COVID-19 Vaccine FAQ Sheet
(updated 1/12/2023)

The AST continues to receive 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 as new information or data becomes available.

KEY RECOMMENDATIONS:

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

- We recommend SARS-CoV-2 vaccination in individuals ages 6 months 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 three-dose series of mRNA vaccine for primary vaccination in SOT recipients who are 6 months and older. Patients 6 months to 4 years who received Pfizer BioNTech mRNA for their first two doses, may receive a bivalent Pfizer BioNTech mRNA dose as the third dose of their primary series. Patients 6 months to 4 years who received a Moderna mRNA series and patients 5 years of age and older who have received all doses of either mRNA primary series are eligible for an additional mRNA bivalent booster dose of their vaccine 2 months after completion of the initial series. We encourage a conversation between the provider and the patient which considers the patient's individual situation regarding patient specific vaccination strategies.

- For those who have received a dose of Johnson & Johnson/Janssen vaccine, we recommend a second dose of mRNA SARS-CoV-2 vaccine, followed by a bivalent booster 2 months following the completion of the primary series. Data from immunocompetent patients shows a higher antibody response when the second dose is one of the mRNA vaccines.

- For those who have received the 2-dose series of Novavax vaccine, a bivalent booster can be administered 2 months after completion of the series.

- A bivalent booster can be given after completion of any primary series for patients 5 and older. See qualifications for those under 5 above.

- Continued adherence of all transplant recipients to protective measures such as masking and social distancing should be considered based on risk of transmission and local infection rates, and vaccination status.

- At this time, there is no recommendation for pre-exposure prophylaxis with any monoclonal antibody, including tixagevimab cilgavimab (Evusheld).

- ~~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.~~ For persons with current or recent COVID-19, the appropriate timing of booster vaccination is unknown and

the decision to receive a booster should be individualized. Depending on patient and clinician preference, and the individual risk of reinfection, up to a 3-month delay from SARS-CoV-2 infection may be considered.

- Whenever possible, vaccination should occur prior to transplantation (ideally with completion of the primary vaccine series at 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 the type and degree of immunosuppression and local circulation of SARS-CoV-2.

- 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 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, there are currently four vaccines available for use as the primary series.

The types of vaccines are as follows (January 2023):

Table 1: Vaccines Under Development or Available in the United States and other countries

Vaccine Type	Compound Name [Sponsor]	Clinical Trial Phase	Notes
mRNA	mRNA-1273 (SpikeVax) [Moderna]	Phase 3/4	FDA approved in US for patients ≥18 years. Emergency Use for ≥ 6 months,Approved in many countries.
	BNT162b2 (tozinameran; Comirnaty) [Pfizer-BioNTech]	Phase 3/4	FDA approved in US for patients ≥12 years, Emergency use in US for age ≥ 6 months. Approved in many countries
Replication-defective adenoviral vector	AZD1222 (Covishield) [Oxford-AstraZeneca]	Phase 3	Approved in U.K., Brazil, India. Emergency use in many countries.

	JNJ-78326735/Ad26.COV2.S [Janssen/Johnson&Johnson]	Phase 3	Emergency use in the U.S., E.U. Approved in many countries including Canada. Limited use in U.S.
Nanoparticle – Saponin based Matrix M Adjuvant	NVX-CoV2373 (Nuvaxovid) [Novavax]	Phase 3	Emergency use in US. Approved in several other countries.
Inactivated Vaccine	BBV152 (CoVaxin) [Bharat Biotech]	Phase 3	Approved in 13 countries (not U.S.)
	BBIBP-CorV (CoronaVac) [Sinopharm]	Phase 3	Approved in China, Bahrain, UAE and 89 countries; Emergency use other countries (not U.S.)

What vaccines are available to transplant recipients?
The Pfizer and Moderna mRNA vaccines, Janssen/Johnson & Johnson Adenovirus- vector vaccine, and Novavax protein subunit vaccine are available for administration in the U.S. The Moderna vaccine is FDA approved for ages 18 and older. The Pfizer vaccine is FDA approved for ages 12 and older, and both have EUA for ages 6 months and older. The Janssen vaccine has received emergency use authorization for 18 years and older, but mRNA vaccines are recommended over J&J due to the risk of serious adverse events such as thrombosis. Novavax is available as a 2 shot primary series.

