

COVID-19 vaccines are widely available in the U.S. and Canada for everyone 6 months 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 January 1, 2023, there are 4 vaccines that are being used in the United States and 6 vaccines that are being used in Canada to prevent COVID-19.

- Like all vaccines, COVID-19 vaccines were tested to make sure they are safe.
- Although mRNA was a relatively new way to make vaccines for COVID-19, 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?

While patients with suppressed immune systems were not included in the initial clinical trials that evaluated the COVID-19 vaccines,

many transplant recipients have now received COVID-19 vaccines since they have become available. 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. 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. Immune suppressed people are likely less protected with the vaccine when compared to people who aren't receiving immunosuppression. Transplant patients are more vulnerable to develop severe disease from COVID-19 infection and have more frequently required hospitalization or intensive unit care. Nevertheless, the vaccine has been protective against developing severe disease. Therefore, benefits of vaccination outweigh unproven risks.

Which vaccines are available in the United States and Canada?

As noted above, there are currently 4 vaccines available in the U.S. and 6 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 US and Canada) and the **AstraZeneca (COVISHIELD)** vaccine (available in Canada). Most recently, the protein subunit based **Novavax** vaccine has been approved in both US and Canada. These vaccines have been shown to be 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 6 months of age or older can receive any of the available mRNA vaccines.

How the vaccines work

What is an mRNA vaccine?

Pfizer-BioNTech and Moderna vaccines contain mRNA, which is a molecule that tells our body to make proteins. The mRNA in these two vaccines instructs our bodies to

specifically 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 is ready to recognize those same proteins on the virus and 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 that contain DNA. Like mRNA, DNA tells our bodies to make proteins. In these vaccines, a modified version of an adenovirus (the vector) is used as a delivery system to carry DNA that instructs our bodies to make 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 DNA, 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.

What is a protein subunit-based vaccine?

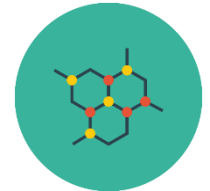
The Novavax vaccine contains a protein (made using moth cells) and an adjuvant (made from tree bark). The adjuvant is an ingredient added to boost a person's immune response, creating higher levels of antibodies. This is an older and more traditional approach to vaccines and is similar to techniques used to protect against flu, pertussis, and meningococcal infection.

How well does the vaccine work in transplant patients?

We know that transplant recipients develop less of an antibody response to the vaccines 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. Additional doses of COVID-19 vaccines are now recommended for transplant recipients to improve their antibody response and increase protection from severe COVID-19 disease and death.



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. In more recent years, newer variants such as the Omicron variant have caused infection even after vaccination. However, in these cases, severity and death are significantly less in people who have received the vaccine. From what we know so far, it does appear that the vaccines are also helping to protect transplant patients from more serious infection.

How long will the vaccine protection last?



We don't know exactly because the longer-term results of vaccine clinical trials are still ongoing. 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.



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For transplant patients 6 months and older, 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, followed by an mRNA shot for the 3rd dose with protection starting 1-2 weeks after your third shot.

The J&J/Janssen vaccine is only approved for ages 18 and above, and 2 doses are recommended. It is preferred that dose #2 is an mRNA vaccine. You can expect to be best protected 2 weeks after receiving the last shot. Protection rates may build further over time. Finally, the Novavax vaccine is recommended at 2 doses.

All the above vaccines are recommended to be followed with a new updated (bivalent) mRNA booster (Moderna or Pfizer) at least 2 months after the last dose. As of December 2022, there is an updated bivalent booster that can offer additional protection against new COVID-19 variants. This updated bivalent booster is recommended for those over 5 years. This booster can be given as the third dose of the primary series for children ages 6 months to 4 years of age.

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 an allergy specialist 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.





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-19 and are no longer contagious. Please discuss the specific timing with your doctor. Currently, scientists don't know how long COVID-19 antibodies from natural infection protect people after their illness but think that 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.



If I get a dose of a 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 next vaccine dose with your health care team.



Please note: Fever, fatigue, sore muscles, and joints in the first few days after the vaccine may be expected 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.

What to expect when I get vaccinated

What is the difference between an additional primary shot and a booster shot?

An additional primary shot of mRNA COVID-19 vaccine is given to people with suppressed immune systems, such as transplant recipients, with the goal of improving a person's response to their vaccine primary series.

A booster shot is given when a person has completed their vaccine primary series to enhance or restore their immune response against COVID-19 which may have decreased over time. Currently all patients who have completed their primary shots and are due for boosters are recommended to receive the new Moderna or Pfizer updated booster (available for ages 5 years and older). You may see this being called the “bivalent booster” – which refers to the two different strains of COVID-19 viruses used to build the vaccines. Even if you had earlier “booster doses,” everyone 5 years of age and older should receive the bivalent booster vaccine dose as well.

What is the dosing schedule for transplant recipients?

The vaccine schedule is attached at the end of this document.

