COVID-19 Vaccine FAQ Sheet
(updated 1/28/22)

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:

- Vaccination against SARS-CoV-2 is strongly recommended as it may prevent or reduce severity of clinical disease regardless of antibody response.

- We recommend SARS-CoV-2 vaccination in individuals ages 5 years and older, including all solid organ transplant (SOT) candidates, recipients, and living donors as well as vaccination of their household members and caregivers to reduce infection risk for these vulnerable patients.

- We recommend a third full dose of mRNA vaccine, >28 days after most recent vaccine, in patients who are 12 years and older who have received two previous doses of mRNA vaccine, as approved by the FDA and CDC. We encourage a conversation between the provider and the patient which considers the patient's individual situation regarding patient specific vaccination strategies.

- We recommend a second dose of SARS-CoV-2 vaccine in patients who have received 1 dose of Johnson & Johnson/Janssen COVID-19 vaccine >2 months following the first dose. While any of the available vaccines are permitted, data from immunocompetent patients shows a higher antibody response when the second dose is one of the mRNA vaccines. The full dose of either Pfizer or Moderna mRNA vaccines is recommended.

- Patients who have received all doses of their primary series are eligible for an additional booster dose of their vaccine 5 months after completion of the initial series.

- 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 symptoms have resolved and the period of isolation has ended.

- Whenever possible, vaccination should occur prior to transplantation (ideally with completion of vaccine series a minimum of 2 weeks prior to transplant).

- 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 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.

- We support the development of institutional policies regarding pre-transplant vaccination as we believe that this is in the best interest of the transplant candidate, optimizing their chances of being safely transplanted, especially at times of continued greater virus circulation.

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:

- **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 (January 28th, 2022):

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., Approved in 76 countries.
	BNT162b2 (tozinameran; Comirnaty) [Pfizer-BioNTech]	Phase 3	FDA approved in US for patients ≥ 16 years, Emergency use in US for age 5-15. Also has approval or conditional authorization in 103 countries.
Replication-defective adenoviral vector	AZD1222 (Covishield) [Oxford-AstraZeneca]	Phase 3	Emergency use in U.K., India. Approved in Canada and 124 other countries. Not approved in US.
	JNJ-78326735/Ad26.COV2.S [Janssen/Johnson&Johnson]	Phase 3	Emergency use in the U.S., E.U. Approved in 75 countries including Canada.
	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	Emergency use in Europe, other countries.

Recombinant-subunit-adjuvanted protein	Recombinant SARS-CoV-2 Protein Antigen + AS03 Adjuvant (Vidprevtyn) [Sanofi Pasteur/GSK]	Phase 3	
Inactivated Vaccine	CoVaxin (BBV152) [Bharat Biotech]	Phase 3	Emergency Use in India.
	BBIBP-CorV (CoronaVac) [Sinopharm]	Phase 3	Approved in China, Bahrain, UAE and 68 countries; Emergency use other countries (not U.S.)

Both of the mRNA SARS-CoV-2 vaccines (Moderna, Pfizer) that have been approved or authorized by Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA), require 2 doses in immunocompetent individuals and cold storage. The Pfizer vaccine is FDA approved for individuals ≥ 16 years old. 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 with a second dose of any vaccine given 2 months after the first dose.

What vaccines are available to transplant recipients?
The Pfizer and Moderna mRNA vaccines and Janssen/Johnson & Johnson Adenovirus- vector vaccine are available for administration in the U.S. (Current: January 28th 2022). The Pfizer vaccine is FDA approved for ages 16 and older, and has EUA for ages 5-15 while Moderna and Janssen vaccines have received emergency use authorization 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:

- **Vaccine Finder:** https://vaccinefinder.org/

What is known about the safety of these vaccines?
Although Pfizer/BioNTech is currently the only licensed mRNA vaccine in the United States, mRNA vaccines have been studied for decades for cancer and other infectious diseases. Moderna has also applied for full license with the FDA. 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. The vast majority of serious side effects, 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; 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. At this time, it is recommended that all vaccine recipients should be monitored on site immediately following vaccination.

Several studies on the mRNA vaccines have been conducted, including third dose studies, with side effect profiles similar to that of patients who did not have a history of transplantation. While there were no transplant recipients in the phase 3 trials for Moderna or Pfizer, many transplanted individuals have already received two to three doses of the vaccine in the United States and elsewhere. There has been no evidence of increased incidence of rejection attributed to the vaccines.

