

Counselling Immunocompromised Individuals on the use of mRNA COVID-19 Vaccines

Interim Information for Health Care Providers Completing Risk Assessments

Background

The National Advisory Committee on Immunization updated its [COVID-19 vaccination use recommendations](#) on January 12, 2021 to clarify that adults who have autoimmune conditions or are immunosuppressed due to disease or treatment (referred to in this document as “immunocompromised”¹) MAY receive COVID-19 vaccination after a risk benefit assessment, and informed consent.

In Alberta it is recommended that immunocompromised¹ people discuss immunization with their health care provider prior to receiving vaccination COVID-19 vaccine. However, with the exception of transplant patients, who require consultation with their transplant team prior to any immunization including for COVID-19, verbal consent from the patient is considered sufficient. A fit to immunize assessment would still be conducted for all clients at the time of immunization.

This document is aimed at health care providers and is a brief summary of considerations to inform pre-immunization assessment. It is considered current as of February 2021.

Are these vaccines effective in immunocompromised people?

The vaccine clinical trials did not include immunosuppressed people, so it is unknown whether they will have a full protective immune response to these vaccines. A small number of people with autoimmune conditions, and well controlled HIV infection were included in the trials but the numbers were small. Studies in several of these immunocompromised populations have started with data expected in upcoming months. Several considerations are relevant when considering vaccine effectiveness:

- The type of immune deficiency matters, as many who are considered immunocompromised get useful protection with conventional vaccines, but some may have a lower level of protection from vaccines.
- In settings with significant COVID-19 risk, even a less effective immune response to vaccine could still be beneficial.

Is there excess risk from these vaccines for immunocompromised people?

- The COVID-19 mRNA vaccines have been shown to be safe and well tolerated.
- These are not live virus vaccines so there is no chance of getting COVID-19 from them. There is no reason to expect that these vaccines would have a different safety profile in immunocompromised people than other non-live vaccines.
- There was an early theoretical concern that mRNA vaccines might cause inflammation triggering auto- or allo-immune response, although this has not been demonstrated in clinical studies. The new COVID-19 vaccines were designed to avoid this risk and there is ongoing safety monitoring to assess for this issue. Over 150 million doses of COVID-

¹ This discussion will use the term “immunocompromised” to refer to people with cancer (hematologic and solid tumour) and on active cancer therapies, HIV infection with immune compromise, congenital immunodeficiencies, solid organ, bone marrow and stem cell transplant, and chronic inflammatory and autoimmune diseases (rheumatologic, gastrointestinal, dermatologic, neurologic) with or without use of immunomodulating medications.

Counselling Immunocompromised Individuals on COVID-19 Vaccines • 2

19 vaccines have been administered so far (current as of February 10, 2021) and this concern has not been reported,

- Several previous studies have not suggested problems due to immunizations with inactivated vaccines (influenza, tetanus, diphtheria and others) for patients with a transplanted organ, or for people with autoimmune rheumatic diseases. There is no data for mRNA vaccines in these groups yet, however the risk is felt to be low.
- Major national and international patient and specialist organizations representing [Multiple Sclerosis](#), [Inflammatory Bowel Disease](#), [psoriasis](#), [rheumatic diseases](#), [hematology](#) and [Canadian](#) and [American](#) transplantation groups have suggested that immunocompromised individuals who are at risk of COVID-19 infection take the vaccines when available to them.

Are there considerations for timing of medications that affect the immune system and the timing of COVID-19 vaccination??

- B cell depleting therapies: The treating physician should be consulted to determine [if dose interruption](#) might be useful in order to increase the likelihood of vaccine response.
 - Comment: Medications that deplete B cells (such as rituximab) are used in cancer, autoimmune conditions and multiple sclerosis. Individuals on these therapies can recover from SARS-CoV-2 infection but may not develop an antibody response to these vaccines. A T cell response to vaccine may offer some protection even if antibody levels are low, but the correlates of protection are unclear. Vaccination is still advised by experts.
- If possible, delaying any immunomodulating or chemotherapy treatments until 2 weeks after the second dose of mRNA vaccine may be considered if clinically reasonable.

