

This advice is for health care professionals and we cannot answer individual patient queries. Those looking for further information are advised to speak to their physician, who are best placed to answer specific questions.

CTS Information and Guidance for Respiratory Health Care Professionals on COVID 19 Vaccination

Introduction

This Canadian Thoracic Society (CTS) document aims to provide guidance and relevant information for respiratory health care professionals on COVID-19 vaccination in Canada. Due to limited data, there are areas of uncertainty which have prompted the CTS, and several other national and international Specialty Societies, to provide advice on vaccination based on available evidence and expertise. We highlight this important information in this paper. A Frequently Asked Questions (FAQ) section of this document seeks to address some of the concerns that may arise in discussion with patients who are immunocompromised, treated with biologic therapy or long-term steroids, pre- or post-transplant, etc. We plan to update this guidance as new information becomes available and recommend periodically checking the Canadian Thoracic Society website (<https://cts-sct.ca/covid-19/>) for updates.

In Canada, there is a gap in the knowledge about the rate of vaccination in patients with respiratory diseases. However, it is clear from Canadian studies¹⁻⁶ that address vaccine uptake that the vaccination rates for seasonal influenza and for pneumococcal infection are below the ideal level of 80%.⁷ A recommendation or contact (visit) with a health care professional was identified in several studies^{2,8,9} as an important predictor influencing an individual's decision to be vaccinated. The study by Bourbeau et al.² found that COPD patients in Quebec and Ontario who had regular contact with their physician had vaccination rates of 80% for seasonal influenza, as reported by their primary care doctors. In the Boerner et al. study,⁸ participants mentioned a physician recommendation along with trust in their physicians as a significant factor in their vaccination decision.

Therefore, the role of physicians, respiratory health care professionals and educators as advocates for vaccination along with consistent messaging on COVID-19 vaccination will likely be effective in improving vaccination rates in this vulnerable population.

Which COVID-19 vaccine is the best?

There's no "best" vaccine option, as there's not enough research to confirm that yet. **Vaccines aren't a silver bullet, especially as the pandemic is ongoing. They must be combined with other public health measures to decrease risk of virus transmission including: frequent hand washing or use of alcohol-based hand sanitizers, wearing face masks, and physical distancing should continue to be observed.** This is especially important in those with chronic medical conditions. No matter which COVID-19 vaccine becomes available to you first, you can feel confident in its ability to protect you, as long as you continue being cautious until positive cases, hospitalizations, and deaths are significantly reduced nationwide. Manufacturers are working toward developing vaccines that provide greater protection against new SARS-CoV-2 variants. For a vaccine to be sold in Canada, it has to be authorized by Health Canada. Health Canada's Biologic and Radiopharmaceutical Drugs Directorate reviews the data in the vaccine submission. A notice of compliance and a drug identification number are then issued after the review is complete, and only if the benefits of the vaccine outweigh any identified risks. After a vaccine is authorized, the manufacturer or health care professionals will continue to generate post-market data for adverse effects and/or new data changing the uses or supporting additional uses of the vaccine.

Drugs and COVID-19 vaccines authorized or in progress by Health Canada

- [List of authorized drugs, vaccines and expanded indications for COVID-19](#)
- [Pfizer-BioNTech COVID-19 vaccine: What you should know](#)
- [Moderna COVID-19 vaccine: What you should know](#)

- [Vaxzevria \(Oxford-AstraZeneca\) COVID-19 vaccine: What you should know](#)
- [Janssen COVID-19 vaccine: What you should know](#)

Summary of efficacy and safety vaccines approved by Health Canada (see summary table on Page 8)

Pfizer-BioNTech and Moderna COVID-19 vaccines:

The first 2 COVID-19 vaccines to receive Health Canada approval for use ([Pfizer-BioNTech](#)¹⁰ and [Moderna](#)¹¹) **have shown over 80% efficacy** for preventing symptomatic and severe disease. The duration of follow up has been limited to 2-4 months.

Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine:

The approval for use of the Vaxzevria ([Oxford-AstraZeneca](#))¹² COVID-19 vaccine in Canada has shown an effectiveness of about 62% in preventing symptomatic COVID-19 disease beginning 2 weeks after the second dose. For the vaccine to work best, 2 doses are required: a first dose and then a second dose 4 to 12 weeks later. The median duration of follow-up was 105 days post-Dose 1 and 62 days post-Dose 2. Additional research is needed to understand longer-term potential protection after a single dose.

