

Information on COVID-19 and Friedreich's Ataxia

There are now several vaccines for COVID-19 that have demonstrated safety and efficacy in human clinical trials. While FARA does not make medical recommendations and does not endorse any particular vaccine, as a resource for the community, we have researched COVID vaccines and reached out to FA experts to create this information document on COVID-19 vaccines.

There are no special concerns with COVID-19 vaccines for persons with FA. However, those with advanced disease may be especially vulnerable to COVID-19 complications; thus, while weighing the current safety and efficacy data, the risk/benefit balance is in favor of vaccination.

What is Immunity? Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming seriously ill or infected. Immunity can be acquired through previous infection with a disease or through **immunization**, which is the process by which a person becomes protected against a disease through vaccination.

What is a Vaccine? A product that stimulates a person's immune system to produce antibodies to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections but can also be administered by mouth or sprayed into the nose.

What COVID-19 vaccines are available? In the US, COVID-19 vaccines are being used under an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). The FDA has issued EUAs for the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to be distributed in the U.S. The Pfizer and Moderna vaccines are approved for those 12 years of age and older. A third vaccine developed by Janssen Pharmaceuticals, a division of Johnson and Johnson, was approved in late February 2021 in the U.S. for use in individuals 18 years of age and older. This vaccine requires only a single injection and can be stored in a refrigerator for months.

The European Medicines Agency (EMA) has granted a conditional marketing authorization for the COVID-19 vaccines from Pfizer-BioNTech, Moderna, AstraZeneca and Janssen. The Medicines and Healthcare products Regulatory Agency (MHRA) in the UK has also approved use of the Pfizer-BioNTech, Moderna and AstraZeneca vaccines. In the UK and in many places in Europe, vaccines are approved for those 18 years of age and older. However, in some European countries, those 12 years of age and over may receive COVID vaccines.

Who is eligible to receive vaccines?

In the US, vaccines are available at no cost to anyone age of 12 and older. In the UK, vaccines are available at no cost to anyone age 18 and older. In the EU, the Pfizer vaccine is available for those age 16 and older, while the others are available to those age 18 and older.

Guidelines for each vaccine list underlying conditions where there was sufficient evidence from the COVID trials to draw conclusions on risk. The CDC recommends that women younger than 50 years old be aware of the rare risk of blood clots with low platelets after vaccination with the

Janssen vaccine. There are other COVID-19 vaccines available for which this risk has not been seen.

There was not enough evidence on rare diseases for those conditions to be listed in the risk assessments. However, individuals with FA should consult their healthcare provider based on your specific underlying conditions (i.e., respiratory, heart, diabetes, etc.)

What are the differences between the types of vaccines?

mRNA vaccines - A new technology was used by both the Pfizer and Moderna to create the first vaccines that use messenger RNA, or mRNA. The mRNA directs cells to produce COVID virus protein and the immune system then responds by making protective antibodies to the COVID-19 virus. Note: The mRNA vaccines don't use any type of virus for delivery, the mRNA is inside lipid nanoparticles, very small particles of fats, to protect it until it is taken up into the cell. Both of these vaccines require two doses to be effective. They also need to be stored cold, but Pfizer's vaccine has to be stored at ultra-cold temperatures, which has made it a bit harder to a ship and distribute. Because these vaccines are based on a newer technology, there are less long-term data on safety and efficacy in many different age groups. These data are being generated now as larger and larger numbers of people are being vaccinated.

Virus Vaccines - Viruses are naturally good at getting genetic material into human cells and therefore can be used to carry the genetic code ("the gene") for a COVID-19 protein into the body. Once there, the gene allows the body to develop immunity to COVID-19. Furthermore, although these viruses are good at carrying genetic material into cells, they are highly modified and unable to make people sick.

The virus delivery system being used for COVID is called adenovirus (AdV). AdV is a completely different virus than Adeno Associated Viruses (AAV) which are being used for gene therapy. Taking a vaccination using AdV will not cause your immune system to make antibodies against AAV.

The AstraZeneca/Oxford (AZ) vaccine approved in the UK contains a modified adenovirus (AdV). The Janssen vaccine also uses a human adenovirus. Each uses a modified virus to deliver the COVID protein. The Janssen vaccine does not require storage at the very cold temperatures which may make it easier to transport and store.

Novavax has produced a vaccine that carries a COVID protein on nanoparticles (nano is one billionth of a unit) given together with a proprietary adjuvant, a substance that hypes up the immune response. This vaccine has not yet been approved.

Are there any special considerations for FAers regarding COVID vaccines? Individuals should discuss COVID vaccines with their health care provider.

Currently, there is no reason to believe that any adverse effects of any of these vaccines is different in FA patients than in the general population. As these vaccines have now been administered to an ever-growing population, we now have a better understanding of the side

effects. Note that the experts we consulted suggested that, once the vaccines are available, the risk/benefit ratio in FA patients are weighted in favor of vaccination given the higher vulnerability of FA patients to COVID-19 complications.

As discussed above, some COVID vaccines are using a virus to help deliver the vaccination material. The viruses being used are modified versions of AdenoVirus (AdV). An antibody or immune response to adenovirus used in these vaccines does not generate a similar immune response to other viruses, including those currently being used to develop FA gene therapy. There is currently no reason to expect that a patient's eligibility for an FA gene therapy trial or the patient's safety in such a trial would be impacted by having received COVID-19 vaccines that use adenovirus.

Most of the gene therapy approaches currently under development for the treatment of FA are using Adeno-Associated Viruses (AAVs). Although the name may be confusing, these are completely different viruses than those used in COVID vaccine. AAVs were discovered because they were found with adenovirus, but they do not have the same genetic or protein makeup. Therefore, an antibody response to adenovirus used in several of the COVID vaccines does not generate a similar immune response to AAV. Just to reiterate, none of the vaccines that have been approved (Pfizer, Moderna, AstraZeneca, Janssen) or are close to approval (Novavax) raise concerns with development of antibodies to viruses currently used in FA gene therapy.

Anyone considering receiving a COVID vaccination should discuss the matter with his or her physician. FARA does not endorse or recommend any particular vaccination.

Please note: This is an evolving situation. The comments provided are based on information available at the time of posting- August 2, 2021.

The following list of COVID-related resources is included here for your reference:

- [New England Journal of Medicine COVID-19 FAQ Page](#)
- <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>
- <https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine/>
- <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines>

References:

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<https://www.nature.com/articles/s41401-020-0485-4>
<https://cen.acs.org/pharmaceuticals/vaccines/Adenoviral-vectors-new-COVID-19/98/i19>
<https://www.youtube.com/watch?v=nXn4KBJ4oD0>
<https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19#vaccines-and-vaccine-safety>



<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>

<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-latest-updates>