General considerations:

- Individuals with a history of severe allergic reaction to a component of the COVID-19 vaccine should not receive the COVID-19 vaccine.
- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma
- Anaphylaxis has been reported, and of the limited list of ingredients in these vaccines, polyethylene glycol is one that has been known to cause anaphylaxis.
- People with a history of allergic reactions to previous vaccinations, mast cell activation syndrome, or idiopathic anaphylaxis should have a review of risk and benefits and be monitored for 30 minutes if vaccine is given.
- People with common allergies (to medications, foods, inhalants, insects and latex) appear to be no more likely than the general public to have an allergic reaction to the mRNA COVID-19 vaccines.

Basic Risk Assessment and Consent Counselling Points

(for health care providers discussing COVID19 mRNA vaccination with immunocompromised² individuals)

- Many immunocompromised people may safely choose to take one of the available vaccines when eligible, recognizing that depending on their type of immune system issue, it is not yet known if they will have a complete vaccine immune response.
- Some immunocompromised people may choose to wait for the results of more studies before deciding to take a COVID-19 vaccine, especially if they can reduce their risk of COVID-19 without undue hardship. People providing care for, or who are close contacts (for example are household members) of immunocompromised people are also encouraged to take the COVID19 vaccine when available for added protection.
- A person's risk of COVID-19 infection relates to their day to day **risk of contacting people with COVID-19** (higher in front-line workers, including health care workers and people who require in-person attendance for needed health care), and the amount of COVID-19 in their community. **A person's risk of severe disease** is affected by their age (higher risk with older age) cardiovascular risk factors such as obesity and high blood pressure, and other medical conditions including [immunosuppression](#). Right now there is not much evidence that autoimmune conditions add to the risk of severe COVID-19, but immune function can be very different between different conditions and medications.
- These vaccines have not yet been specifically studied in immunocompromised so it is not known whether they will have a full protective immune response or not. Like other non-live vaccines, these vaccines are expected to have a similar safety profile people with and without immunocompromise although studies are ongoing.
- People should be advised to continue to practice recommended public health measures for prevention of SARS-CoV-2 infection and transmission whether you receive the vaccine or not.
- **Further information about the COVID-19 vaccines is available on the [Alberta Health Services vaccine website](#)**

This document has been reviewed by the Vaccine Task Force, representatives of specialty and subspecialty clinical groups that deal with immunocompromised patients, and members of the AHS Scientific Advisory Group

² This discussion will use the term "immunocompromised" to refer to people with cancer (hematologic and solid tumour) and on active cancer therapies, HIV infection with immune compromise, congenital immunodeficiencies, solid organ, bone marrow and stem cell transplant, and chronic inflammatory and autoimmune diseases (rheumatologic, gastrointestinal, dermatologic, neurologic) with or without use of immunomodulating medications

Works Cited

American College of Rheumatology guidance
<https://www.rheumatology.org/announcements>

American Society of Hematology guidance
<https://www.hematology.org/covid-19/ash-astct-covid-19-and-vaccines>

American Society of Transplantation guidance
https://www.myast.org/sites/default/files/2021%2001%2025%20COVID19%20VACCINE%20FAQS_update%20v%203.pdf

Canadian Society of Transplantation guidance
[https://www.cst-transplant.ca/Library/Coronavirus/National Transplant Consensus Guidance on COVID vaccine-20210123_FINAL.pdf](https://www.cst-transplant.ca/Library/Coronavirus/National%20Transplant%20Consensus%20Guidance%20on%20COVID-19%20Vaccines-20210123_FINAL.pdf)

Crohn's & Colitis Foundation Inflammatory Bowel Disease guidance
<https://www.crohnscolitisfoundation.org/coronavirus/vaccines>

National Advisory Committee on Immunization recommendations
<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html>

