



American Society of Transplantation COVID-19 Vaccination Guidance

COVID-19 vaccines are free and widely available in the U.S. for everyone 5 years of age and older



You may have questions about how the COVID-19 vaccines work in transplant recipients and how safe they are. As of October 23, 2021, there are 3 vaccines that are being used in the United States and 4 vaccines that are being used in Canada to prevent COVID-19. Two are mRNA type vaccines, and two are adenovirus vector-based vaccines.

- Like all vaccines, COVID-19 vaccines were tested to make sure they are safe.
- Although mRNA is a new way to make vaccines, it has been studied for decades.
- Adenovirus vector-based vaccines have been used for other infections such as Ebola.
- None of the currently authorized COVID-19 vaccines contain live virus and these vaccines carry no risk of causing COVID-19 infection.
- Transplant patients do not have as strong of an immune response to the COVID-19 vaccine and are therefore recommended to receive additional doses.

Vaccine Safety

Have any COVID-19 vaccines been studied in transplant recipients?

Patients with suppressed immune systems were not included in the initial clinical trials that evaluated the COVID-19 vaccines. However, many transplant recipients have now received COVID-



19 vaccines since they have become available and there are now a number of studies evaluating these vaccines in transplant patients. All studies to date show the vaccine to be safe in transplant patients with similar side effects to non-transplanted individuals. Expert opinion is that it is unlikely that the vaccines will cause rejection episodes, and no rejection episodes definitively linked to COVID-19 vaccines have been seen so far. How well the vaccine will work to protect immune suppressed people is not fully known but are likely to be less than people who aren't receiving immunosuppression. Transplant patients can have severe disease from COVID-19 infection and may be more likely to require hospitalization or intensive unit care, and the vaccine may still help prevent severe disease. Therefore, benefits of vaccination appear to outweigh any unproven risks.

Which vaccines are available in the United States and Canada?

As noted above, as of October 26, 2021, there are 3 vaccines available in the U.S. and 4 in Canada. The **Pfizer-BioNTech** COVID-19 Vaccine and the **Moderna** vaccine are currently available in the US and Canada. These are both mRNA vaccines and work the same way. They have similar side effects and similar rates of protection from COVID-19 disease. The adenovirus-vector vaccines include the **Johnson & Johnson/Janssen** Vaccine (available in U.S. and Canada) and the **AstraZeneca** (COVISHIELD) vaccine (available in Canada). These vaccines have been shown to be



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highly effective in preventing severe COVID-19 disease. None of the currently approved vaccines contain live virus.

We recommend receiving any brand of the currently authorized vaccines. Vaccine centers may not be able to accommodate requests for a specific vaccine type.

Can transplant recipients receive the currently approved COVID-19 vaccines?

Yes, transplant recipients who are 18 years of age or older can receive any of the available vaccines. The Pfizer -BioNTech vaccine is also approved and available for children 5 years of age or above.

How the vaccines work

What is an mRNA vaccine?

Pfizer-BioNTech and Moderna vaccines are mRNA vaccines. mRNA is a molecule that tells our body to make proteins only found on the surface of the COVID-19 virus. Our immune system learns from the vaccine to recognize these proteins as foreign. After vaccination, if we get exposed to the COVID-19 virus, our immune system recognizes those same proteins on the virus and then knows to attack and block the COVID-19 virus. mRNA COVID-19 vaccines do not cause COVID-19 infection.

What is an adenovirus-vector vaccine?

The Johnson & Johnson/Janssen vaccine and the Astra-Zeneca vaccine are adenovirus-vector vaccines. This means that a modified version of an adenovirus (the vector) is used as a delivery system to carry pieces of the COVID-19 surface proteins. The modified adenovirus itself is also safe as it is not live and cannot multiply in our bodies, and therefore cannot cause adenovirus infection. The vaccine only uses pieces of the COVID-19 virus, and therefore cannot cause

COVID-19 infection. These types of vaccines have most recently been used for Ebola virus outbreaks and have been studied against other diseases such as Zika, flu, and HIV with excellent safety records.

How well does the vaccine work in transplant patients?

