

COVID-19 Vaccine FAQ Sheet
(updated **8/13/2021**)

The AST has received queries from transplant professionals and the community regarding the COVID-19 vaccine. The following FAQ was developed to relay information on the current state of knowledge. This document is subject to change and will be updated frequently as new information or data becomes available.

KEY RECOMMENDATIONS:

- We recommend continued SARS-CoV-2 vaccination in all solid organ transplant (SOT) recipients (12 years and older) as well as priority vaccination of their household members and caregivers to reduce infection risk for these vulnerable patients.
- Preliminary safety data of mRNA vaccination in SOT recipients suggest low rates of local and systemic reactions.
- Although data on clinical efficacy of mRNA vaccines in SOT recipients are incomplete it is still strongly recommended as vaccination may prevent or reduce severity of clinical disease regardless of antibody response.
- Continued adherence of all transplant recipients to protective measures such as masking and social distancing is recommended regardless of vaccination status.
- We recommend vaccination for SARS-CoV-2 in patients who have recovered from COVID-19, after all symptoms have resolved and the period of isolation has ended.
- For pre-transplant patients, we recommend vaccination completion at least 2 weeks prior to transplantation if possible. For post-transplant patients, we recommend administering vaccination beginning as early as 1-3 months after transplantation. This can be individualized based on immunosuppression.
- We do not recommend routinely checking antibody responses to the vaccine.
- We recommend a third dose of mRNA vaccine in patients who have received two previous doses of mRNA vaccine, as approved by the FDA. We encourage a conversation between the provider and the patient which considers the patient's individual situation.
- We do not recommend routine adjustment of immunosuppressive medications prior to vaccination outside of clinical trials.
- We recommend each center develop approaches to educate patients on the

importance of vaccination and consider tracking vaccination rates.

What kinds of vaccines are available or under development to prevent COVID-19?

There are currently several vaccine candidates in use or under development. In the United States, the Government is supporting six separate vaccine candidates. Several other vaccines are also undergoing development outside of the United States government sponsorship and further information can be found here:

- **NYTimes Coronavirus Vaccine Tracker:**
<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>
- **London School of Hygiene and Tropical Medicine:** https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/
- **World Health Organization (WHO) Vaccine Tracker:**
<https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

The types of vaccines are as follows (August 12th, 2021) ^{1,2}:

Table 1: Vaccines Under Development or Available Through EUA

Vaccine Type	Compound Name [Sponsor]	Clinical Trial Phase	Notes
mRNA	mRNA-1273 [Moderna]	Phase 3	Emergency use in U.S., E.U., other countries Approved in Canada, Switzerland.
	BNT162b2 (tozinameran; Comirnaty) [Pfizer]	Phase 2/3	Emergency use in U.S., E.U., other countries Also approved in Canada and other countries, including 12 yrs. and older (US, CA)
Replication-defective adenoviral vector	AZD1222 (Covishield) [AstraZeneca]	Phase 2/3	Emergency use in U.K., India. Approved in Canada, other countries. (not U.S.)
	JNJ-78326735/Ad26.COVS.2.S [Janssen/Johnson&Johnson]	Phase 3	Emergency use in the U.S., E.U., Canada, other countries.
	rAd26 and rAd5 (Sputnik V) [Gameleya Research Institute]	Phase 3	Emergency use in Mexico, Russia, India, other countries (not U.S.)

Nanoparticle – Saponin based Matrix M Adjuvant	NVX-CoV2373 [Novavax]	Phase 3	
Recombinant-subunit-adjuvanted	Recombinant SARS-CoV-2 Protein Antigen + AS03 Adjuvant [Sanofi Pasteur/GSK]	Phase 2	
Inactivated Vaccine	CoVaxin (BBV152) [Bharat Biotech]	Phase 3	Emergency Use in India.
	BBIBP-CorV (CoronaVac) [Sinopharm]	Phase 3	Approved in China, Bahrain, UAE; Emergency use other countries (not U.S.)

