Clinical Guidance on COVID- 19 Vaccines for People with Autoimmune Neuromuscular Disorders Receiving Immunosuppressive/ Immunomodulating Therapy

This guidance is intended for health-care providers and is based on known evidence as of January 20, 2022.

Background and Context

- Some patients with significant autoimmune/inflammatory diseases of the neurologic system (including the brain, spinal cord, motor nerves, neuromuscular junction and muscles – referred to broadly as neuromuscular) require treatment with immunotherapies. [1]
- These diseases (including multiple sclerosis, neuromyelitis optica, chronic inflammatory demyelinating polyneuropathy, myasthenia gravis, and inflammatory myopathy) result from immune tolerance dysfunction such that the patient's immune system attacks their own tissues.
- Patients with neuromuscular conditions who require treatment with immunosuppressive medications are at increased risk of hospitalization and mortality from COVID-19.[2]

This guidance is based on a review of the vaccines approved by Health Canada for the prevention of COVID-19 disease caused by the SARS-CoV-2 virus:

- **mRNA vaccines:** tozinameran (COMIRNATY, Pfizer-BioNTech),[3] elasomeran (SPIKEVAX, Moderna)[4]
- **Replication-defective adenoviral vector vaccine:** ChADOx1-S (VAXZEVRIA, AstraZeneca),[5] Ad26.COV2.S (Janssen COVID-19 Vaccine, Janssen)[6]

Currently, anyone in British Columbia who is 5 years and older is eligible for COVID-19 immunization. Health Canada has authorized COMIRNATY (Pfizer-BioNTech) vaccine made for children aged 5 to 11. NACI has released their statement for this age group[7]. It is anticipated that SPIKEVAX (Moderna) will be approved shortly for children aged 6-11. Both of the mRNA vaccines, COMIRNATY (Pfizer-BioNTech) and SPIKEVAX (Moderna), are currently authorized for youth aged 12-17.

People who receive the mRNA vaccine (COMIRNATY [Pfizer-BioNTech] or SPIKEVAX [Moderna]) for their first dose, will usually be offered the same vaccine for their second dose. However, they may be offered the other mRNA vaccine as the vaccines are very similar. No data currently exist on the interchangeability of the COVID-19 mRNA vaccines. However, there is no reason to believe that mRNA vaccine series completion with a different authorized mRNA vaccine product

will result in any additional safety issues or deficiency in protection.[8] It is not recommended to receive VAXZEVRIA (AstraZeneca) vaccine for the second dose.[9]

Third doses:

To date, people who are moderately to severely immunocompromised have been observed to have generally lower antibody responses and lower vaccine effectiveness from COVID-19 vaccines compared to the general population. The National Advisory Committee on Immunization[10] has reviewed this evidence and recent studies that demonstrate that some people who are immunocompromised develop an improved antibody response after a third dose of vaccine.

As such, as of September 15, 2021, people (12 years and older) who are severely immunocompromised in B.C. are eligible to receive a third dose of an mRNA COVID-19 vaccine.

A minimum interval of 28 days between dose 2 and dose 3 is recommended for those eligible for a third dose. As per the BC Immunization Manual, SPIKEVAX (Moderna) is preferred for the third dose. However, if SPIKEVAX (Moderna) is unavailable (or if the individual prefers), COMIRNATY (Pfizer-BioNtech) vaccine may be provided.[11]

Specifics on current eligibility for a third dose may be reviewed here: https://www2.gov.bc.ca/gov/content/covid-19/vaccine/register#immunocompromised

Booster doses:

While data on a fourth dose of a COVID-19 vaccine after the recommended three-dose primary series in moderately to severely immunocompromised individuals are currently limited, many of these individuals are at a higher risk of severe outcomes of COVID-19 and also at increased risk of decreasing protection over time since vaccination. Therefore, the National Advisory Committee on Immunization recommends that immunocompromised individuals receive a booster dose six months from their last dose.[12]

Other vaccines:

The VAXZEVRIA (AstraZeneca) vaccine program has been stopped in B.C. for first doses, unless there is a contraindication to the mRNA vaccines, or as advised by the Medical Health Officer or an allergist,[8] due to infrequent (1:50,000) but serious Vaccine-Induced Thrombotic Thrombocytopenia (VITT) blood clotting events after the first dose.[13] The risk of VITT is more than six times lower for the second dose (1:600,000). People who had the VAXZEVRIA (AstraZeneca) vaccine for their first dose have the option of receiving VAXZEVRIA (AstraZeneca) for their second dose, or, receiving an mRNA vaccine as their second dose. Receiving a mixed vaccine series (VAXZEVRIA (AstraZeneca) for first dose and an mRNA vaccine for the second dose) is permitted based on small studies that suggest that this is likely safe and likely as effective and may be even more effective, but not enough is known to make firm conclusions and data collection is ongoing. There may also be heightened side effects experienced with a mixed vaccine series.

