The LAM Foundation COVID-19 Vaccine Statement

Revised on **3.3.2021** – Please read carefully.

Since our last vaccine update of December 2020, there have been some new developments in the field, chief among them being a rapidly expanding repertoire of vaccinations around the world. The following is an updated guide aimed at providing answers to some of the most commonly asked questions pertaining to COVID-19 vaccination. Although there are multiple different COVID-19 vaccines being used worldwide, this document is focused on the following four major vaccines: Pfizer/BioNTech, Moderna, Oxford/AstraZeneca, and Janssen (aka the Johnson and Johnson vaccine) (Table 1). There are several other vaccine candidates in advanced stages of development and testing. We are closely monitoring developments in this field and will update this page as new information becomes available.

What vaccines have been granted Emergency Use Authorization by the United States Food and Drug Administration?

Three vaccines have been granted Emergency Use Authorization (EUA) by the US Food and Drug Administration (FDA). The Pfizer/BioNTech vaccine was the first to receive EUA by the FDA on December 11, 2020, followed by the Moderna vaccine that received EUA on December 18, 2020, and most recently, the Janssen vaccine received EUA on February 27, 2021.

What vaccines have been granted approval in other parts of the world?

The European Medicines Agency (EMA, similar to the US FDA) has granted conditional marketing authorization (similar to EUA) for the Pfizer/BioNTech vaccine (also known as Comirnaty), the Moderna vaccine, and the Oxford/AstraZeneca vaccine for use throughout the European Union (EU). The same three vaccines have been approved for use in the United Kingdom (UK).

The Pfizer/BioNTech vaccine has also been approved for use in Australia, New Zealand, Canada, Japan, and several other countries across South America and the Middle East. In addition to US, EU and UK, the Moderna vaccine has been approved for use in Canada and Singapore, and the Oxford/AstraZeneca vaccine has been approved in multiple countries in South America and Asia, including Brazil and India.

How do these vaccines work?

The Pfizer/BioNTech and the Moderna vaccines use messenger RNA (mRNA) technology. The vaccines do not contain viruses or protein, instead they contain a small piece of viral genetic material that instruct our cells to produce a portion of the spike protein. The Janssen and the Oxford/AstraZeneca vaccines use a viral vector approach, where a portion of the SARS-CoV-2 gene that is responsible for making the spike protein is inserted into a genetically-engineered harmless human virus that enables the human body to temporarily make the spike protein. The end result from both of these approaches is a priming of our immune system to where it is better prepared to protect us when faced with the real virus.

What is the vaccine dosing schedule?
The Pfizer/BioNTech, Moderna, and Oxford/AstraZeneca vaccines require two doses to obtain maximal benefit, while the Janssen vaccine is a single shot. The Pfizer/BioNTech vaccine requires a second dose 21 days after the first dose, the Moderna vaccine requires a second dose 28 days after the first dose, and the Oxford/AstraZeneca vaccine requires a second dose 4-12 weeks after the first dose.

For vaccines that require two doses, can I skip the second dose of the vaccine?
Although even one dose of the vaccine confers some protection against COVID-19, both doses are needed to obtain maximal sustained protection. As such, it is imperative that patients take both doses of the vaccine.

Can I acquire COVID-19 from these vaccines?
Neither of the above-mentioned vaccines are live vaccines. As such, there is no risk of acquiring COVID-19 infection from vaccination.

What is the efficacy of these vaccines?
The Pfizer/BioNTech and the Moderna vaccines have a greater than 90% efficacy in providing protection against COVID-19. The Janssen vaccine is roughly 70% effective at preventing moderate/severe COVID-19, while the Oxford/AstraZeneca vaccine is approximately 60% effective in preventing COVID-19 infections.

Which vaccine should I take?
It is not possible to compare the efficacy of different vaccines without head-to-head clinical trials. Furthermore, the clinical trials for these vaccines occurred in different geographic regions and at different time points with varying incidence of COVID-19, which could explain the differences in the reported efficacy among these products. LAM patients should take the earliest available vaccine that is offered to them.

What are the side effects of these vaccines?
The most common side effects from the COVID-19 vaccines are local reactions such as injection site soreness, pain and swelling. Other common side effects include (in decreasing order of frequency) fatigue, headache, chills, joint pains and fever. These reactions are generally worse after the second dose than the first dose, and worse in younger subjects as opposed to people ≥55 years of age. The majority of these side effects are mild-to-moderate in nature and self-limited with a resolution time of 1-2 days. Over-the-counter medications such as Tylenol (acetaminophen) and NSAIDs (e.g., ibuprofen) may be needed for symptom relief in some cases and are OK to use. Patients with history of serious allergic reactions should discuss the safety of vaccination with their healthcare providers. It is possible that with more widespread vaccination, some other unexpected side effects or serious adverse reactions to the COVID-19 vaccines may occur, however, we expect these to be infrequent. Overall, the COVID-19 vaccines appear to be both safe and effective for the vast majority of recipients.

