- The majority of HIV providers strongly recommend that people with HIV receive one of the currently available vaccines rather than wait for further data.

**What are the long-term side effects or complications of getting the vaccine?**

- Currently no data suggest that the vaccines cause long-term side effects. Data will continue to be collected and monitored for signs of long-term side effects or complications. As of July 2021, more than one year has passed since the first volunteers received some of these vaccines.

**Should I take the vaccine if I already had COVID-19? If so, what are the side effects? How long should I wait between my COVID-19 illness and the vaccine?**

- Because people’s immune responses to having COVID-19 can vary (some people may develop a weak immune response, others a stronger one), and because we don’t know how long people maintain an immune response after getting COVID-19, the CDC recommends offering the vaccine to individuals who have already had COVID-19. For individuals who are still experiencing symptoms of COVID-19, vaccination should be delayed until they have recovered, and can be delayed for up to 90 days after illness. Data will be collected on people who have had COVID-19 receiving vaccinations so we will learn more.

**Does the vaccine cause post-acute sequelae of COVID-19 (PASC) or “long-COVID” syndrome?**

- None of the vaccines available in the US contain the virus that causes COVID-19. They cannot make you sick from COVID-19 nor can they cause “long-COVID.”
• Preventing COVID-19 infection through vaccination is the best way to prevent “long-COVID.”

Why do some people develop COVID-19 after being vaccinated?
• According to the CDC, it takes a few weeks for the body to develop enough immunity to protect you from the virus, so you could still get sick from COVID-19 while your body is in the process of developing immunity.

What is the frequency of Bell’s palsy?
• Bell’s palsy is one of the conditions that is monitored in all vaccine trials. While there were cases of Bell’s palsy in clinical trials for the COVID-19 vaccines, the number of cases reflected the number in the general population. No relationship between receiving the vaccines and Bell’s palsy has been established. Monitoring for Bell’s palsy is ongoing, as more people receive the vaccines.

What should I do if I had bad reactions to other vaccines? What if I had Guillain-Barré syndrome from Shingrix (or any other vaccine)? Can I take the COVID-19 vaccine safely?
• It is important to let your health care provider know if you have had a bad reaction to other vaccines.
• No cases of Guillain-Barré syndrome (GBS) have been reported in people receiving the Moderna or the Pfizer/BioNTech COVID-19 vaccines.
• Rare cases of the neurological disorder Guillain-Barré syndrome (GBS) have been reported through the Vaccine Adverse Event Reporting System (VAERS) in individuals receiving the J&J/Janssen vaccine. In July 2021, the FDA added a warning for GBS to the EUA for symptoms occurring within 42 days of vaccination with the J&J vaccine. Common symptoms are weakness or tingling sensations in legs or arms; difficulty walking, difficulty with speaking, chewing or swallowing; double vision or inability to move eyes, and difficulty with bladder control or bowel function.
• Based on the data currently available, you may receive an mRNA COVID-19 vaccine safely. Even if you have had a bad reaction to another vaccine, if that vaccine doesn’t have any of the same ingredients that are in the COVID-19 vaccines, you should not have the same reaction.

HIV MEDICATIONS

I’ve heard my HIV medicines protect me from getting COVID-19, so do I even need the vaccine?
• There is no evidence that HIV medications can prevent or treat COVID-19. Some HIV medications, such as a combination of tenofovir/emtricitabine, are currently being studied to see if they can treat COVID-19 but the results of these studies are pending. Studies on lopinavir/ritonavir, a protease inhibitor combination, have not found it to be effective. Read more in the CDC’s What to Know About HIV and COVID-19.
• Because there is no evidence that HIV medications can treat or prevent COVID-19, guidelines recommend against changing your HIV treatment regimen to prevent or treat COVID-19. More information on HIV treatment recommendations and COVID-19 is available in the HHS Interim Guidance on COVID-19 and Persons with HIV.