Since April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mNRA vaccines (both Pfizer-BioNTech and Moderna), particularly in young adults and adolescents under 40 years of age. The risk is highest in males 18 through 24 years at 39 cases per 1 million doses administered. In most cases, patients who presented for medical care have responded well to medications and rest. Onset is typically within several days after mRNA COVID-19 vaccination, and cases occur more often after the second dose rather than the first dose.

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. 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.

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 vaccine-induced thrombotic thrombocytopenia (VITT) 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. Approximately 100 episodes of Guillain-Barre Syndrome have also been reported after the administration of the J&J/Janssen vaccine. Most cases were in older men, and presentations were similar to GBS from other causes with a rate of 16 cases per 1 million doses administered in males 50 through 64 years. There was no association with immunosuppression.

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

How effective are COVID-19 vaccines in transplant recipients?

Initial studies in immunocompetent patients showed that the 2-dose Pfizer and Moderna mRNA vaccines were 94.1% to 95% effective in preventing infections and near 100% prevention of severe disease. The single-dose Janssen vaccine demonstrated a 66% efficacy in preventing COVID-19 infection with US data showing a 72% efficacy against symptomatic disease and 84% efficacy in preventing severe COVID-19. With time and with circulation of the Delta variant, vaccine efficacy has reduced.

Clinical benefit of 2-dose vaccine in transplantation has been demonstrated in a number of studies. The CDC has estimated that 2-dose vaccine effectiveness in a combined population of organ and stem cell transplant recipients is 59% (95%CI 38-73). A study using the UK NHS transplant registry, found that 2-dose vaccine was associated with significant reduction in

mortality from 438 deaths (12.6%) in unvaccinated to 11 deaths (7.7%) in vaccinated transplant recipients. Other studies have shown that despite having a higher rate of breakthrough infections than healthy adults, vaccines still reduce the frequency of infections significantly in transplant patients. The relative effectiveness of different products is not known in the transplant setting, but there is some data to suggest lower humoral immunity with J&J than with mRNA vaccines.

Although transplant recipients have low antibody responses (approximately 30-54% antibody positivity), some patients despite not developing antibody still generate virus-specific T-cell responses suggesting that protection may be dependent on multiple arms of the immune system. Lastly, patients vaccinated pre-transplant, may have reduced protection post-transplant, particularly if therapies that reduce B-cell function (e.g. rituximab) are used. The impact of specific therapies, such as belatacept also warrant specific study. Existing data suggest that transplant patients have better antibody responses with mRNA vaccines than adenovirus vectored vaccines.

Third doses of mRNA vaccines are recommended for immunocompromised patients, including SOT recipients (see third dose section below). For patients who have previously received the Janssen vaccine, a second dose is recommended at least 2 months after the first dose; given the improved antibody responses in healthy patients, using one of the mRNA vaccines will likely result in improved responses. There is no preference between the two mRNA vaccines for administration after the Janssen vaccine.

What do the data show for third dose mRNA vaccine?
Current data support providing an additional dose of mRNA vaccine to boost immune responses in SOT recipients.

Studies of third dose mRNA vaccines in adult 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). 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 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 response. 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 vaccine. 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 rejection. 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 transplant patients receive a fourth dose of mRNA vaccine?
At this time, the optimal number of doses of SARS-CoV-2 vaccine is unknown but current CDC guidelines (January 7, 2022) recommend booster dosing in transplant recipients 5 months following completion of the initial 3 dose series of mRNA vaccines.

In a study with 92 kidney transplant recipients who had demonstrated weak response to 3 vaccine doses from France, a fourth vaccine dose increased median antispike IgG levels from 16.4 BAU/mL (IQR 5.9 to 62.3 BAU/mL) to 145 BAU/mL (IQR 27.6 to 243 BAU/mL). The

percentage of patients who had antispike IgG titers above 143 BAU/mL after the fourth dose was 48% after the BNT162b2 vaccine and 52% for the mRNA-1273 vaccine. Patients who received mRNA-1273 vaccine had higher IgG titers (median 150 vs 122 BAU/mL). There was no significant increase in adverse events.

