COVID-19 and people with neuromuscular disorders:

World Muscle Society advice - Vaccines

(updated Feb. 28th 2021)

The WMS has provided advice for people with neuromuscular disorders, and their healthcare providers since the start of the COVID-19 pandemic. This is a document aiming to answer questions regarding the newly developed vaccines against Coronavirus SARS-CoV2 asked by people with neuromuscular disorders. This is a rapidly developing field, and the WMS will keep this advice in regular review.

Background:

Control of the SARS-CoV2 pandemic hinges on a worldwide program of vaccination designed to reduce the likelihood of contracting COVID-19.

A large number of vaccines have been developed since the start of the pandemic 12 months ago. According to the New York Times Coronavirus Vaccine Tracker, 71 vaccines are currently in clinical trials on humans, and to this date 20 have reached the final stages of testing (Phase 3 trials). 12 vaccines have been approved for full or limited use in different countries. The current leading vaccines offer different modes of action:

- mRNA-based vaccines (Moderna and Pfizer/BioNTech) promoting an immune response against viral spike proteins
- Adenovirus-based vaccines (CanSino, Gamaleya, Johnson&Johnson, Oxford-AstraZeneca) raise the immune response against coronavirus via genetically modified adenoviruses containing the DNA instructions for spike proteins. <u>Note:</u> None of these vaccines use adeno-associated viruses (AAV) as employed in some genetic therapies.
- Protein-based vaccines (Vector, Novavax) based on triggered immune response against various proteins contained in the Coronavirus
- Inactivated virus-based vaccines (Sinopharm-Beijing, Sinopharm-Wuhan, Sinovac, Bharat Biotech) based on the response to inactivated Coronavirus

For exact information on which of these vaccines has approval in a specific country, we refer to national information. Approved vaccines have been tested in healthy study subjects without a serious underlying medical condition over 16 years of age, and in these have demonstrated high effectiveness in preventing SARS-CoV2 infection.

Vaccination programs are currently underway in many countries, and in some countries have attained and advanced stage. Side-effects have so far been minor, consisting of local pain, fever, chills and muscle aching over days. So far, no clear evidence has emerged that favourises one vaccine over another, where vaccination programs have been analysed. The potential impact of "variants of concern" on effectiveness of vaccines remains to be seen.

COVID-19 vaccination and Neuromuscular Disorders

The following questions are the ones most often raised by people with neuromuscular disease and by their carers and physicians:

1. Am I eligible to be vaccinated when one or more vaccines are approved?

Distribution of vaccines in most countries follows a vaccination program in which vaccination is offered first to vulnerable groups. These are in essence the elderly and those vulnerable through severe underlying health conditions, and, potentially, their carers, but definitions of vulnerable groups vary from one country to another. National health authority or health department websites may provide detailed information and guidelines on distribution processes, but may not specifically mention neuromuscular disorders. In addition, depending on the vaccines' approval, only certain age groups may be eligible.

2. Am I in a priority group for vaccination?

The WMS position and advice document "COVID-19 and people with neuromuscular disorders", (paragraph 1), provides criteria that define a "vulnerable" group amongst people with neuromuscular disorders, who should be observing strict measures to avoid COVID-19 infection. A further "highly vulnerable" group may be identified (see WMS position and advice document)), and in these people vaccination may be a priority, but national health authority guidelines and definitions vary from one country to another. We advise all people with neuromuscular disorders to stay in contact with their healthcare providers and clarify their status, and the vaccination eligibility of their carers, once a vaccination program is available in their country.

3. Can I be vaccinated once a vaccine is approved or am I at risk of developing COVID-19 or other severe side effects through the vaccination?

There is no risk of developing COVID-19 from the vaccines currently approved or in final stages of development. We are not aware of any live vaccines under development. Side effects in the study subjects have been mild and transient, and are outweighed by the benefits; this has held true in vaccination programs so far. There is no indication that neuromuscular patients should be different in this respect.

For certain vaccines, with regard to specific neuromuscular treatments, particularly in clinical trials, there may be restrictions on when vaccination can take place, and uncertainties around interaction between the vaccination and the neuromuscular treatment. People with neuromuscular disorders on such treatments should contact their neuromuscular specialist or neuromuscular centre, who can contact the drug company providing treatment.

4. Will my neuromuscular condition affect the way the vaccine works?

The mechanisms of action of the vaccines approved so far does not suggest that neuromuscular disorders give an increased risk of side-effects. Neither should neuromuscular disorders that do not involve the immune system affect the way the vaccine works. However, the studies were carried out in healthy adults; studies involving children aged 12 and above are underway. None had neuromuscular conditions, as far as we are aware, and therefore, there is no evidence regarding specific effects on people with neuromuscular disorders, or effects of the neuromuscular condition on the vaccination.

5. I take medication that affects the immune system (immunosuppressant drugs). Can I be vaccinated?

Yes. There is no risk of infection through the vaccinations that have been approved or are in development so far. However, we do not yet know if immunomodulation/immunosuppression

diminishes the effectiveness of the vaccination, so recommendations have been produced by professional and government agencies advising on delays between such treatments and vaccination. After vaccination, precautions (wearing a mask, social distancing) will still be necessary.

6. What are the important unknowns at present?

Where the immune system is involved, either through the neuromuscular disease itself or through its treatment, there is uncertainty whether the vaccine will be as effective as in the studies. This does not mean that the vaccine may be no good, but it does mean that caution and measures to avoid infection such as wearing masks and social distancing are still important. People undergoing such treatments should seek advice before setting a date for vaccination; likewise, healthcare professionals planning to start such treatments should ideally coordinate administration with the date of COVID-19 vaccination.

Currently, there is not enough evidence to advise whether one particular vaccine is preferable to the other. There is no evidence theoretical preferences may justify delaying vaccination using any of the currently approved vaccines.

Whether interactions might exist between any genetic neuromuscular therapies and genetic vaccines employing viral vectors or mRNA mechanisms remains a subject of close scrutiny. So far, concerns of cross-reactions remain unsubstantiated.

There is no evidence that muscle atrophy impacts on the effectiveness of vaccines applied by intramuscular injection, although this has not been specifically investigated. Muscle cells do not play a significant role in the immune response, according to current knowledge.

The full range of side effects, including the rarer ones, will only be known in the further course of the vaccination program. So far, however, there has been no indication of any evidence to support a position rejecting vaccination for any group of the population, including people with neuromuscular disorders.

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Web-based resources:

https://www.worldmusclesociety.org/news/view/150

https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-

vaccines?adgroupsurvey={adgroupsurvey}&gclid=Cj0KCQiAifz-

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https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

https://www.gov.uk/government/collections/covid-19-vaccination-programme

https://myasthenia.org/MG-Community/COVID-19-Resource-Center

https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

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 $https://www.sarepta.com/sites/sarepta-corporate/files/2020-12/Community\%20Bulletin_COVID19.pdf$

https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu

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https://www.rheumatology.org.uk/practice-quality/covid-19-guidance