Both of the mRNA SARS-CoV-2 vaccines (Moderna, Pfizer) that have been authorized by Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA), require 2 doses and cold storage³. The Janssen/Johnson & Johnson vaccine uses a replication-deficient Adenovirus 26 for the vaccine vector and has been authorized by EUA by the FDA as a 1 dose vaccine.

What vaccines are available to transplant recipients?

The Pfizer and Moderna mRNA vaccines and Janssen/Johnson & Johnson Adenovirus-vector vaccine are approved for Emergency Use Authorization (EUA) in the U.S. (Current: August 10, 2021). The Pfizer vaccine is approved for ages 12 and older; Moderna and Janssen vaccines are approved for 18 years and older.

Further updated information on vaccinations administered across the U.S. can be found here:

- **Bloomberg Vaccine Tracker:** <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/>

Information for patients on where to find vaccines nearby can be found here:

- **NPR Vaccine Distribution Information per State:** <https://www.npr.org/sections/health-shots/2021/02/18/967448680/how-to-sign-up-for-a-covid-19-vaccine-in-your-state>
- **Vaccine Finder:** <https://vaccinefinder.org/>

What is known about the safety of these vaccines?

Table 2. Reported vaccine adverse events

The unprecedented speed of the vaccine development has been built upon prior research conducted in previous coronaviruses as well as vaccine approaches for other novel viruses. Rigorous standards for safety were set forth by the FDA in June 2020, and all vaccine candidates must meet safety and effectiveness standards.

Although there are no licensed mRNA vaccines in the United States, they have been studied for decades for cancer and other infectious diseases. Both Pfizer/BioNTech and Moderna have applied for full license with the FDA (Current: May 10, 2021). As of July

Reported adverse events	VAERS Adverse Events		FDA Approval Documentation				
	Pfizer-BioNtech %	Moderna %	Pfizer-BioNtech %		Moderna %		Janssen/J&J %
			Dose 1 N=4,093	Dose 2 N=3,758	Dose 1 N=15,163	Dose 2 N=13,944	
Pain (Injection site, extremity)	29.2	37.9	77.8	72.6	83.7	88.4	46.9
Fatigue	15.5	15.4	41.5	55.5	37.2	65.2	38.2
Headache	20.0	23.4	34.5	46.1	32.7	58.6	38.9
Myalgia	N/A	N/A	18.0	33.5	22.7	57.6	33.2
Chills	13.0	18.3	10.6	29.6	8.3	43.7	N/A
Fever	13.4	18.9	2.7	13.6	0.8	15.6	9.0
Swelling	N/A	N/A	6.1	6.8	6.2	12.2	5.2
Joint Pain	N/A	N/A	9.9	20.5	16.6	42.6	N/A
Nausea	12.8	15.3	N/A	N/A	8.3	18.9	14.2
Vomiting	N/A	N/A	0.9	1.4			N/A

*Data from reports through v-safe/Vaccine Adverse Event Reporting System (VAERS) as reported in ACIP meeting (March 1, 2021) with v-safe lock point February 16, 2021. Side effects reported on at least one health check-in completed on days 0-7 after receipt of vaccine. Pfizer-BioNtech with N=48,196, Moderna with N=56,567 ¹

1st, 2021, over 154 million people in the US alone, have received at least one dose under the Emergency Use Authorization without significant concerns. The mRNA SARS-CoV-2 vaccines, similar to other common vaccines, are noted to cause fevers, muscle aches, and headaches; most are mild to moderate in severity, but some may be severe enough to briefly limit activities and typically resolve within 1-2 days. At this time given the available data, the vast majority of serious side effects, if any, are noted in the first few days after vaccination. We do not expect that there will be significant side effects reported beyond the early post vaccination period.

The potential for anaphylaxis to either mRNA vaccine may range from 2.5-4.7/million doses ⁴; this is currently being closely monitored in the US and other countries. Persons with a known (diagnosed) allergy to polyethylene glycol (PEG), another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Individuals with any immediate allergic reaction to other vaccines or injectable therapies should be counseled about the unknown risk of severe allergic reaction and should be monitored for 30 minutes after vaccine. Likewise, patients with allergy to oral medication, history of food, pet, insect, venom, environmental or latex allergies or family history of allergy should still obtain the vaccine but also be monitored for 30 minutes after vaccine ⁵. At this time, it is recommended that all vaccine recipients should be monitored on site immediately following vaccination.