Janssen (Johnson & Johnson) COVID-19 vaccine:

The [Janssen](#)¹³ COVID-19 vaccine is a one dose vaccine with 72% effective in preventing symptomatic COVID-19 disease beginning 2 weeks after vaccination. In study COV3001, up to a cut-off date of January 22, 2021, 54.6% of individuals had follow-up duration of 8 weeks. The median follow-up duration for all individuals was 58 days.

Data are continuously coming in regarding the efficacy of the different vaccines with respect to the variants. However, it is too early to know if and how the new variants may affect vaccine efficacy. From the clinical trials, all vaccines **are safe**. Severe adverse events are rare and usually self-limited. However, local and systemic side effects are in keeping with known side effects associated with vaccines and are usually self-limited. Long-term side effects are highly unlikely. Regarding anaphylaxis, Moderna has reported 2.5 cases per million (*as of Jan 10, 2021: [MMWR January 29, 2021/670 \(4\): 125-129](#)*) and Pfizer 11 cases per million (*as of Dec 23, 2020: [MMWR: January 15, 2021/ 70 \(2\): 46-51](#)*). The majority of cases involved patients with documented/known allergies or allergic reaction, and 1/3 to 1/2 had previous history of anaphylaxis. Severe adverse events, excluding those related to confirmed COVID-19, were reported by 0.4% (n=83) of individuals who received the Janssen COVID-19 Vaccine (N= 21,895) and 0.4% (n=96) of individuals who received placebo (N= 21,888).

With regards to the Vaxzevria (Oxford-AstraZeneca), according to [United Kingdom \(UK\) safety-monitoring system the Yellow Card Scheme](#), about 4,000 doses out of every million administered lead to adverse events. In the clinical trials, the side effects that followed vaccine administration were mild or moderate. They included things like pain at the site of injection, body chills, feeling tired and feeling feverish. The [Medicines and Healthcare products Regulatory Agency](#) in the United Kingdom closely monitors reports of anaphylaxis or anaphylactoid reactions with the Vaxzevria vaccine. These are reported less frequently than with the Pfizer/BioNTech vaccine, with 105 UK spontaneous adverse reactions associated with anaphylaxis or anaphylactoid reactions reported, and is very rare. Rare cases of serious blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been recently reported in Europe following post-licensure use of Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine.^{14,15} Cases identified so far have been primarily in women under the age of 55 years; although cases in men have also been reported and have mostly occurred between 4 and 16 days after receipt of vaccine. This adverse event is being referred to as Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT).¹⁶ This entity is associated with the development of antibodies that "activate" platelets, which stimulate the formation of clots and result in thrombocytopenia. The mechanism of action is similar to heparin-induced thrombocytopenia (HIT). The exact mechanism by which the

Vaxzevria vaccine triggers VIPIT is still under investigation. At this time, no other risk factors have consistently been identified in patients who develop VIPIT. This adverse event has not been identified following receipt of mRNA COVID-19 vaccines to date.

The rate of this adverse event is still to be confirmed. Based on information from the European Medicines Agency on March 18, 2021 it was originally estimated at approximately 1 per 1,000,000 people vaccinated with the Vaxzevria vaccine, however a higher rate of 1 per 100,000 was reported by the Paul-Ehrlich Institut in Germany.¹⁷ Additional information is currently being gathered to characterize more accurately the rate of VIPIT. Based on available information, the case fatality of VIPIT is approximately 40%, however, the case fatality may decrease with increased awareness of the adverse event and appropriate early treatment.

Recommendations on priority populations of COVID-19 vaccines in Canada

The National Advisory Committee on Immunization (NACI) provides the Public Health Agency of Canada (PHAC) with independent, ongoing and timely medical, scientific, and public health advice in response to questions from PHAC relating to immunization. NACI has provided independent expert advice regarding priority populations for early vaccinations.