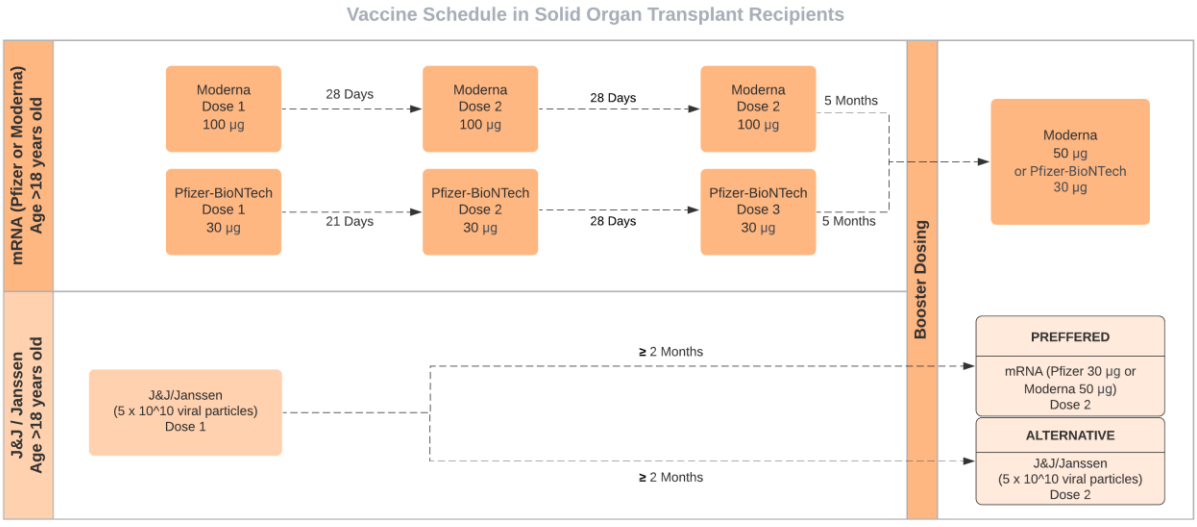
When should a transplant recipient or candidate receive COVID-19 vaccines?
It is recommended that all transplant candidates receive a minimum of 2-doses of vaccine before transplant. Ideally, vaccines are recommended for completion at least 2 weeks prior to transplantation. Additional vaccine doses in the post-transplant setting can be given starting at least 1 month after transplantation. In certain situations, it may be appropriate to wait at least 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. Household contacts of transplant candidates and recipients should also be fully vaccinated.

Can a transplant recipient still receive the vaccine even if they have had COVID- 19?
The current guidance is that everyone should receive the vaccine, irrespective of past COVID-19 infection or prior evidence of humoral immunity. Immunosuppressed patients can develop COVID-19 reinfection, suggesting lack of appropriate immune response especially against variants or waning immunity after the first infection. In addition, emerging data highlights that after COVID-19 infection, vaccinated individuals are less likely to acquire a new infection compared to unvaccinated people. If a transplant recipient has had COVID-19, they should wait until all symptoms are resolved and the period of isolation has ended before receiving vaccine. 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.

Recommended Vaccine Schedule



Can the COVID-19 Vaccine be given at the same time as other vaccines?
There are limited 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 discontinued and coadministration of vaccines is now allowed. If multiple vaccines are being given concurrently, they should be given in different sites.

What is the optimal timing of the COVID-19 vaccine with respect to monoclonal antibody administration, including tixagevimab/cilgavimab (EVUSHELD)?

When monoclonal antibodies (e.g., sotrovimab) are used for treatment of COVID-19 infection, it is recommended that vaccination be delayed for 90 days. This is based on the half-life of the antibody and the potential interference of the antibody with vaccine-induced immune responses.

Data on vaccination after monoclonal antibody prophylaxis are extremely limited. Currently, only tixagevimab/cilgavimab (EVUSHELD) has FDA EUA for pre-exposure prophylaxis. Tixagevimab/cilgavimab is not a substitute for vaccination and is recommended to be only used in patients that have already been fully vaccinated or have a medical contraindication to vaccination. It is recommended that patients wait for 2 weeks after vaccination for receipt of tixagevimab/cilgavimab. Note that the clinical efficacy of tixagevimab/cilgavimab against Omicron variant is not yet defined. The full AST statement on the use of monoclonal antibodies for pre-exposure prophylaxis can be accessed here.

In cases where patients need additional vaccine doses after receiving tixagevimab/cilgavimab, the optimal timing is not known and there is lack of data. While it is advised to wait at least 90 days after receipt of monoclonal antibodies for vaccination (and potentially longer after tixagevimab/cigavimab specifically), we recommend each center to weigh the risk of infection with circulating variants of concern as well as each individual patient scenario to determine potential administration of vaccine earlier than the 90 days.

Should we check for antibody response after vaccination in solid organ transplant recipients?
Currently, we do not recommend routinely checking antibody responses after any dose and do not recommend its use to determine need for additional vaccine doses. There are a range of assays with different targets, not all detect neutralizing antibodies, and many 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. 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 and could be pursued in a trial setting.

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 omicron 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.

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

Weighing the risks and benefits of getting vaccinated is important. While robust 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 immunosuppression. 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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