The safety of mRNA vaccines is still under investigation in solid organ transplant recipients. There were no transplant recipients in the phase 3 trials for Moderna or Pfizer, however, many transplanted individuals have already received vaccination as part of the EUA. Based on their mechanism of action, expert opinion is that these vaccines are unlikely to trigger rejection episodes or have novel or more severe side effects in transplant recipients, but more data will be needed.

A study of 741 SOT recipients who received both doses of SARS-CoV-2 vaccine doses provided early insight into safety and efficacy of the mRNA vaccine in this population ⁶.

Equal numbers of recipients received the Pfizer and Moderna vaccines and had the expected rates of local (84% after dose 1 and 77% after dose 2 and systemic (overall: 49% after dose 1 and 69% after dose 2; fatigue 36% after dose 1 and 56% after dose 2; headache 28% after dose 1 and 42% after dose 2) reactions. Only 1 patient developed acute rejection following the second dose of vaccine ^{7, 8}.

The safety of Adenovirus-vector vaccines is still under investigation in solid organ transplant recipients as transplant recipients were not included in the phase 3 trials of the Janssen/Johnson & Johnson vaccine or the Oxford/Astra-Zeneca vaccine. Unlike live virus vaccines, Adenovirus-vector vaccines have been genetically engineered to not replicate, and therefore cannot cause Adenovirus infection in the recipient. Based on the mechanism of action, expert opinion is that this vaccine is unlikely to trigger rejection episodes or have novel or more severe side effects in transplant recipients, but more data are needed. Based on recent safety review of the J&J/Janssen COVID-19 vaccine, rare events of thrombosis with thrombocytopenia syndrome (TTS) were observed at a rate of 7 per 1 million doses administered in women between 18 and 49. Given the rarity of this adverse event, vaccine administration has resumed in the U.S, no concerns specific to immunocompromised recipients have been reported thus far.

The safety of other candidate vaccines will be updated as they get closer to emergency use authorization by updating this document.

How effective are these vaccines in transplant recipients?

The Pfizer and Moderna mRNA vaccines have data in immunocompetent people showing 94.1-95% efficacy in preventing infection COVID-19; vaccine efficacy appears similar in patients older than 65 years of age compared to younger patients. Data also suggest that when breakthrough infection occurs, disease is generally mild, showing the vaccines are also effective in preventing severe disease. Data regarding the durability of vaccine titers are still being gathered although it currently appears that antibody titers persist for at least 6 months ^{9, 10}.

The Janssen vaccine trials in immunocompetent people shows a 66% efficacy to prevent COVID-19 infection. Data from US patients demonstrated a 72% overall efficacy against symptomatic COVID-19 infection and 86% efficacy in preventing severe forms of COVID-19.

Any of the currently authorized vaccines can be used when indicated, we currently do not state a product preference. Efficacy rates may be lower in transplant than the general population for any of the available vaccines and relative efficacy of different products is not known in the transplant setting. The effectiveness of COVID-19 vaccines continues to be studied in the solid organ transplant recipient. Solid organ transplant recipients have generally been observed to have lower antibody responses to mRNA COVID vaccines than those without transplants. ¹¹⁻¹⁵ Interestingly, some patients who do not develop antibody may still generate virus-specific T-cell responses suggesting that protection may be dependent on multiple arms of the immune system ¹⁶. Lastly, patients vaccinated pre-transplant, may have reduced protection post-transplant, particularly if therapies that reduce B-cell function (e.g. rituximab) are utilized. The impact of specific therapies, such as belatacept also warrant specific study.