- AstraZeneca (COVISHIELD) Vaccine (Ages 18 and older, not available in the US): There are two recommended doses separated by 4 weeks, followed by an mRNA vaccine for the third dose

(Moderna or Pfizer) in an additional 4 weeks.

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





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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 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, many transplant patients have already received the vaccines and there is no information to suggest that transplant recipients would be at higher risk of vaccine adverse effects than anyone else.

Should I get a 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.

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 increase transplant candidates' chances of being safely transplanted.

Because the risks of COVID-19 infection in the absence of vaccination outweigh the risks of COVID-19 vaccination, several 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?

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, transplant

patients and their households should continue to consider the additional benefits of practicing COVID-19 safety measures including:

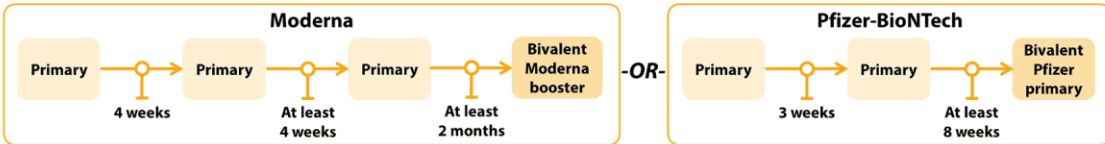


- Wearing masks around others outside of their household, particularly if amongst crowds indoors or outdoors
- Practice good handwashing

PLEASE ENCOURAGE YOUR FAMILY AND FRIENDS TO GET VACCINATED TOO. This will help protect you.

COVID-19 Vaccination Schedule Infographic for People who ARE Moderately or Severely Immunocompromised

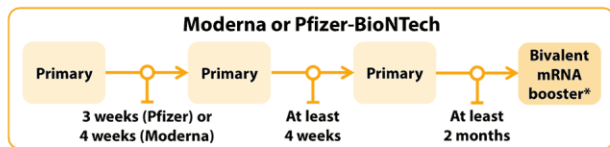
People ages 6 months through 4 years



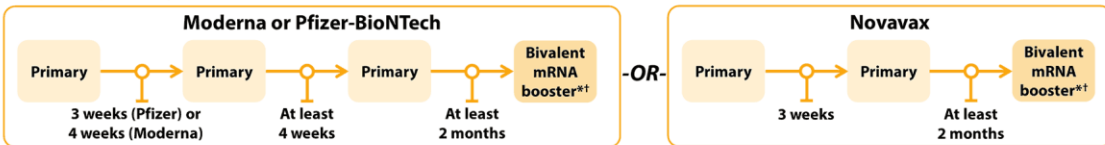
People age 5 years



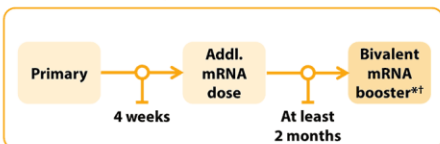
People ages 6 through 11 years



People ages 12 years and older



People ages 18 years and older who previously received Janssen primary series dose‡

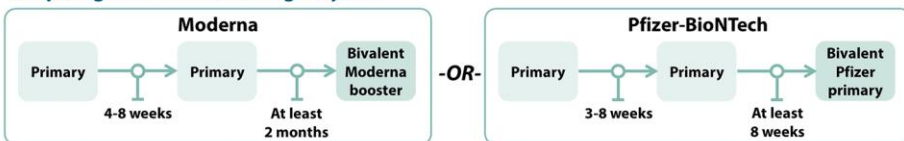


*For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.
 †A monovalent Novavax booster dose may be used in limited situations in people ages 18 years and older who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered **at least 6 months** after completion of a primary series.
 ‡Janssen COVID-19 Vaccine should only be used in certain limited situations. See: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a>

For Pre-Transplant Candidates or Transplant Household Members:

COVID-19 Vaccination Schedule Infographic for People who are NOT Moderately or Severely Immunocompromised

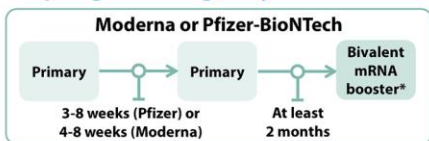
People ages 6 months through 4 years



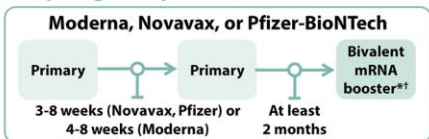
People age 5 years



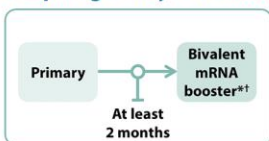
People ages 6 through 11 years



People ages 12 years and older



People ages 18 years and older who previously received Janssen primary series dose[‡]



*For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.
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 ‡ Janssen COVID-19 Vaccine should only be used in certain limited situations. See: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a>

Related Links

- **CDC Recommendations** <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.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>