Will the vaccine be contraindicated by my HIV medications? Should I stop taking them while I am getting the vaccine doses?
• The three authorized vaccines have no interactions with HIV medications. It is not recommended that people with HIV stop their HIV medicines when they receive a COVID-19 vaccine. Stopping your HIV medications could put you at greater risk for HIV-related illnesses and at greater risk for serious infection due to COVID-19.

Will the vaccine be effective or recommended if I have CD4 < 200 / A low immune system?

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The CDC advises that people who are immunocompromised, including people with HIV, be eligible to receive the vaccine because of their potential increased risk for serious illness due to COVID-19. The safety and effectiveness in immunocompromised populations is not yet known, however, particularly whether the protection from COVID-19 will be as strong as it is for the general population.

COVID-19 VACCINES & HIV RISK

Does the COVID-19 vaccine increase the risk of contracting HIV?

- There is no reason to think COVID-19 vaccines will increase a person’s risk of acquiring HIV, nor are there any data to suggest that this is the case. These concerns have been raised because a previous adenoviral-vector vaccine being studied to prevent HIV about a decade ago may have increased risk for HIV infection, but that vaccine was constructed differently and was not related to the structure of the COVID-19 vaccines authorized in the U.S.

VACCINE ACCESS & ADMINISTRATION

Can I choose which COVID-19 vaccine I get?

- You may be able to choose which vaccine you receive depending on the supply available. Based on the clinical trial data, the vaccines available in the U.S. have high levels of safety and efficacy and there is no information available to indicate at this time that one is better for people with HIV. With the J&J/Janssen vaccine, a serious blood clotting disorder has occurred in less than two out of million individuals who have received the vaccine. The events have primarily occurred in women under 50 and none of them had HIV.

Can I get vaccinated at my HIV clinic?

- Vaccines are being provided in a variety of settings and while some HIV clinics may be providing vaccines, many may not yet have access to the COVID-19 vaccines. Check with your HIV provider to see if they are providing vaccines. An online web tool allows you to search online for vaccination sites near you at www.vaccines.gov (English) or vacunas.gov (Spanish). Or you can text GETVAX to 438829 for English or VACUNA to 822862 for Spanish to receive vaccine sites nearby.

Will I have to pay when I get vaccinated? Is it covered by my insurance or the Ryan White Program?

- The federal government is covering the cost of the vaccines for everyone. There may be a fee for administering the vaccine, but that fee should be charged to your health insurance provider, including Medicaid or Medicare. If you are uninsured, your provider should bill the Provider Relief Fund that is administered by HRSA, or your Ryan White Program may be covering it.

Is it necessary to get the second dose of the Moderna or Pfizer/BioNTech vaccines? What if I move after I got the first dose – How do I get the second?

- For the Moderna and Pfizer/BioNTech vaccines, receiving two doses of the vaccine is important to achieve the highest level of protection based on the clinical trials data that we have now. Not only do people have a lower response after one dose compared to two, but we also don’t know how long immunity lasts after a single dose of the vaccine lasts. Let your vaccine provider know if you are unable to come back to the same location for your second dose so they can help you make arrangements to ensure you receive your second dose on time.
- Reminders for receiving the second dose of the COVID-19 vaccines are available by signing up for VaxText – a free text messaging platform.

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For the Moderna and Pfizer/BioNTech vaccines, can I get one dose of one vaccine and the second dose of the other vaccine?
  • The second dose of your vaccine should be the same as the first one. Mixing the two vaccines has not been studied, and vaccine providers should be following guidance from the CDC and their state Department of Health regarding appropriate administration of the second dose.

PREGNANCY & BREASTFEEDING

Can I take the vaccine if I am pregnant? Breastfeeding?
  • Pregnancy has been associated with an increased risk of having severe COVID-19. Individuals who are pregnant or breastfeeding may choose to be vaccinated, according to CDC. While data about the safety of COVID-19 vaccines in these situations are limited, experts believe the authorized vaccines are unlikely to pose a risk for individuals who are pregnant or to breastfeeding infants. There is no reason to think the vaccines will affect the placenta.
  • The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) recommend that pregnant and lactating individuals be vaccinated against COVID-19. The professional organizations strengthened their recommendations for pregnant and lactating individuals given the increase in COVID-19 cases due to the Delta variant and the increased risk for serious illness from COVID-19 for pregnant individuals.