The BCCDC has prepared two information sheets to help navigate that choice:

- For health care professionals: www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/Doctor_letter_Recommendations_AZ_COVISHIELD.pdf)
- **For patients**: Why your 2nd dose is important (www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/AstraZeneca_2ndDose.pdf)

The Janssen COVID-19 Vaccine (Janssen)[6] one-dose viral vector vaccine is now available in limited supply in B.C. However, mRNA vaccines are preferred over viral vector vaccines due to better effectiveness and immunogenicity of mRNA vaccines and the possible adverse effects specifically associated with viral vector vaccines (e.g., Thrombosis and Thrombocytopenia Syndrome [TTS]). The Food and Drug Administration (FDA) have issued a for the Janssen COVID-19 vaccine about the increased risk of developing Guillain-Barré syndrome (GBS) in the 42 days after vaccination.[14]

As well, another emerging vaccine candidate developed by Novavax may also be approved by Health Canada in the coming months. This vaccine works differently than the approved vaccines in Canada. This guidance will be updated as more information becomes available.

People were generally excluded from COVID-19 vaccine trials if they were on immunosuppressant treatment. Therefore, there are still uncertainties as to whether COVID-19 vaccine is efficacious and safe in patients with autoimmune neuromuscular disorders on therapy, as well as to the timing of immunization in relation to their treatments. [1,15]

Is COVID-19 immunization recommended for patients with neuromuscular disorders receiving immunosuppressive/immunomodulating therapy?

COVID-19 immunization is not contraindicated and should be encouraged for patients with neuromuscular disorders receiving immunosuppressive/immunomodulating therapy, including those who have had COVID-19 infection. This recommendation is based on the following review:

- The National Advisory Committee on Immunization recommends that immunosuppressed individuals may be offered the vaccine if the benefits of vaccine outweigh the potential risks.[8]
- Based on the GBS/CIDP Foundation Global Medical Advisory Board's statement on November 11, 2021: "We recommend vaccination for all GBS, CIDP, and MMN patients as soon as possible as per their provincial authorities… If a patient has developed their disease within 6 weeks after receiving a COVID-19 vaccination, the patient should make an informed consent after discussing the risks versus benefits with their healthcare professional about receiving a second dose of vaccine that is of a different type, preferentially mRNA, as per the NACI guidance."[16]
- Based on the statement from the National Multiple Sclerosis (MS) Advisory Board/ The Canadian Network of Multiple Sclerosis Clinics Statement on February 10, 2021: "Most people with relapsing and progressive forms of MS should be vaccinated. The risks of COVID-19 disease outweigh any potential risks from the vaccine…The vaccines are not likely to trigger an MS relapse or to worsen your chronic MS symptoms. The risk of getting COVID-19 far outweighs any risk of having an MS relapse from the vaccine." [17]

While data specific to the safety and efficacy of the Pfizer and Moderna COVID-19 vaccines in people who take immunosuppressant or immunomodulating therapies is currently limited, the authors of this guidance agree that the benefits of vaccine-induced immunity against COVID-19 for this population outweigh any theoretical risks of immunization.