Stage 1

NACI recommends that initial doses of authorized COVID-19 vaccine(s) should be offered to individuals without contraindications in the following populations:

- Residents and staff of congregate living settings that provide care for seniors
- Adults 70 years of age and older, beginning with adults 80 years of age and older, then decreasing the age limit by 5-year increments to age 70 years as supply becomes available
- Health care workers (including all those who work in health care settings and personal support workers whose work involves direct contact with patients)
- Adults in Indigenous communities where infection can have disproportionate consequences

Stage 2

As additional COVID-19 vaccine supplies become available with sufficient supply to vaccinate the above populations, authorized COVID-19 vaccine(s) should be offered to individuals without contraindications in the following populations:

- Health care workers not included in the initial rollout
- Residents and staff of all other congregate settings (e.g., quarters for migrant workers, correctional facilities, homeless shelters)
- Essential workers

Prioritization of Canadians with lung disease in the vaccination rollout

The COVID-19 Respiratory Roundtable led by the CTS issued a [joint statement](#) in January urging the federal, provincial and territorial governments to prioritize people living with lung disease who are at higher risk for more serious COVID-19 complications in the vaccination rollout.

In February, NACI released [recommendations on the prioritization of key populations for COVID-19 immunization](#) which includes chronic lung disease as a risk factor for poor outcome. [PDF document](#) (People who are at risk of more severe disease or outcomes from COVID-19)

Provincial and Territorial vaccination rollout plans

While NACI provides guidance on vaccination priorities, vaccination rollout plans are province- and territory-specific. For the latest detailed vaccination rollout plans, visit this website and go to the vaccine page for your province or territory: <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/covid-19-vaccine-treatment/vaccine-rollout.html#a3>

NACI recommendations on the use of COVID-19 vaccines¹⁸ (updated recommendations March 29, 2021)

NACI recommendations are now worded as “should” (strong) or “may” (discretionary).

- A **strong recommendation** applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach.
- A **discretionary recommendation** may be offered for some population/individuals in some circumstances.

Rec #1 - A complete vaccine series with a currently authorized COVID-19 vaccine **should be** offered to:

- Individuals in the authorized age group without contraindications to the vaccine. In the context of limited vaccine supply, initial doses of mRNA COVID-19 vaccine should be prioritized for the key populations outlined in [NACI’s Guidance on the prioritization of key populations for COVID-19 immunization](#) which now lists [chronic lung disease](#) as a risk factor for poor outcomes.
 - a. Due to suggested superior efficacy, mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications, especially in those at highest risk of severe illness and death and highest risk of exposure to COVID-19 who are prioritized for early COVID-19 immunization.
 - b. In the context of limited vaccine supply, Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine may be offered to individuals 55 years of age and older without contraindications if:
 - i. the advantages of earlier vaccination outweigh the limitations of vaccinating with a less efficacious vaccine;
 - ii. the ease of transport, storage and handling of this vaccine facilitates access to vaccination which may otherwise be challenging; and
 - iii. informed consent includes discussion about current vaccine options and the timing of future vaccine options

Rec #2 - Based on emerging evidence of the protection provided by the first dose of a two-dose series for COVID-19 vaccines currently authorized in Canada, NACI recommends that in the context of limited COVID-19 vaccine supply and ongoing pandemic disease, jurisdictions should maximize the number of individuals benefiting from the first dose of vaccine by **extending the second dose of COVID-19 vaccine up to four months after the first**. NACI will continue to monitor the evidence on effectiveness of an extended dose interval and will adjust recommendations as needed.

- In addition to emerging population-based data, this recommendation is based on expert opinion and the public health principles of equity, ethics, accessibility, feasibility, immunological vaccine principles, and the perspective that, within a global pandemic setting, reducing the risk of severe disease outcomes at the population-level will have the greatest impact. Current evidence suggests high vaccine effectiveness against symptomatic disease and hospitalization for several weeks after the first dose, including among older populations.
- This recommendation applies to all COVID-19 vaccines currently authorized for use in Canada.

- In situations where informed consent included assumptions about second dose timing, jurisdictions may consider offering second doses at shorter intervals for those who provided consent for the vaccine series prior to this recommendation.
- The vaccine effectiveness of the first dose will be monitored closely and the decision to delay the second dose will be continuously assessed based on surveillance and effectiveness data and post-implementation study designs. Effectiveness against variants of concern will also be monitored closely, and recommendations may need to be revised.

NEW - NACI recommends that Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine should not be used in adults under 55 years of age at this time while the safety signal of Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) following vaccination with Vaxzevria COVID-19 vaccine is investigated further.

