

### COVID-19 Vaccines and People with HIV Frequently Asked Questions

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The HIV Medicine Association and the 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 COVID-19 vaccines. Unless otherwise noted, 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 (CDC) resources: Facts About COVID-19 Vaccines, Frequently Asked Questions About COVID-19 Vaccination, COVID-19 ACIP Vaccine Recommendations, and Vaccine Considerations for People with Underlying Medical Conditions. Please email us if you or your patients have a question that is not covered.

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### **SAFETY**

### ARE THE COVID-19 VACCINES SAFE FOR PEOPLE WITH HIV?

- Safety data specific to people with HIV are not yet available but based on how the vaccines work, we do not anticipate safety concerns unique to people with HIV. Because people with HIV may be at increased risk for severe illness due to COVID-19, 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 allergic reaction to the COVID-19 vaccine or its components. The vaccines authorized for use in the United States (the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine) do not contain infectious virus.
- It is possible that the level of protection from the vaccines may not be as strong for people with HIV who are immunocompromised although it is also possible that the level of protection will be the same in people with HIV as people without HIV. Everyone who receives a COVID-19 vaccine, including people with HIV, should continue to wear face coverings, stay 6 feet apart from others,

- avoid crowds and regularly wash their hands to protect themselves and others until more is known.
- 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.

### **PRIORITY GROUPS**

### WHEN WILL PEOPLE WITH HIV BE ABLE TO GET VACCINATED? WILL I BE PRIORITIZED HIGHER BECAUSE I HAVE HIV?

- Due to limited vaccine supplies, the CDC has made recommendations for the groups that should receive vaccines first. Initially, health care workers and individuals in long-term care facilities were prioritized. Now in many states persons who are 65 years and older and other essential workers are eligible to receive the vaccine, but there are still not enough vaccines to meet demand in most areas. People with HIV who fall into a group that is prioritized (e.g., a health care worker or 65 or older) should be eligible to receive the vaccine.
- The guidance about groups that are prioritized for vaccination will continue to change based on vaccine availability. Check with your <u>local</u> or <u>state</u> health department for the latest information specific to your community. Information on your state plan is <u>available online</u>.
- While people with HIV may be at higher risk for serious illness due to COVID-19, the data
  available so far do not indicate that their risk is as high as those with other underlying
  conditions, such as heart disease, diabetes and obesity, and people with HIV have not been
  specifically named as a priority group. People with HIV may also have these higher-risk
  conditions, however, that make severe COVID-19 more likely.

#### **SIDE EFFECTS**

### WILL I HAVE MORE SIDE EFFECTS BECAUSE I HAVE HIV?

• The effects of the vaccine on people with HIV are still being studied, so we do not yet know if it will affect people with HIV differently. Side effects common among 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. Rare, serious allergic reactions have occurred and are 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 an injectable therapy.

### 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 both approved vaccines, it is not clear that they were caused by the vaccine, and the number of people who got Bell's palsy in the studies was the same as the number who get Bell's palsy annually in the general population.
- There have been four reported cases of Bell's palsy for the Moderna's COVID-19 vaccine among more than 30,000 clinical trial participants. Three of the participants who got Bell's palsy received the vaccine instead of a placebo.
- Similarly, Pfizer-BioNTech's trial had four reported cases of Bell's palsy out of some 43,000 participants. All four Bell's palsy cases in Pfizer-BioNTech's trial got the vaccine and not the placebo. There is ongoing monitoring for Bell's palsy as more people receive the vaccines.

## 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?

- Currently the only vaccines available in the U.S. are the Pfizer-BioNTech and Moderna COVID-19 vaccines. Based on the current data available, these vaccines have strong safety and effectiveness data for the general population. We do not yet know what the safety and efficacy data will look like for the other vaccine candidates.
- Data specific to people with HIV is not yet available, but both of the vaccine trials included people with HIV so additional data should become available in the future.

### 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.

## 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 <u>CDC currently recommends</u> 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 "LONG-COVID" SYNDROME?

 None of the vaccines available contain the virus that causes COVID-19. They cannot make you sick from COVID-19 nor can they cause "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. For this reason, and because we do not know if the vaccine prevents
infection even if it prevents getting sick with COVID-19, it is important to continue to wear a
mask, stay at least 6 feet from others, avoid large crowds or gatherings and regularly wash your
hands.

## WHAT DO I DO IF I HAD BAD REACTIONS TO OTHER VACCINES? WHAT IF I HAD GUILLAIN-BARRE 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, but there have been no cases of Guillain-Barre syndrome reported in people receiving the mRNA COVID-19 vaccines to date. 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 <a href="HHS Interim">HHS Interim</a>
  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 two 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?

The CDC advises that people who are immunocompromised, including people with HIV, 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
certain type, an adenovirus vector, of 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?**

• The supply of vaccines is very limited. When it is your turn to receive a vaccine, you will most likely not have an option to choose which vaccine you will receive. Based on the clinical trial data, both the Moderna and Pfizer-BioNTech vaccines 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.

#### **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 <u>state</u> or <u>local</u>
health department or your HIV provider to see who is eligible to receive a vaccine in your state,
how to sign up and where vaccines are being provided

### 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 <a href="Provider Relief Fund">Provider</a>
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?

 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.