The risks of COVID-19 infection to neuromuscular patients treated with immunotherapy include the following factors:

- During the COVID-19 pandemic, patients with neuromuscular disorders may be at greater risk of worse outcomes than otherwise healthy people because of an immunocompromised state related to immunotherapy. Immunosuppressive therapies can limit immune competence.[15,17] This can affect the risk of infections[22]; some therapies are associated with an increased risk from particular types of pathogens.
    - Patients with autoimmune neuromuscular disorders (such as myasthenia gravis) who are infected with SARS-CoV-2 are frequently admitted to hospitals, have disease exacerbations and a higher mortality than the general population with COVID-19. [20]
    - Patients must continue with immunotherapy to avoid increasing symptoms including weakness of respiratory and bulbar muscles; the risk of relapse may result in permanent disability.
- Infections are a well-recognised trigger of symptom exacerbation in autoimmune conditions such as myasthenia gravis and multiple sclerosis. [21]
- Individual considerations regarding the appropriateness of the vaccine in patients with neuromuscular disease include, but are not limited to:
    - Level of activity of virus in the patient's local community
    - Individual risk of severe disease or death in patient contracting SARS-CoV-2 due to their neuromuscular condition and independent of their neuromuscular diagnosis (e.g., age and other comorbidities)
    - Whether family, care providers, and close contacts of the patient can receive immunization if they have no contraindication.

Is COVID-19 immunization efficacious and safe for patients with neuromuscular disorders receiving immunosuppressive/immunomodulating therapy?

- GBS cases following COVID-19 vaccination have been identified in Canada and internationally, but rarely.[22] There does not appear to be an increase from baseline incidence with mRNA vaccines.[23, 24, 25]
- As per NACI, safety data in immunocompromised individuals, including those receiving immunosuppressive therapy, were available from observational studies in people who were taking immunosuppressive therapies.[8] The frequency and severity of adverse events following vaccination with an mRNA COVID-19 vaccine were comparable to that of non-immunocompromised individuals in these studies and what was reported in clinical trials. Safety data in these populations following vaccination with a viral vector vaccine is not available.
- There is one study that suggests that a third dose of COVID-19 vaccine in immunocompromised patients can increase antibody levels.[23] Small studies on third doses of the mRNA COVID-19 vaccines have shown that immunogenicity (immunity measured in the blood) may increase with a third dose. The safety of a third dose is unknown at this time, but in these small studies reactions were found to be similar to that of prior doses. The impact of additional doses on the worsening of underlying disease or on rare adverse events, including the risk of myocarditis and/or pericarditis, is unknown at this time.[10]

- Informed consent should include discussion about the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines, as well as a discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in these populations.[7] The recommendations in this clinical guidance are based on these small observational studies, extrapolation of data from other viral infections, immunology of immunizations and from expert opinion.
- There is limited information on the effectiveness of vaccines in individuals who are on immunosuppressive medications.[9] However, even reduced efficacy may confer benefits against COVID-19 infections. [1]
- As immune response to COVID-19 immunization is unknown for those taking immunosuppressant or immunomodulating therapy, patients with neuroimmunological disease who receive the COVID-19 vaccine should continue to closely follow public health recommendations including social distancing, regular hand washing and/or disinfection.
- An increased risk of developing autoimmune or inflammatory disorders was not observed in clinical trial participants who received an mRNA COVID-19 immunization compared to placebo. Rate of recurrent GBS is infrequent after mRNA COVID-19 vaccine.[24, 25]

Are there any specific contraindications or exceptions for patients with neuromuscular disorders receiving immunosuppressive/immunomodulating therapy?

Allergy to vaccine components

Individuals should not receive the vaccines if they have a history of severe allergic reaction to a previous dose of the respective vaccine or any component of the vaccines.[6] the vaccine monographs found at:

- tozinameran (COMIRNATY, Pfizer BioNTech): https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf
- elasomeran (SPIKEVAX, Moderna): https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf
- ChADOx1-S (VAXZEVRIA, AstraZeneca): https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf
- Ad26.COV2.S (Janssen COVID-19 Vaccine, Janssen): https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf

For individuals with a history of anaphylactic reaction to a previous dose of an mRNA COVID-19 vaccine, re-vaccination (i.e., administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Prior to revaccination, consultation with an allergist or another appropriate physician (e.g., Medical Health Officer) is advised. If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation of at least 30 minutes after re-vaccination.

Health Canada continues to monitor any adverse events following immunization through their post-authorization surveillance process.

Guillain Barre Syndrome (GBS)

Individuals with past history of Guillain Barre Syndrome (GBS) unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine. When mRNA COVID-19 vaccines are contraindicated or inaccessible, individuals may receive a viral vector COVID-19 vaccine after weighing the risks and benefits in consultation with their health care provider.

Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive another dose of an mRNA COVID-19 vaccine, after consultation with their health care provider (i.e., if the benefits outweigh the risk and informed consent is provided).