National Multiple Sclerosis Society guidance
<https://www.nationalmssociety.org/coronavirus-covid-19-information/multiple-sclerosis-and-coronavirus/covid-19-vaccine-guidance>

National Psoriasis Foundation guidance
<https://www.psoriasis.org/covid-19-task-force-guidance-statements/>

Scientific Advisory Group immunosuppression evidence review
<https://www.albertahealthservices.ca/assets/info/ppih/if-ppih-covid-19-sag-immunosuppression-and-covid-19-risk-rapid-review.pdf>

Baker, D., Roberts, C.A.K., Pryce, G., *et al.* COVID-19 vaccine-readiness for anti-CD20-depleting therapy in autoimmune diseases. *Clin Exp Immunol* 202(2), 149-1161 (2020).
<https://doi.org/10.1111/cei.13495>

Pardi, N., Hogan, M., Porter, F. *et al.* mRNA vaccines — a new era in vaccinology. *Nat Rev Drug Discov* 17, 261–279 (2018). <https://doi.org/10.1038/nrd.2017.243> (on theoretic concern of type 1 immune response and autoinflammation in earlier mRNA vaccines, and comment from author on new mRNA vaccines at <https://apnews.com/article/fact-checking-afs:Content:9889529642>)

Additional Resources

[Centre for Effective Practice PrOTCT PLAN for the COVID-19 vaccine discussion](#)

Pfizer-BioNTech COVID-19 vaccine

- [Pfizer-BioNTech COVID-19 Vaccine Info Sheet \(MOH, December 13, 2020\)](#)
- [Administration of Pfizer-BioNTech COVID-19 Vaccine \(MOH, December 18, 2020\)](#)
- [Pfizer-BioNTech COVID-19 vaccine: What you should know \(Health Canada, December 16, 2020\)](#)
- [Pfizer-BioNTech COVID-19 vaccine: Patient medication information handout \(English and French\)](#)
- [Safety and Efficacy of the BNT162b2 mRNA COVID-19 vaccine \(NEJM, Dec 10, 2020\)](#)
- [Product monograph, including patient medication information: Pfizer-biontech covid-19 vaccine \(2020\)](#)
- [Details for: Pfizer-BioNTech COVID-19 Vaccine \(Health Canada, Nov 13, 2020\)](#)

Moderna COVID-19 vaccine

- [Product monograph, including patient medication information: Moderna COVID-19 Vaccine \(Moderna, December 2020\)](#)
- [Moderna COVID-19 vaccine: What you should know \(Health Canada, December 23, 2020\)](#)
- [Moderna COVID-19 vaccine: Patient medication information handout \(English\)](#)
- [Moderna COVID-19 vaccine: Authorization information \(Health Canada December 23, 2020\)](#)
- [Moderna COVID-19 vaccine: Interim order authorization – terms and conditions \(Health Canada, December 23, 2020\)](#)
- [Product details: Moderna COVID-19 Vaccine \(mRNA-1273 SARS-CoV-2\) \(Health Canada, December 23, 2020\)](#)
- [Consumer information: Details for Moderna COVID-19 vaccine / vaccin de Moderna contre la COVID-19 \(Health Canada, December 23, 2020\)](#)
- [Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine \(NEJM, December 30, 2020\)](#)

General vaccine information (development and approval process, availability, etc.)

- [Vaccine development and approval in Canada Infographic \(Government of Canada, 2020\)](#)
- [Vaccine Approval Process and Safety \(MOH, December 30, 2020\)](#)
- [What you need to know about the COVID-19 vaccine for Canada \(PHAC, 2020\)](#)
- [Recommendations on the use of COVID-19 vaccine\(s\) \(NACI, December 23, 2020\)](#)
- [Health Canada: Guidance on the prioritization of initial doses of COVID-19 vaccine\(s\)](#)
- [COVID-19 mRNA vaccines \(Health Canada, December 11, 2020\)](#)