When considering which groups to offer the Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine to when an authorized mRNA COVID-19 vaccine is unavailable or inaccessible, the assessment may vary between jurisdictions and groups and will depend on:

- **Local COVID-19 epidemic conditions** (e.g., consider offering available Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine in regions of high epidemic transmission where immediate protection is needed to prevent symptomatic disease and preserve health system capacity; carefully considering the local transmission potential for viral variants of concern and anticipated protection against them)
- **Local vaccine supply** (e.g., consider how long a group will need to wait to be offered an mRNA vaccine, based on available and expected vaccine supply)
- **Risk of severe illness and death** (e.g., consider offering available Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine to groups at lower risk of severe illness and death who will need to wait to receive mRNA vaccine)
- **Risk of exposure** (e.g., consider offering the available Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine to groups at risk of exposure SARS-CoV-2 who will need to wait to receive mRNA vaccine)
- **Logistical considerations** (e.g., consider offering available Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine to those who would not otherwise get vaccinated due to personal barriers accessing mRNA vaccination sites despite jurisdictional efforts to increase access. Due to ease of transport, storage and handling of the Vaxzevria (Oxford-AstraZeneca) vaccine, a variety of alternate vaccination sites could increase convenience of vaccination and reduce vaccine hesitancy)

Decisions on the type of second dose that will be offered to those individuals under 55 years of age who have been vaccinated with Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine will be determined based on the latest evidence and research. NACI will continue to review evidence as it emerges, including evidence on mixed COVID-19 vaccine schedules, to provide advice to public health programs on the potential for completing the series with other vaccine products.

Refer to the [Management options table for COVID-19 vaccines authorized for use in Canada](#) for a summary of evidence and factors for jurisdictions to consider when implementing COVID-19 immunization programs.

Rec #3 - A complete vaccine series with a currently authorized COVID-19 vaccine **may be** offered to:

- Individuals in the authorized age group without contraindications to the vaccine who have had previously polymerase chain reaction (PCR)-confirmed SARS-CoV-2 infection. In the context of limited vaccine supply, initial doses may be prioritized for those who have not had previously PCR-confirmed SARS-CoV-2 infection. Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination.

For **some specific populations** who were either excluded from, or were represented by small numbers of participants in clinical trials. Vaccine may be offered to some individuals in these populations in some circumstances on a case-by-case basis with a risk-benefit analysis (where the risk of exposure and/or severe COVID-19 disease outweighs the risk of vaccination), and with transparency about the insufficiency of evidence. Preference for mRNA COVID-19 vaccine (as outlined in Recommendation #1, above), if available, also applies to the populations described below:

- Immunosuppressed due to disease or treatment
- Individuals with an autoimmune condition
- Pregnant or breastfeeding women

These recommendations may change as more evidence on safety and/or effectiveness in these populations becomes available. The complete list of NACI recommendations are available at:

<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#a7>

Contraindications

The **Health Canada approved COVID-19 vaccines are contraindicated in individuals with a history of anaphylaxis after previous administration of the vaccine.** Vaccine is also contraindicated in persons with proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its packaging. Clinical trials of the authorized COVID-19 vaccines excluded individuals with a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Individuals with a history of severe allergic reaction to a component of the COVID-19 vaccine should not receive the COVID-19 vaccine.

Patients should be screened prior to receipt of each vaccine dose. Here's an example of a pre-vaccination checklist for COVID-19 vaccines from the Centers for Disease Control and Prevention :

<https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf>

For a comprehensive list of components in the vaccine and packaging, please consult the product leaflet or information contained within the product monograph available through [Health Canada's Drug Product Database](#).

Advice for specific populations

To assist with the decision on which vaccine to offer to different populations or groups, a comparison of the relative merits of both have been summarized in [Table 4: Management options for types of COVID-19 vaccines authorized for use in Canada](#).

Children under 16 years of age

The Pfizer-BioNTech COVID-19 vaccine is currently approved for individuals who are 16 years of age and older, the Moderna and Janssen COVID-19 vaccines for 18 years of age and older, and the Vaxzevria (Oxford-AstraZeneca) COVID-19 vaccine for 55 years of age and older. The COVID-19 vaccine(s) **should not be offered** to individuals who are not in the authorized age group. There are ongoing clinical trials on vaccine efficacy and safety in children aged 12 years and older and more data will be available in the coming months.