We know that transplant recipients develop less of an antibody response to the vaccine due to their immunosuppressive medications. This could result in a decrease in the vaccine's ability to provide protection against COVID-19, but some protection is still expected for most transplant patients. For this reason, experts strongly recommend that transplant recipients should still be vaccinated against COVID-19 to lower the chance of severe COVID-19 disease and death if a transplant recipient were to be exposed and infected. A third dose of mRNA vaccine is now allowed under the Emergency Use Authorization by the FDA for transplant recipients ages 12 and older at least 28 days after the 2nd dose to improve protection from the vaccine. Currently children ages 5-11 are not eligible for booster vaccines.



Will the vaccine protect me from getting COVID-19 or just make me less likely to get sick?

In the initial clinical trials, the vaccines proved to be highly effective at completely preventing COVID-19 disease in most people. We also know that the vaccines reduced the severity of COVID-19 sickness if people catch it after being vaccinated, even with the delta variant. Scientists are currently working to get a better answer on protection in transplant recipients. From what we know so far, it does appear that the vaccines are helping to protect transplant patients from more serious infection.

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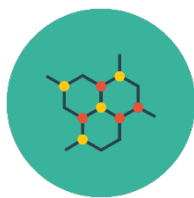
How long will the vaccine protection last?

We don't know exactly because the longer-term results of vaccine clinical trials are not complete. The clinical trial participants (who were not transplant patients) have been protected for at least 6 months. Whether the length of time transplant patients will be protected will be the same is not known.

It takes time for your body to build protection after any vaccination.

For transplant patients, COVID-19 mRNA vaccines (Pfizer-BioNTech and Moderna) require three shots to build protection, so you will not be fully protected until a week or two after your third shot. Astra-Zeneca also requires two shots with protection starting 1-2 weeks after your second shot.

The J&J/Janssen vaccine initially required one shot. As of October 23, 2021, we also recommend that patients who have received J&J/Janssen to receive a 2nd dose vaccine 2 months after their initial vaccine dose with an mRNA (Pfizer or Moderna) vaccine or a repeat J&J. You can expect to be best protected 2 weeks after receiving the second shot. Protection rates may build further over time.



When should I receive the COVID-19 vaccine?

Pre- and post-transplant patients are eligible for vaccination throughout the US and Canada as long as they are 5 years of

age or older.

We are encouraging patients to get vaccinated at whichever location is available to them first. COVID-19 vaccines can also be given on the same day with other vaccines, preferably in different body sites.

Is the vaccine safe for people with mild or severe allergies?

If you have had a severe allergic reaction to other vaccines or injectable therapies, you should ask your physician if you should get a COVID-19 vaccine. Your doctor will help you decide if it is safe for you to get vaccinated. If you have ever had a severe allergic reaction to any ingredient in a COVID-19 vaccine (such as polyethylene glycol, which is in both mRNA vaccines, or polysorbate 80, which is in the Johnson & Johnson/Janssen vaccine), the Centers for Disease Control and Prevention (CDC) recommends that you not get that specific type of vaccine.



If you have a severe allergic reaction after getting the first shot, you should not get the second shot. Your primary care provider may refer you to a specialist in allergies and immunology to provide more care or advice. If you have had a severe allergic reaction to the first dose of any of the mRNA vaccines (Pfizer-BioNTech, Moderna) and were unable to receive the second dose, it is safe to receive the J&J/Janssen vaccine.

The CDC recommends that people with a history of severe allergic reactions that are not related to vaccines or injectable medications—such as allergies to food, pets, venom, pollen/environmental substances, or latex—can safely get vaccinated. People with a history of allergies to oral medications or a family history of severe allergic reactions, or who might have a milder allergy to vaccines (no anaphylaxis) may also still get vaccinated. The only reason to avoid vaccination that is related to allergies is if you've ever had a severe allergic reaction to any ingredient in the COVID-19 vaccine.

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When should I be vaccinated?

What is the timing of vaccination relative to different transplant-related events?