When can I expect to receive vaccination?
The COVID-19 vaccination is being rolled out in a staggered fashion with the initial supplies being provided to healthcare personnel and people residing in long-term care facilities. The next group of people being prioritized for vaccination includes teachers, first responders, other essential workers outside of health care, people ≥65 years of age and people at risk of serious complications from COVID-19 such as people with underlying health conditions. LAM patients, by virtue of their lung disease, will fall in this category. While the exact timelines for vaccine availability for this group are constantly evolving depending upon the available supplies and authorization of more candidate vaccines, it is likely to be available for most LAM patients by late spring/early summer 2021.

Can I take the COVID-19 vaccination if I am on mTOR inhibitors (sirolimus/everolimus)?
The safety and efficacy of COVID-19 vaccination has not been well studied in patients taking immunosuppressive medications such as mTOR inhibitors. Although there is no direct evidence, there is no reason to think that the side effect profile from vaccination will be different in patients taking mTOR inhibitors versus patients not on these drugs. The major concern with vaccination in patients on mTOR inhibitors pertains to their efficacy, i.e., will the mTOR inhibitors impair the immune response to the vaccination leading to suboptimal protection? While the exact answer to this question is not known, it is likely that patients on mTOR inhibitors will mount at least some response to vaccination and derive at least partial immunity from COVID-19 as opposed to the prospect of no protection without vaccination. As such, we recommend that LAM patients should take the COVID-19 vaccine regardless of their use of mTOR inhibitors.

Should I get vaccinated if I have previously had COVID-19?
Previous infection with COVID-19 provides you some natural immunity against re-infection. However, the efficacy and duration of natural immunity to prevent COVID-19 reinfection is not well understood. At the present time, we suggest getting vaccinated for COVID-19 even if you have previously been infected, similar to the recommendation for Shingles.

Will these vaccines provide protection against new viral variants/strains?
It is common for viruses to mutate and evolve over time. We do not know if the currently available vaccines will provide the same degree of protection against some of the newer variants/strains of SARS-CoV-2. However, the vaccines are likely to confer at least some protection against the variants. As such, the best course of action is to get vaccinated with the earliest vaccine available to you.

Do I need to continue to social distance and wear mask after I have received the COVID-19 vaccine?
Yes. While the availability of COVID-19 vaccination represents a landmark moment in our quest to quell the pandemic, the staggered roll out of the vaccine and the time it will take to mount an effective response to vaccination (~2 weeks following the second dose) implies that we need to continue to take all the necessary precautions such as hand hygiene, social distancing, and mask use in order to maximize our chances of staying safe and controlling community spread.

The LAM Foundation's recommendation regarding vaccination
Considering the severity of illness that patients with COVID-19 may experience, the increased risk of disease-related complications in patients with underlying lung disease, and the overall favorable safety and efficacy profile of the vaccines, we strongly recommend LAM patients to get vaccinated against COVID-19 at the earliest opportunity available to them.

Additional Resources
Centers for Disease Control and Prevention (CDC): https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

Table 1: Key features of the four major COVID-19 vaccines

	Type of vaccine	Dosing schedule	Efficacy	Major side effects	Approved for age	Approved in
Pfizer/ BioNTech	mRNA	Two doses, 21 days apart	>90% effective at preventing symptomatic COVID-19	Injection site pain, fatigue, headache, chills, joint pains and fever	16 and above	USA, EU, UK, Israel, Japan, Australia, Canada, New Zealand and multiple others
Moderna	mRNA	Two doses, 28 days apart	>90% effective at preventing symptomatic COVID-19	Injection site pain, fatigue, headache, chills, joint pains and fever	18 and above	USA, EU, UK, Canada, Israel, Singapore and some others
Janssen	Viral vector	Single dose	~70% effective at preventing moderate/severe COVID-19	Injection site pain, fatigue, headache, chills, joint pains and fever	18 and above	USA, Bahrain, Saint Vincent and the Grenadines
Oxford/ AstraZeneca	Viral vector	Two doses, 4-12 weeks apart	~60% effective at preventing symptomatic COVID-19	Injection site pain, fatigue, headache, chills, joint pains and fever	18 and above	EU, UK, Brazil, India, Pakistan, Mexico, South Africa, and multiple others