- No instances of GBS were seen during clinical trials of the Pfizer and Moderna mRNA vaccines [3,4], and neither the U.S. Centers for Disease Control and Prevention (CDC) nor the Food and Drug Administration (FDA) recommends against the vaccine due to GBS. [14]
- The incidence of GBS in the United Kingdom decreased by 50% during the first wave of COVID-19, likely due to COVID-19 control measures put in place which reduced the incidence of viral infection generally, compared to the same period during the four years prior. [28]
- An analysis of the genetic and protein structure of SARS-CoV-2 showed that it contains no additional immunogenic material known or proven to drive an immune response that would trigger GBS. [29]

Bell's palsy

Cases of Bell's palsy were reported in participants in the mRNA COVID-19 vaccine clinical trials. However, there was not an excess of Bell's palsy in the COVID-19 vaccine arm and the FDA does not consider these to be above the rate expected in the general population. They have not concluded these cases were caused by immunization. Therefore, the U.S. CDC recommends that individuals who have previously had Bell's Palsy may receive an mRNA COVID-19 vaccine. [26]

Multiple Sclerosis

Systematic reviews have not shown that vaccines cause or worsen multiple sclerosis. [30]

Other vaccinations

COVID-19 vaccines can be given concomitantly with, or any time before or after any other live or inactivated vaccine. This is a change from the previous recommendation for a 14-day interval before or after receipt of a COVID-19 vaccine. The original advice against co-administration was based on a cautionary approach, as specific studies of co-administration with other vaccines have not been performed. However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized by Health Canada. Extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone. The basis for this change in recommendation is

referenced to general administrative guidance for vaccines and guidance from the US Advisory Committee on Immunization Practice (ACIP).

Are there specific recommendations or considerations for safe and/or most effective vaccine administration?

Aligned with the Canadian Rheumatology Association's guidelines, [31] our recommendations are:

1) For patients on the following medications, there is **no need** to adjust or delay the medication:
    - **Hydroxychloroquine,**
    - **Prednisone less than 20mg/day,**
    - **IVIg**[20]
    - **Sulfasalazine,**
    - **Teriflunamide leflunomide,**
    - **Azathioprine,**
    - **Oral cyclophosphamide ,**
    - **Tacrolimus tocilizumab,**
    - **Cyclosporin, interferons,**
    - **Glatiramer acetate,**
    - **Dimethyl fumerate,**
    - **Natalizumab.**
2) For patients on the following medications, there are two options:
    a) Do not change medication dosing or
    b) Adjust medication dosing to optimize the immune response to the vaccine:
        i. For patients on weekly **methotrexate**, an option is to skip the methotrexate dose the following week after each vaccine dose.
        ii. For patients on intravenous **cyclophosphamide**, an option is to take each vaccine dose at least one week prior to the next cyclophosphamide infusion.
        iii. For patients on **rituximab** or **ocrelizumab**, the COVID-19 vaccination should ideally be timed four to five months after their last infusion and two to four weeks prior to their next infusion, when possible, in order to optimize vaccine response. However, in patients who require immediate infusion or who are unable to optimize timing of infusion product and vaccine, it is likely more important to have the COVID-19 vaccine earlier than to delay based on timing of B-cell therapy.
        iv. For MS patients who are requiring first or repeat dosing of **cladribine** or **alemtuzumab** a delay could be considered until after full vaccine course plus four weeks. If treatment with **alemtuzumab** is required because of active disease, then vaccination will need to be delayed for 12 weeks after treatment dose. Bridging with natalizumab can be considered in order to give full vaccination before initiating alemtuzumab. Vaccination after **cladribine** can occur 4 weeks after treatment dose.[32]
        v. For patients on **mycophenolate mofetil**, if the disease is stable, the medication may be held for one week following each COVID-19 dose.[33]
        vi. For patients on **prednisone** 20mg/d or higher, consider waiting until the prednisone dose is tapered to below 20mg/d to receive both vaccine doses. (Note: for individuals with Duchenne's Muscular Dystrophy on deflazacort, Parent Project Muscular Dystrophy and Muscular Dystrophy Canada recommend vaccination on

current prednisone dose) [34] Pediatric patients on high-dose steroids should consult with their pediatric rheumatologist to decide on the best time to receive the vaccine.[36]

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