Can I take any vaccine if I am pregnant? Breastfeeding?
  • ACOG advises that women under 50 years may receive any of the FDA authorized COVID-19 vaccines. They should be advised that a rare blood clotting disorder has been associated with the J&J/Janssen vaccine and that other COVID-19 vaccines are available.

Can the mRNA vaccines cause infertility?
  • There is no evidence to suggest that the COVID-19 vaccines cause infertility. This idea has arisen because of false online statements that COVID-19 proteins and the proteins in the human placenta are similar, and that, as a result, a vaccine that makes people immune to COVID-19 it can also make the body attack the placenta. This is not true. Coronavirus proteins and placental proteins are very different, so there is no reason to think the vaccines will affect the placenta. In addition, theoretical damage to a placenta and infertility are different. Infertility is the inability to get pregnant. There is no evidence that either placental damage or infertility arise from COVID-19 vaccines.

DNA

Can the mRNA vaccines alter my DNA because it is an mRNA vaccine?
  • The mRNA delivered by the mRNA-based COVID-19 vaccines do not enter the cell nucleus where DNA is located, so it cannot alter your DNA.

STEM CELLS

Were fetal stem cells used to make the COVID-19 vaccines?
  • Fetal stem cells were not used in production of the Moderna or the Pfizer/BioNTech vaccines.
  • The J&J/Janssen vaccine does not include any fetal tissue but cells derived in a lab from fetal stem cells are used in its production. The Vatican issued guidance in December 2020 indicating that it was acceptable to receive COVID-19 vaccines that have used fetal stems cells in their research and production processes when options and supplies are scarce. It is important to weigh the risks of severe illness and
death due to COVID-19 with the benefits of receiving a vaccine that is highly effective at preventing serious illness due to COVID-19.

IMMUNITY OR LEVEL OF PROTECTION

How long will the immunity last after the vaccine?
- The length of time the vaccine will prevent you from getting sick from COVID-19 is still being studied. Because the virus is so widespread in the U.S., even short-term immunity or protection from the virus is important because it can help to prevent you from getting sick due to COVID-19 and help slow the spread of the virus.

Does the vaccine prevent illness? Can I still have the coronavirus (SARS-CoV-2), have no symptoms and spread the virus to others?
- The trials for the vaccines available in the U.S. found that they were highly effective at preventing serious illness due to COVID-19.
- The Pfizer-BioNTech and Moderna vaccines are highly effective at preventing people from acquiring COVID-19 and at preventing serious illness including from the Delta variant. However, according to CDC, while the risk of acquiring and transmitting the Delta variant is significantly lower for fully vaccinated individuals, the risk is not eliminated. To help stop community spread, unvaccinated and fully vaccinated individuals should be advised to wear masks in public indoor spaces, particularly in communities with substantial or high community spread.
- Insufficient data are currently available for the effectiveness of J&J/Janssen vaccine against the Delta variant, but it has been found to be protective against other variants.

HIV VACCINE

A COVID-19 vaccine was developed in less than a year but we still don’t have an HIV vaccine after 40 years – why can’t they develop an HIV vaccine as quickly? When is an HIV vaccine going to be approved?
- The virus that causes COVID-19 is very different than HIV. The body rids itself of the virus that causes COVID-19 within weeks while HIV stays in the body and is not removed or eradicated and has a complex way of undermining the immune system. These differences, and many others, make creating an HIV vaccine much more complicated.
- Work on developing an HIV vaccine continues and some of the early work in developing an HIV vaccine contributed to the creation and the success of the COVID-19 vaccines. We also have learned a lot from the development of the COVID-19 vaccines that should contribute to the future development of other effective vaccines, including for HIV.