Recent reports of breakthrough infection in SOT recipients indicate vaccine decreases risk for infection and severe disease but highlights that vaccinated SOT recipients remain at risk. A

study among 18215 vaccinated SOT recipients has identified 151 breakthrough infections (0.83%) with a mortality rate of 9.3%, which is lower than the mortality reported in unvaccinated SOT¹⁷. Another large registry study including 48213 SOT recipients in the UK has clearly found both a lower rate of COVID-19 in fully vaccinated (0.3%) compared to unvaccinated (51%) and decreased vaccine-induced mortality from 12.6% in unvaccinated individuals and 12.0% patients after the first vaccine dose, to 7.7% in patients after a full course of vaccination¹⁸.

When should a transplant recipient or candidate receive these vaccines?

The immunogenicity and efficacy of COVID-19 vaccines are unknown in transplant recipients. However, based on previous vaccination guidelines for solid organ transplant recipients, it is recommended that all transplant candidates and their household members receive vaccination when it becomes available. Ideally, transplant candidates should be targeted for vaccination while they are awaiting transplant. In general, vaccines are recommended for completion at least 2 weeks prior to transplantation or starting at 1 month after transplantation.¹⁹ If given prior to transplant, ideally both doses should be completed before transplant to allow full protection however, transplant deferral to complete the vaccine series should not be routinely done and needs to be decided on a case-by-case basis. In certain situations, it may be appropriate to wait until 3 months after transplantation to vaccinate, such as when T- or B-cell ablative therapy (anti-thymocyte globulin or rituximab) was used at the time of transplant. If someone is transplanted after receipt of only 1 dose of vaccine, the optimal timing of the second dose is not defined. Expert opinion suggests waiting for at least 4 weeks to administer the second dose of vaccine, to allow time to decrease immunosuppression prior to second dose administration.

Can a transplant recipient still receive the vaccine even if they have had COVID-19?

The current guidance is that everyone receives the vaccine, irrespective of past COVID-19 infection or prior evidence of humoral immunity. There are case reports of immunosuppressed patients developing COVID-19 reinfection²⁰, suggesting lack of appropriate immune response or waning immunity after the first infection. In addition, emerging data highlights after COVID-19 infection, vaccinated individuals are less likely to acquire a new infection compared to unvaccinated people²¹. If a transplant recipient has had COVID-19, he/she should wait until all symptoms are resolved and the period of isolation has ended. The ideal period for vaccination after infection is still being investigated.

If a patient develops COVID-19 infection *after* the first dose of mRNA vaccination, but before the second dose, if possible, the second dose should be given once symptoms have resolved and the patient is outside the infectious window.

The impact of delaying the second dose on vaccine efficacy and durability has not been studied in transplant patients and should be avoided where possible. However, if a delay occurs because of incident COVID-19 infection, vaccine unavailability, or interval transplantation, delay should be kept as short as possible. Infectious diseases consultation is advisable in these situations.

Can patients stop wearing a mask after vaccination?

No. After vaccination, patients should be counseled to continue to practice COVID-19 safety measures including wearing masks around others, hand hygiene, and physical

distancing in public places. It is likely that the efficacy and immunogenicity of vaccine in transplant recipients will be lower than shown in the vaccine clinical trials

Due to the emergence of the delta variant, CDC suggests that fully vaccinated people who gather indoors wear masks. We recommend continued adherence to masking and physical distancing when with non-household members until more is known about the immune response and clinical effectiveness of the vaccine in the transplant population.

Can the COVID-19 Vaccine be given at the same time as other vaccines?

There are no data on safety or efficacy of the mRNA COVID-19 vaccines when administered with other vaccines. Although initially the Advisory Committee on Immunization Practices recommended that the COVID-19 vaccine series should be administered alone and with a minimum of 14 days before or after giving any other vaccines, this recommendation has been changed and coadministration of vaccines is now allowed.²² If multiple vaccines are being given concurrently, they should be given in different sites.

Should patients receive an additional dose of mRNA vaccine?

Current data support providing an additional dose of mRNA vaccine in order to boost immune responses in SOT recipients.