#### 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 may not provide the same level of protection.

### **HIV VACCINE**

## A COVID-19 VACCINE WAS DEVELOPED IN LESS THAN A YEAR AND 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 and the HIV virus are very different. The body rids itself of the virus that causes COVID-19 within weeks, while the HIV virus stays in the body and is not removed or eradicated. This difference, and many others, makes it much more complicated to create an HIV vaccine.
- Work on developing an HIV vaccine continues and some of the early work in developing an HIV vaccine contributed to 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.

### **PREGNANCY & BREASTFEEDING**

### CAN I TAKE THE VACCINE IF I AM PREGNANT? BREASTFEEDING?

• Individuals who are pregnant or breastfeeding may choose to be vaccinated, according to the <u>CDC</u>. While there are limited data about the safety of COVID-19 vaccines in these situations, experts believe the authorized mRNA-based vaccines are unlikely to pose a risk for women who are pregnant or to the breastfeeding infant. The <u>American College of Obstetricians and Gynecologists</u> recommends that COVID-19 vaccines not be withheld from pregnant individuals who meet criteria for vaccination based on <u>ACIP-recommended priority groups</u>. Of note, pregnancy has been associated with an increased risk of having severe COVID-19.

### **CAN THE MRNA VACCINES CAUSE INFERTILITY?**

• There is no evidence to suggest that the COVID-19 vaccines cause infertility. This idea has arisen because some people online falsely stated that COVID-19 proteins and the proteins in the human placenta are similar, and so if the vaccine 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; if a woman has a placenta she is pregnant. If the placenta is damaged, she could lose her pregnancy, or her fetus could be affected. Infertility is the inability to get pregnant. There is no evidence that either placental damage or infertility arise from vaccination with an mRNA COVID-19 vaccine.

### **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?

 No. Neither of the COVID-19 vaccines authorized for use in the U.S. were developed using fetal stem cells.

#### **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 can help to prevent you from getting sick due to COVID-19 and help slow the spread of the virus.

### CAN I GET INFECTED WITH COVID-19 AFTER THE VACCINE, HAVE NO SYMPTOMS, AND THEN SPREAD THE VIRUS TO OTHERS EVEN IF I AM NOT SICK?

 The two vaccines currently authorized were studied to see if they prevented people from getting sick due to COVID-19. The study did not indicate whether the vaccines prevented infection. Until more is known about whether the vaccines prevent infection itself, everyone, even those who are vaccinated, should continue to wear masks, keep a safe distance from others, avoid crowds and regularly wash hands.

#### **DOES THE VACCINE PREVENT ILLNESS?**

• The trials for the vaccines available in the U.S. found that the mRNA-based vaccines were highly effective at preventing illness due to COVID-19. The trials did not look at whether the vaccines prevented asymptomatic infection (that is getting the virus without getting sick). Data collection continues as the vaccines roll out and learning if the vaccines also prevent infection will be important. In the meantime, all of us should continue to wear masks, stay 6 feet apart, avoid large gatherings or crowds and regularly wash our hands to protect others.

### HOW SOON AFTER I GET VACCINATED WILL I BE PROTECTED FROM BECOMING ILL FROM COVID?

 According to the CDC, it typically takes a few weeks after vaccination for the body to develop enough immunity for protection. For the mRNA-based vaccines, they are most effective a few weeks after both doses have been received.

### **HIV CLINICIAN QUESTIONS**

# ARE THERE ANY PLANS TO DO PHASE 4 STUDIES IN IMMUNOCOMPROMISED HOSTS? PEOPLE WITH TRANSPLANTS, PEOPLE CHRONICALLY IMMUNOSUPPRESSED FOR AUTOIMMUNE DISORDERS? PEOPLE WITH HIV?

 The FDA emergency use authorization (EUA) recommends that immunocompromised individuals and other subpopulations with specific comorbidities be studied in post-authorization observational studies. People with stable HIV were included in both the Pfizer-BioNTech and Moderna trials, although their numbers were low.

### IN PATIENTS WITH HIV, ARE THERE ANY RECOMMENDATIONS FOR GETTING THE VACCINE IN PATIENTS BASED ON CD4 COUNT AND VIRAL SUPPRESSION?

• The CDC currently states that individuals who are immunocompromised, including people with HIV, may receive the mRNA-based vaccines if there are no contraindications, such as known allergic reaction to an ingredient in the vaccine. The recommendation is for all people with HIV and is not based on CD4 count or viral suppression. Given that the mRNA vaccines do not contain SARS-CoV-2 (live or attenuated), there is no reason to believe the vaccine will be less safe in persons with low CD4 counts. People with HIV should be counseled that we do not yet know if their level of protection from the virus will be as strong as for those who do not have HIV, or for those with lower CD4 counts or measurable viral loads. Everyone, including people with HIV, should continue to wear face coverings, stay 6 feet apart from others, avoid crowds and regularly wash their hands to protect themselves and others until more is known

### IF THE PFIZER OR MODERNA MRNA IS INTRODUCED INTO A CELL IN WHICH HIV-1 IS REPLICATING, WILL ANY PORTION OF THE VACCINE MRNA BE REVERSE TRANSCRIBED INTO DNA?

HIV-1 replication occurs in the cell nucleus; the mRNA delivered by the mRNA COVID-19 vaccines does not enter the nucleus. Rather, it stays in the cytoplasm to be translated. Therefore, the mRNA cannot be transcribed into DNA.