



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

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**NOTE: On April 13, 2021 - the Food and Drug Administration and the Centers for Disease Control and Prevention [recommended a pause](#) on the Janssen (Johnson & Johnson) COVID-19 vaccine due to six reported U.S. cases of a rare type of blood clot in individuals after receiving the Janssen (J&J) COVID-19 vaccine. The cases have been rare among the 6.85 million doses of the Janssen (J&J) vaccine that have been administered in the U.S. This FAQ will be updated as more information becomes available. We strongly encourage clinicians to review the [CDC Health Alert](#) to learn more about the potential for these events to occur and the unique treatment required for the type of blood clots that have been reported. More [information](#) is available from IDSA's Real-Time Learning Network.**

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 the three COVID-19 vaccines authorized for use in the U.S. by the Food and Drug Administration (FDA). The two mRNA vaccines are referred to by the manufacturer's names – Moderna and Pfizer/BioNTech, and the adenoviral-vector vaccine is referred to by the manufacturer's name Janssen (which is a subsidiary of Johnson and Johnson). Unless otherwise specified, the information provided is applicable to all three 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 (CDC) 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](#)

[EFFICACY](#)

[PRIORITY GROUPS](#)

[SIDE EFFECTS](#)

[HIV MEDICATIONS](#)

[COVID-19 VACCINES & HIV RISK](#)

[VACCINE ACCESS & ADMINISTRATION](#)

[HIV VACCINE](#)

[PREGNANCY & BREASTFEEDING](#)

[DNA](#)[STEM CELLS](#)[IMMUNITY OR LEVEL OF PROTECTION](#)[HIV CLINICIAN QUESTIONS](#)**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 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.
- 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, when in public places or indoors with non-household members who have not been vaccinated 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.
- The Centers for Disease Control and Prevention has [released information](#) on people who have received the vaccines so far confirming the vaccines are safe.

**ARE THE PFIZER/BIONTECH AND MODERNA (MRNA) VACCINES OR THE JANSSEN (ADENOVIRAL-VECTOR) COVID-19 VACCINE SAFER? WHICH TYPE OF VACCINE HAS FEWER SIDE EFFECTS?**

- During the clinical trial, the most common reactions in people who received the 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. All the currently authorized COVID-19 vaccines are safe.

**EFFICACY****ARE THE MRNA (PFIZER/BIONTECH AND MODERNA) VACCINES MORE EFFICACIOUS THAN THE ADENOVIRAL-VECTOR (JANSSEN) VACCINE? HOW DOES THE SINGLE DOSE OF THE 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 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 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.

## DO THE VACCINES PROTECT AGAINST THE VARIANTS OF THE CORONAVIRUS (SARS-COV-2) THAT HAVE EMERGED?

- Scientists are still evaluating how well the vaccines protect against the variants. There is some evidence that some variants affect vaccine efficacy. In the study of the Janssen vaccine, the efficacy was lower in South Africa than in the U.S., but in both regions the vaccine protected against hospitalization due to COVID-19. Studies of the ability of different vaccines to protect against variants are ongoing.

## 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, other essential workers and in some states people with high-risk medical conditions or who are at higher risk of exposure, e.g., due to unstable housing, 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 should be eligible to receive the vaccine.**
- The [Interim Guidance for People with HIV and COVID-19](#) developed by the National Institutes of Health Office of AIDS Research recommends that, because people with HIV appear to be at high risk for serious illness due to COVID-19 due to high rates of co-morbidities and other factors such as poor access to health care and unstable housing, they should be included for prioritization within the high-risk medical condition category.
- The guidance about groups that are prioritized for vaccination will continue to change based on vaccine availability. A [review of state policies](#) conducted by KFF found that 12 states include HIV as a high-risk medical condition for vaccination prioritization with most states including HIV within the broader category of persons who are immunocompromised.<sup>1</sup> Check with your [local](#) or [state](#) health department for the latest information specific to your community. Information on your state plan is [available online](#).

### WHEN I AM ABLE TO GET VACCINATED – HOW WILL THAT CHANGE WHAT CAN I DO?

- According to [the CDC](#), individuals who are fully vaccinated can meet in indoors with others who are fully vaccinated without wearing masks or physical distancing. When in public places, everyone, including individuals who are vaccinated, should continue to wear masks, stay at least 6 feet from others, avoid large crowds or gatherings and regularly wash their hands.

## 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 all study participants included pain and

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<sup>1</sup> The 12 states identified as including HIV with the category of immunocompromised persons were: Kansas, Montana Nebraska, New Hampshire, New Mexico, New York, North Carolina, Pennsylvania, Rhode Island, Tennessee, Utah, and Virginia.