What is known about the safety of these vaccines?
Both Pfizer/BioNTech and Moderna are currently licensed vaccines in the United States. mRNA vaccines have been studied for decades for cancer and other infectious diseases. 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 have not observed 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 continues to be 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.

Since April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mRNA 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. The risk does not increase with booster dosing. In most cases, patients who presented for medicalcare 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 thefirst 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 and thus far mRNA vaccines have not been observed to trigger increased rejection in transplant recipients.

There are fewer data on adenovirus-vector vaccines in SOT recipients as those patients 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 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 per1 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. To date, there have been no reports of rejection triggered by adenovirus vector vaccines.

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?

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 warrants 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 as the primary series for immunocompromised patients to complete their primary series, including SOT recipients (see third dose section below). For patients who have previously received the Janssen vaccine, a second dose with an mRNA vaccine is recommended at least 28 days after the first dose. There is no preference between the two mRNA vaccines for administration after the Janssen vaccine. Since multiple studies suggest waning of vaccine efficacy, we recommend booster doses as described above.

Why are three doses of mRNA vaccine the primary series for transplant recipients?

Three doses of mRNA vaccine are recommended as the primary series for immunosuppressed individuals, including SOT recipients.

Studies of third dose mRNA vaccines in adult SOT show that the third dose significantly increases humoral and cellular immune responses. 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. In addition, patients who have received >=3 doses of mRNA vaccine develop less severe disease if they contract breakthrough COVID-19. Safety of multiple vaccine doses, including rejection, needs to be further studied; however, it is reassuring that thousands of transplant recipients have now received three or more mRNA vaccine doses without a significant adverse effect signal. 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 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).

Should transplant patients receive a fourth dose (booster) of mRNA vaccine?

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 anti-spike 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. Patients who exhibited some response to prior vaccine doses were more likely to respond to the 4th dose of an mRNA-based vaccine than those who had not responded to prior vaccination; however, there were a limited number of non-responders who developed an antibody response to a 4th dose of vaccine [13/31 (41.9%) of non-responders became seropositive after the 4th dose of an mRNA vaccine].

At this time, the optimal number of doses of SARS-CoV-2 vaccine is unknown but current CDC guidelines (updated December 22, 2022) recommend bivalent booster dosing in transplant recipients at least 2 months following completion of the initial 3-dose series of mRNA vaccines or 2 months after their last booster dose. The original mRNA monovalent vaccines are no longer approved for booster doses.

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 but ideally all three doses 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.