Patient Group	Timing of Vaccine	Comments
Pre- Organ Transplant	Ideally complete at least 2 weeks prior to transplant	Do not delay transplantation because of COVID vaccine schedule
Post-Organ Transplant	1 month after transplant surgery (ask your transplant team for specific timing)	

Can someone who has had COVID-19 infection get the COVID-19 vaccine?

Yes. **You should get the vaccine once you have completely recovered from COVID infection and are no longer contagious.** Please discuss the specific timing with your doctor. If you were treated with monoclonal antibodies or convalescent plasma for COVID-19 infection, you should wait at least 90 days before getting vaccinated. Due to the severe health risks associated with COVID-19 and the fact that re-infection is possible, people who previously tested positive can and should still receive the COVID-19 vaccine when it is available to them. Currently, scientists don't know how long COVID-19 antibodies from natural infection protect people after their illness but think that the protection after




infection is less than the protection after vaccination and the vaccine will provide additional protection. Testing for antibodies to COVID-19 as a marker of past infection is not recommended or needed prior to vaccination

For three-dose vaccines (Pfizer-BioNTech or Moderna), if I get a dose of the vaccine and then get infected with COVID-19, can I get the next dose?

Protection from symptomatic infection (meaning you are infected with COVID-19 and showing symptoms) starts as soon as 12 days after the first dose of the vaccine but is not complete. Even after your second or third dose, it is still possible to catch COVID-19 and become contagious. If you do happen to become symptomatic with COVID-19 after the first or second dose of the vaccine, you should receive the next dose after the symptoms, such as fever, have completely resolved, and after you have completed a standard period of home isolation. Please discuss the timing of your second (or third) vaccine with your health care team.




Please note: Fever, fatigue, sore muscles and joints in the first few days after the vaccine may be vaccine side effects. If these symptoms do not clear within a couple of days or become worse, call your provider and consider scheduling a COVID-19 test.



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What to expect when I get vaccinated

What is the dosing schedule for transplant recipients?

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- Johnson & Johnson / Janssen Vaccine: The CDC now recommends that anyone who received a single dose of J&J/Janssen vaccine should get a second dose of a COVID vaccine 2 months after the first dose. It is preferred to use an mRNA vaccine (Moderna or Pfizer) for the best immune response. However, if this is unavailable, a repeat dose of J&J/Janssen can be given instead.
 - AstraZeneca (COVISHIELD) Vaccine: There are two doses, with the second dose 4-12 weeks later.
 - Pfizer-BioNTech COVID-19 Vaccine: There are three doses, with the second dose as close as possible to 21 days later, but no earlier than 17 days after the first dose. The third dose is recommended at least 28 days after the second dose.
 - Moderna COVID-19 Vaccine: There are three doses, with the second dose as close as possible to 28 days later, but no earlier than 24 days after the first dose. The third dose is recommended at least 28 days after the second dose.
 - For mRNA vaccines, if it is not possible to adhere to the recommended intervals as above, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose.

Is it safe to take pain relievers before vaccination? Can I take them if I develop side effects from the vaccine?

If you regularly take aspirin, acetaminophen (Tylenol) or ibuprofen (Motrin, Advil) for other medical conditions, continue to do so as directed by your physician or as needed. It is unknown if taking pain relievers before getting vaccinated will reduce the effectiveness of vaccine; therefore, it is recommended to generally avoid taking them before vaccination.

If you have pain or discomfort after receiving the vaccine, it's ok to take pain relievers that you normally take. Side effects should go away in a few days. If you have concerns about what medications are safe for you to take, check with your doctor.

After vaccination

What are the potential adverse effects of the vaccine?

In the vaccine clinical trials, minor side-effects, which include headache, fatigue, fever and injection site pain (redness, swelling) were seen in the 1-3 days after vaccination. These symptoms are typically more noticeable after the second dose and in younger patients. Transplant patients should continue to call their transplant team for fever, or any other symptoms experienced in the days after the vaccination as they normally would to see if any further tests or treatments are needed.