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](#) 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?**

- Currently the vaccines available in the U.S. are the Pfizer/BioNTech, Moderna and the Janssen 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 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 March 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 currently 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. Also, none of the vaccines protect 100% against COVID-19. For this reason, and because it is not yet clear to what extent these vaccines also prevent asymptomatic but transmissible infection (that is getting the virus without getting sick), it is important to continue to wear a mask in public places or when indoors with non-household members who have not been vaccinated, stay at least 6 feet from others, avoid large crowds or gatherings and regularly wash their hands.

### WHAT IS THE FREQUENCY OF BELL'S PALSYP?

- 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. A relationship between receiving the vaccines and Bell's palsy has not been established. Monitoring for Bell's palsy is ongoing, as more people receive the vaccines.

### 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.
- No cases of Guillain-Barre syndrome (GBS) have been reported in people receiving the Moderna or the Pfizer/BioNTech COVID-19 vaccines. In the Janssen trial, one case of GBS was reported in a study participant vaccinated with the Janssen vaccine and one case also was reported in a study participant who received the placebo. The relationship of the vaccine to GBS is unclear.
- 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.

### HOW DO I REPORT SIDE EFFECTS?

- 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 [v-safe](#) that can be used to report side effects.
- **If you are experiencing a medical emergency, contact your health care provider or call 911.**

## 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?

- 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. The [Interim Guidance for People with HIV and COVID-19](#) recommends that because people with HIV appear to be at

increased risk for serious illness due to COVID-19 due to comorbidities and other factors that people with HIV without regard to CD4 count should be included in the high-risk medical category for vaccine prioritization.

## 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?

- 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, 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.

### 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 [state](#) or [local](#) 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 [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.

### 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.

## 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 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.

## 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 the [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 women who are pregnant or to breastfeeding infants. There is no reason to think the vaccines will affect the placenta. See also [Provider Considerations for Engaging in COVID-19 Vaccine Counseling with Pregnant and Lactating Patients](#).
- The [American College of Obstetricians and Gynecologists](#) recommends that COVID-19 vaccines not be withheld from pregnant individuals who meet criteria for vaccination based on [ACIP-recommended priority groups](#).
- The [Society for Maternal-Fetal Medicine](#) has stated that [the safety risk of mRNA vaccination for pregnant or lactating people appears low](#), recommended pregnant people be offered vaccination and noted the decision to receive the vaccine should be guided by an individual's risk of contracting COVID-19 and other individual factors.

### 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; 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 the available 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 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 stem 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 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 THE CORONAVIRUS (SARS-COV-2) AFTER THE VACCINE, HAVE NO SYMPTOMS, AND THEN SPREAD THE VIRUS TO OTHERS EVEN IF I AM NOT SICK?

- The vaccines currently authorized were studied to see if they prevented people from getting sick due to COVID-19. The studies did not directly test whether the vaccines prevented asymptomatic infection (that is getting the virus without getting sick). Although these vaccines reduce the possibility of spreading infection to some extent, until more data are available and the overall rates of COVID-19 are lower, it is important for everyone when in public places, even those who are vaccinated, to continue to wear masks, keep a safe distance from others, avoid crowds and regularly wash their hands.

### DOES THE VACCINE PREVENT ILLNESS?

- 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 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 to what extent the vaccines also prevent asymptomatic infection will be important. In the meantime, when in public places or indoors with non-household members who have not been vaccinated 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.
- According to the clinical trial data reviewed by the FDA, the Janssen vaccine is highly effective at preventing hospitalization due to COVID-19 after 28 days. In the clinical trial, **no** hospitalizations or

deaths due to COVID-19 occurred in individuals 28 days after they had received the Janssen vaccine.

## **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 the Pfizer/BioNTech, Moderna and Janssen 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, when in public places or indoors with non-household members who have not been vaccinated, 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/BIONTECH 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.

### **IN THE JANSSEN COVID-9 VACCINE TRIAL, WHAT WAS THE VACCINE EFFICACY IN HIV PATIENTS? WHAT ARE THE IMPLICATIONS?**

- The phase III trial of the Janssen vaccine included 1218 individuals living with HIV, which constituted 2.8% of the total study population. There were too few outcomes among this subgroup to draw any meaningful conclusions about vaccine efficacy. Specifically, there were five cases of moderate to severe/critical COVID-19 in both the vaccine and placebo group starting at least 14 days after vaccination, and two cases in the vaccine group and four in the placebo group starting at least 28 days after vaccination. Safety and immunogenicity studies in “immunocompromised individuals” are planned, but details of these studies are not yet available.