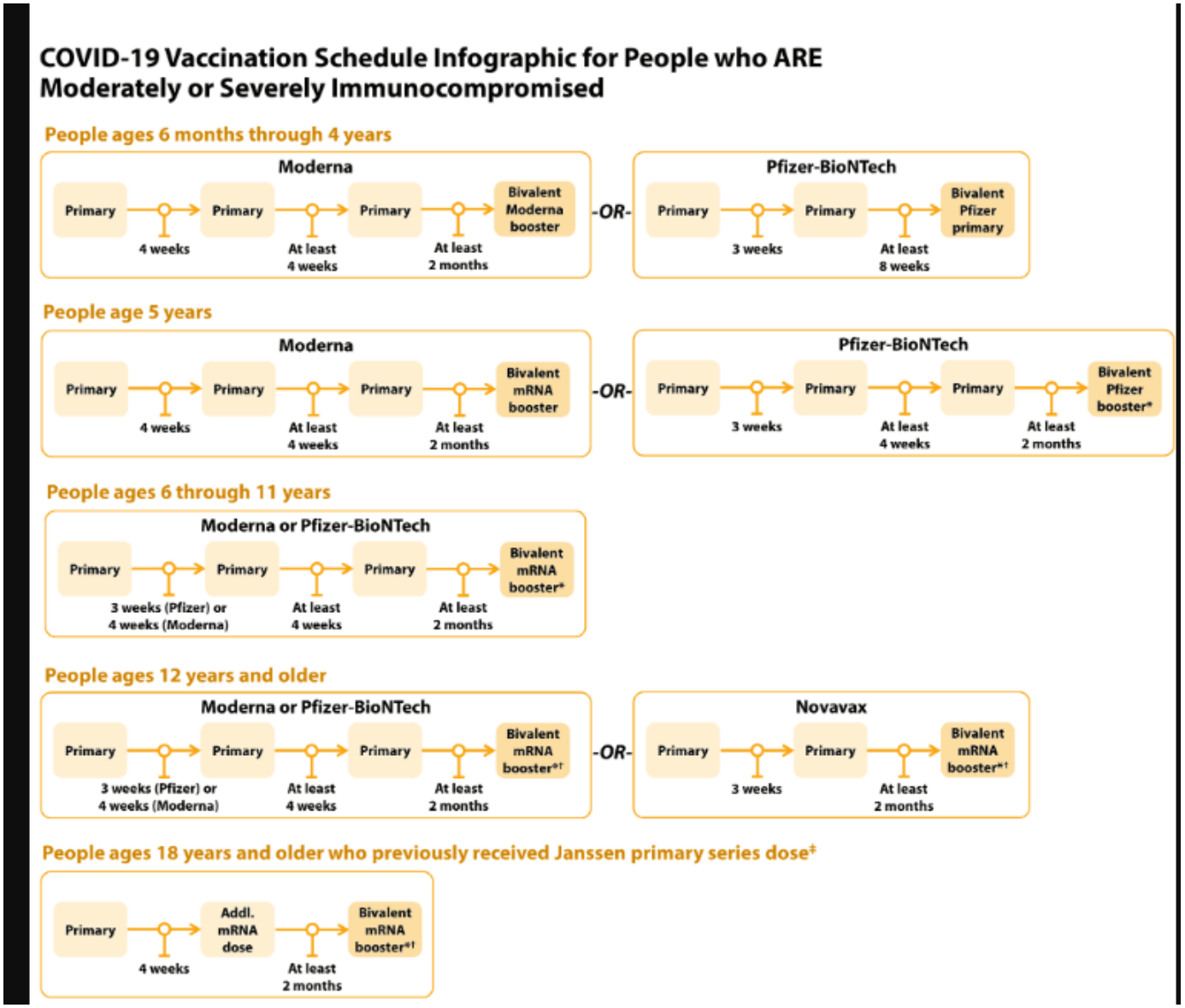
Can a transplant recipient still receive the vaccine even if they have had COVID- 19?
Yes. The current guidance is that everyone should receive the vaccine, irrespective of past COVID-19 or prior evidence of humoral immunity. Immunosuppressed patients can develop SARS-CoV-2 reinfection, suggesting lack of appropriate immune response especially against

variants or waning immunity after the first infection. In addition, emerging data highlight that after COVID-19, 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.

