COVID-19 Vaccine FAQ Sheet
(updated 12/24/2020)

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.

What kinds of vaccines are available or under development to prevent COVID-19?
There are currently several vaccine candidates 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
- **Washington Post Vaccine Tracker:** https://www.washingtonpost.com/graphics/2020/health/covid-vaccine-update-coronavirus/

The types of vaccines are as follows (December 24, 2020) [1]:

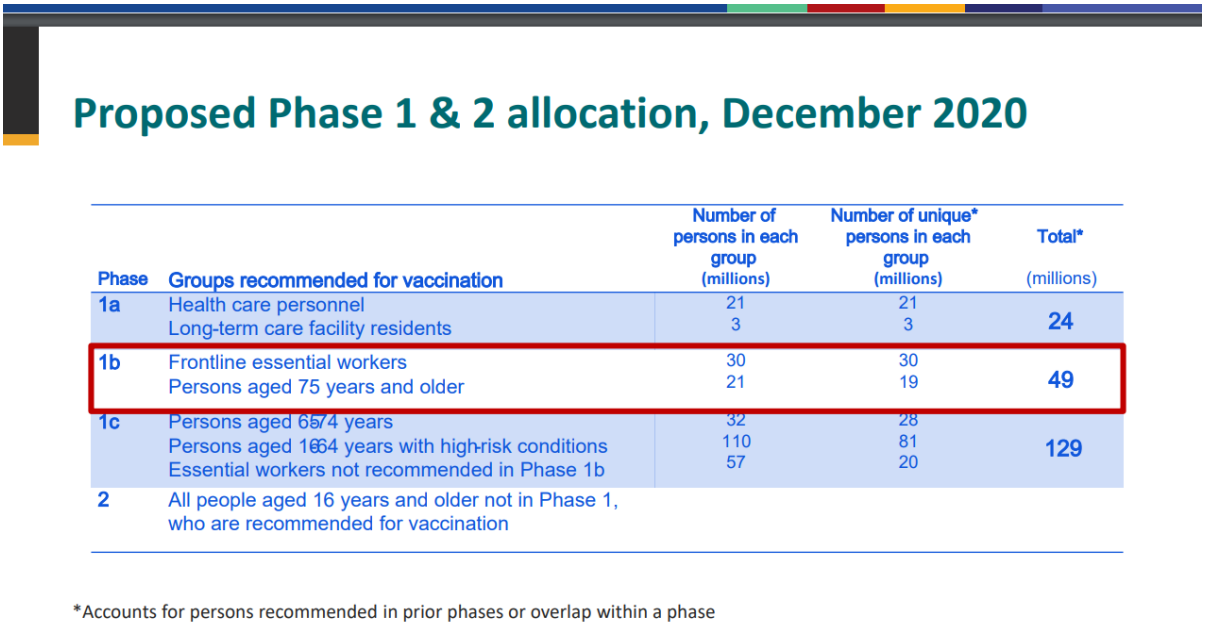
Table 1: Vaccines Under Development by Operation Warp Speed

Vaccine Type	Compound Name [Sponsor]	Clinical Trial Phase	Notes
mRNA	mRNA-1273 [Moderna]	Phase 3	U.S. EUA approved 12/18/2020 Approved in Canada
	BNT162b2 [Pfizer]	Phase 2/3	U.S. EUA approved 12/11/2020 Also approved in Canada and other countries
Replication-defective adenoviral vector	AZD1222 [AstraZeneca]	Phase 2/3	
	Ad26.COV2.S [Janssen]	Phase 3	
Recombinant-subunit-adjuvanted protein	NVX-CoV2373 [Novavax]	Phase 1	
	Recombinant SARS-CoV-2 Protein Antigen + AS03 Adjuvant [Sanofi Pasteur/GSK]	Phase 1/2	

Both of the mRNA (Moderna, Pfizer) have been approved by Emergency Use Authorization by the U.S. Food and Drug Administration (FDA) [2]. They have a 2-dose vaccination schedule and require cold storage.

When will these vaccines become available to transplant recipients?
Both Pfizer and Moderna vaccines are approved for Emergency Use Authorization (EUA) in the U.S. (Current: December 24, 2020).
As shown in the figure, the CDC Advisory Committee on Immunization Practices (ACIP) has proposed a phased distribution for the vaccine[3,4]:

Figure 1: Current Prioritization by Advisory Committee on Immunization Practices[5]



Most transplant recipients and candidates will fall under “people at high risk for severe COVID-19 due to underlying medical conditions.” ACIP notes that persons on immunosuppressive medications might be at increased risk for severe COVID-19 and that data are not available at this time to establish vaccine safety and efficacy in these individuals. They recommend that these people may receive COVID-19 vaccine along with counseling that there is unknown vaccine safety and efficacy profiles. In addition, there is a potential for reduced immune responses in those on immunosuppressive therapy.

States are allowed to define their own prioritization scheme which may affect how priority is determined; thus vaccine distribution may differ state by state. Although the

exact timing and availability of vaccines are unknown, it is anticipated that transplant recipients may be included in groups for earlier vaccination.

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/

What is known about the safety of these vaccines?
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. The safety profile of the mRNA SARS-CoV-2 vaccines administered to over 70,000 participants has not revealed any significant concerns at a median of 2 months follow up. 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 and that with other vaccines, 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 be as high as 1/100,000; this is currently being closely monitored in the US and other countries. Patients who have known anaphylaxis to other vaccines should be counseled for the potential of a similar response and may be monitored up to 30 minutes after getting vaccinated. Those with allergies not related to vaccines, such as drug or food allergies should still receive the vaccine. 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. Expert opinion is that based on their mechanism of action, they are unlikely to trigger rejection episodes, but more data will be needed in transplant recipients.

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 4 months [6].

The effectiveness of COVID-19 vaccines will need to be further studied in the solid organ transplant recipient. Solid organ transplant recipients may have generally lower antibody responses than those without transplants. Likewise, waning titers to other routine vaccines are well documented after transplantation. Lastly, patients vaccinated pre-transplant, may have reduced protection post-transplant, particularly if therapies that reduce B –cell function (e.g. rituximab) are utilized.

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 more than 2 weeks prior to transplantation, or starting at 1-6 months after transplantation[7]. If given prior to transplant, both doses should be completed before transplant. In certain situations, it may be appropriate to wait until 3 months after transplantation to vaccinate, such as with T or B cell ablative therapy (thymoglobulin or rituximab) at time of transplant.

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 reinfection [8], suggesting lack of appropriate immune response or waning immunity after the first infection. 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 CDC currently recommends that vaccination should be postponed for 90 days following a more remote COVID-19 infection or following receipt of convalescent plasma or monoclonal antibody. The ideal period for vaccination after infection is still being investigated, however.

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

Weighing the risks and benefits of getting vaccinated is important. While data are currently lacking specific to the vaccine in transplant recipients, it is reasonable to anticipate that vaccination will offer benefit. Likewise, transplant recipients appear to have clinically worse outcomes from SARS-CoV-2 infection compared to non-transplant recipients due to comorbidities or immunosuppression [9]. 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 in order to inform future recommendations.

References

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