For both the J&J/Janssen and Astra-Zeneca vaccine, extremely rare cases of thrombosis (blood clots) with thrombocytopenia syndrome (TTS)/vaccine-induced thrombotic thrombocytopenia (VITT) have been reported. Most reported cases have occurred after the first



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dose in young females, at a rate of 1 per 100,000 doses or 1 per 125,000 doses of vaccines given.

Very rare events of Guillain-Barre Syndrome, a rare neurologic disorder characterized by weakness and paralysis, have also been reported after the administration of J&J/Janssen vaccines. Most cases were in older men (ages 50 through 64) at a rate of 16 cases per 1 million doses administered.

mRNA vaccines have very rarely been associated with 'myocarditis', an inflammation of the heart muscle or 'pericarditis', an inflammation of the lining of the heart. This has occurred within the first week of vaccine mostly in young males age 18 through 24. The overall risk is low with 30-40 cases per million doses in the 12-29 age group. Most cases are mild and have recovered. Myocarditis can occur with COVID-19 infection itself also. Therefore, the CDC recommends that the benefit of vaccination outweighs the low risk of myocarditis.

At present, there is no information to suggest that transplant recipients would be at higher risk of vaccine adverse effects than anyone else.

Should I get an COVID-19 antibody (serology) test after vaccination?

The CDC is currently not recommending COVID-19 antibody testing after vaccination, outside of research studies, because it is unknown what antibody level is protective. Antibody testing also does not measure all components of immunity needed against COVID-19 and are therefore may not be able to predict the actual protection gained from the vaccine.

Should I get a third dose or extra dose of vaccine to boost my immune response?

On August 12, 2021, the FDA amended the Emergency Use Authorization for both the Pfizer-

BioNTech and Moderna COVID-19 vaccines and now recommends third doses in immunocompromised individuals. This includes solid organ transplant recipients. In October, 2021, the CDC also allowed for the option of a fourth dose of mRNA vaccine (Pfizer-BioNTech and Moderna) as a booster at least 6 months following a 3-dose primary series. Currently children ages 5-11 are not eligible for booster vaccines.

As of October 21, 2021, it is recommended that patients who have received a single dose of J&J/Janssen also consider receiving a second dose of a COVID-19 vaccine. Data show that there may be a higher antibody response when the second dose is one of the mRNA vaccines (Pfizer-BioNTech or Moderna). Therefore, it is preferred that the second dose be given as an mRNA vaccine. If this is not available, a repeat J&J/Janssen dose can be given as well.

Please speak with your health care provider regarding the best course of action for you regarding an extra dose of vaccine based upon your individual circumstances.

Why are some transplant programs considering requiring COVID-19 vaccines for patients listed for transplantation?

Vaccines are less effective if administered after a transplant due to anti-rejection medications. Patients who become infected with COVID-19 after transplantation also have a higher chance of complications and death when compared to those without a transplant.

This has led many transplant centers to require pre-transplant COVID-19 vaccination prior to being added to the transplant list. The goal is to optimize transplant candidates' chances of being safely transplanted. Because the risks of COVID-



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COVID-19 infection in the absence of vaccination outweigh the risks of COVID-19 vaccination, programs have been adopting more stringent vaccine requirements. Please check with your transplant center regarding their specific vaccination policies.



Can I stop wearing a mask after I have been vaccinated for COVID-19?

No. At this time, we do not fully understand the level of protection transplant patients gain after receiving the vaccination. As many places reduce restrictions, wearing a mask can feel burdensome. However, until we have a better understanding of protection, even after vaccination, transplant patients and

their households should continue to practice COVID-19 safety measures including:

- Continue to wear masks around others outside of their household, particularly if
 - Indoors
 - Amongst crowds even outdoors
- Practice good handwashing
- Maintain physical distancing in public places

PLEASE MAKE SURE THAT YOUR FAMILY AND FRIENDS GET VACCINATED TOO. This will help protect you.

Related Links

- **CDC Recommendations** <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html>
- **AST Vaccine FAQ Sheet** <https://www.myast.org/covid-19-vaccine-faq-sheet>
- **AST COVID-19 Information** <https://www.myast.org/covid-19-information>
- **ISHLT COVID-19 Information** <https://ishlt.org/covid-19-information>