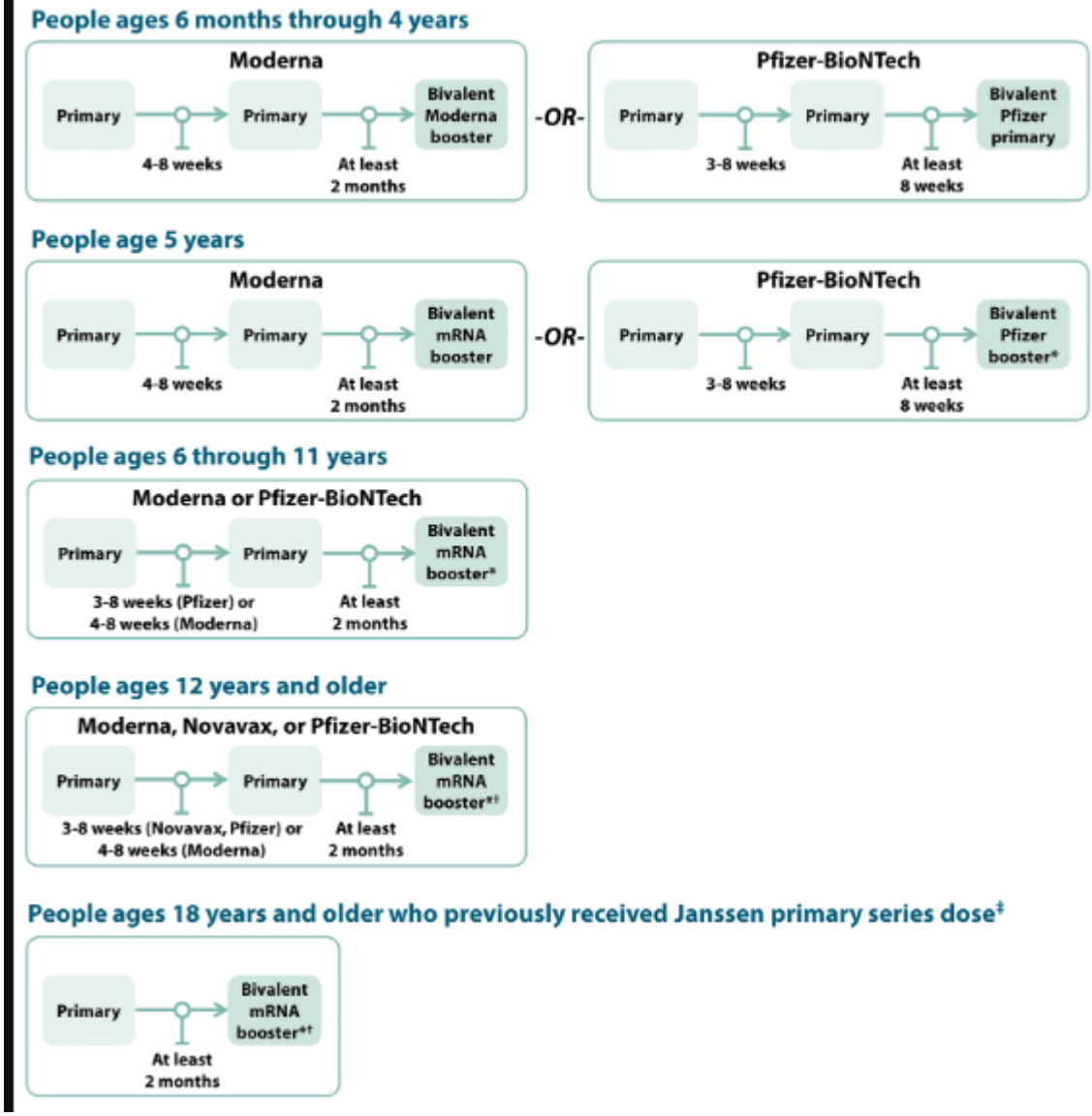
If a patient develops COVID-19 *after* the first dose of mRNA vaccination, but before the second dose, if possible, the second dose should be given once symptoms have resolved, and the patient is outside the infectious window.

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, vaccine unavailability, or interval transplantation, delays should be kept as short as possible. Infectious diseases consultation is advisable in these situations.

The optimal timing of the bivalent booster following COVID-19 infection is unknown but may be delayed up to 3 months after infection.



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



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 initially 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 including co-administration with influenza vaccine. If multiple vaccines are being givenconcurrently, they should be given in different sites.

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. Lastly, it may be difficult to interpret antibody levels in patients who already received either pre-exposure tixagevimab-cilgavimab (Evusheld) or monoclonal antibody therapy for prior COVID-19 episodes. 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 on 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 outside of a trial setting.

Can patients stop wearing a mask after vaccination?

No. After vaccination, patients should be counseled to continue to practice COVID-19safety measures including wearing masks around others, hand hygiene, and physical distancing in public places. It is likely that the efficacy and immunogenicity of vaccine intransplant recipients will be lower than shown in the vaccine clinical trials.

Although masking requirements have been removed for the general public in many locations, we recommend continued adherence to masking and physical distancing when gathering indoors with non-household members until more is known about the immune response and clinical effectiveness of the vaccine in the transplant population. Attention to these behavioral preventive strategies is particularly important when there is significant COVID-19 activity in a community and when immunosuppression levels are high such as early after transplantation and with rejection treatment.

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COVID-19 Updated CDC recommendations

- Stay Up to Date with COVID-19 Vaccines Including Boosters | CDC