A number of studies have looked at the serologic response to one and two doses of mRNA vaccines in SOT recipients. Detectable antibodies have been demonstrated to be relatively infrequent after the first dose but detectable in up to 30-54% of patients after both doses of the vaccine^{15,16}. When quantitative titers were available, they were frequently below the median titer in immunocompetent patients. However, the level of protective antibody has not yet been defined. Furthermore, the protective components of both cellular (T and NK T cells) and humoral responses (IgG/IgM or IgA) may not be linked in individual SOT recipients, and it is possible to still have active acquired immune response in the absence of antibody and vice versa¹⁶. Breakthrough infections following vaccination have been reported in transplant patients; the true rate is unknown but appears to be higher than in the general population^{17,23-26}. Information linking these breakthrough infections to diminished vaccine response is limited, although it seems likely that those with decreased immune responses to vaccine are more likely to develop breakthrough infection.

Studies of third dose mRNA vaccines in SOT suggest that at least some recipients will develop new and/or increased humoral and cellular immune responses to an additional dose of vaccine (three doses).²⁷⁻³⁰ However, in these studies, 67% of patients with negative titers after the 2nd dose still continue to have negative titers after the 3rd dose; and up to 32% of patients still had undetectable antibody titers 4 weeks after the third dose^{27,28}. A more recent prospective, randomized placebo-controlled study of additional dosing demonstrated significantly increased anti-RBD response (55% third dose vs. 18% placebo; $p < 0.001$), enhanced viral neutralization and increased SARS-CoV-2-specific polyfunctional CD4+T cell response³¹. Safety of booster vaccine, including rejection, in SOT recipients has not been extensively examined. From the available data, 1 heart transplant patient developed a biopsy-proven, antibody-mediated rejection 7 days after her third dose of vaccine²⁷. In the prospective randomized trial, the third dose was well-tolerated with no Grade 3 or 4 adverse events noted and no episodes of acute

rejection³¹. Further studies evaluating the potential for vaccine-induced allo-upregulation should involve larger cohorts of patients to provide more definitive safety data. Nevertheless, available data suggest that SOT recipients will have an enhanced immune response to an additional dose of vaccine. Further research should be done to look for strategies to improve protection in non-responders (e.g. immunosuppression adjustment, passive immunization strategies or a different vaccine platform) as well as non-kidney organ transplant patients and early post-transplant patients. More data are needed to inform best practices especially related to optimal timing and non-mRNA vaccines. Monitoring the long-term responses and adverse effects of vaccines will be important for future study.

Should we check for antibody response after vaccination in solid organ transplant recipients?

Currently, we do not recommend routinely checking antibody responses to vaccine **including with third doses of vaccine**. There are a range of assays with different targets, not all detect neutralizing antibodies, and most do not provide results with titers. As such, presence of antibodies may represent reaction to vaccine but not protection from infection. Further, there is not a well-established protective threshold to target. As with other vaccines, patients may still see reduced severity of breakthrough infection, even if seronegative. Assessment of responses should be done in the context of trials with experts who can interpret results and provide data on titers of neutralizing antibodies.

Should we hold mycophenolate mofetil or other immunosuppressants around the time patients are vaccinated?

Mycophenolate appears to significantly decrease antibody response to COVID-19 mRNA vaccine ^{7, 11, 12, 15}. This is consistent with previous data of the impact of mycophenolate on influenza vaccine responses. However, mycophenolate is a critical part of the overall immunosuppression regimen. These data are observational and insufficient to support the reduction or cessation of any immunosuppression to improve vaccine efficacy. Therefore, the adjustment of mycophenolate or other immunosuppression for the sole purpose of increasing the antibody response is NOT routinely recommended.

Are there other things that transplant recipients need to consider about the vaccine?

Weighing the risks and benefits of getting vaccinated is important. While clinical effectiveness data are currently lacking specific to the vaccine in transplant recipients, it is reasonable to anticipate that vaccination will offer some benefit. Likewise, transplant recipients have clinically worse outcomes from SARS-CoV-2 infection compared to non-transplant recipients due to comorbidities or immunosuppression³². Thus, the benefits of vaccination outweigh any theoretical risks especially in countries where SARS-CoV-2 transmission continues at a high level. The transplant community is encouraged to collect data with regards to vaccination to inform future recommendations. We do recommend each center to consider developing their own approaches to educate patients on the importance of vaccination and track vaccination rates.

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