Advice for pregnant and breastfeeding women

Please see the advice on the Society of Obstetricians and Gynaecologists of Canada (SOGC) website here:

- [SOGC Statement on COVID-19 Vaccination in Pregnancy](#)

Advice for organ transplant recipients

Please see the advice from the Canadian Society of Transplantation website here:

- [National Transplant Consensus Guidance on COVID-19 Vaccine](#)

Advice for high-risk rheumatology patients

Please see the advice from the Canadian Rheumatology Association (CRA) website here:

- [CRA Recommendation on Covid-19 Vaccination in Persons with Autoimmune Rheumatic Disease](#)

Advice for individuals with alpha-1 antitrypsin deficiency

- [What Alphas need to know by Dr. Ken Chapman](#) – January 2021

Side by side comparison of COVID-19 Vaccines approved in Canada (as of April 6, 2021)

Vaccine	Type	Dose	Age	Efficacy "symptomatic Covid-19"		Side effects	Storage	Variant
				Mild	Severe**			
Pfizer-BioNTech*	mRNA	2♦ 21 days apart	16 (+)	95% (no difference in ≥65 yrs old)	100%	Chills, headache, pain, tiredness, and/or redness and swelling at the injection site, all of which generally resolve within a day or two Anaphylactic reaction [†]	At -70°C	Lab data suggest effective, against UK South-African and Latin American
Moderna	mRNA	2♦ 28 days apart	18 (+)	94.1% (86% in those of ≥65 yrs old)	100%	Similar to the Pfizer vaccine Anaphylactic reaction [†]	At 2°C up to 30 days -25° to -15°C up to 6 months	Similar to the Pfizer vaccine
Vaxzevria (Oxford-Astra-Zeneca) ^{&}	Adenovirus based (virus vector)	2♦ 4 to 12 weeks apart	55 (+)	62%	85%	Tenderness, pain, warmth, redness, itching, swelling or bruising at the injection site, all of which generally resolve within a day or two. && - adverse event Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) under investigation	At 2° to 8° C for at least 6 months	Seems to work better against the mutation that emerged in Great Britain than the one that emerged in South Africa.
Janssen (Johnson & Johnson)	Adenovirus based (virus vector)	1	18 (+)	72%	85%	Fatigue, fever headache, injection site pain, or myalgia (pain in a muscle or group of muscles), all of which generally resolve within a day or two. [#]	At 2°C and 8°C for at least 3 months	Vaccine's effectiveness (FDA) B.1.1.7 variant of 64% overall and 82% against severe disease in South Africa (B.1.351 variant)

** Efficacy "symptomatic SEVERE COVID-19" may be defined differently from one study to the other. For example, for the RCTs of the vaccines AZ or Johnson, severe COVID-19 included hospital admission and death but not specifically for the RCTs of the vaccines of Pfizer and Moderna.

♦ Based on emerging evidence of the protection provided by the first dose of a two dose series for COVID-19 vaccines currently authorized in Canada, NACI recommends that in the context of limited COVID-19 vaccine supply jurisdictions should maximize the number of individuals benefiting from the first dose of vaccine by extending the second dose of COVID-19 vaccine up to four months after the first.

* Pfizer-BioNTech is still testing the vaccine in kids ages 12-15 and in pregnant women. In mid-February, the company submitted new data to the FDA demonstrating the stability of the vaccine at temperatures more commonly found in pharmaceutical refrigerators and freezers. Approval would make the vaccine easier to distribute.

[†] During December 14, 2020 through January 18, 2021, a total of 9 943 247 doses of the Pfizer-BioNTech vaccine and 7 581 429 doses of the Moderna vaccine were reported administered in the US (CDC unpublished data, February 2021). CDC identified 66 case reports received by VAERS that met Brighton Collaboration case definition criteria for anaphylaxis (levels 1, 2 or 3): 47 following Pfizer-BioNTech vaccine, for a reporting rate of 4.7 cases/million doses administered, and 19 following Moderna vaccine, for a reporting rate of 2.5 cases/million doses administered. **Twenty-one (32%) of the 66 case reports noted a prior episode of anaphylaxis from other exposures.** 7 patients were admitted to ICU; 7 of those intubated received epinephrine, 6 received corticosteroids, and 5 received antihistamines; facial, tongue, or laryngeal angioedema was present in 4 of these patients; and hospitalization ranged from 1 to 3 days. No deaths from anaphylaxis after vaccination with either product were reported.

[&] Similar to the Johnson & Johnson's vaccine, this is a carrier vaccine, made from a modified version of a harmless adenovirus. The analysis also showed the potential for the vaccine to reduce asymptomatic transmission of the virus by as much as 67%.

^{&&} Rare cases of serious blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been recently reported in Europe following post-licensure use of Vaxzevria COVID-19 vaccine – more information at: <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-recommended-use-astrazeneca-covid-19-vaccine-younger-adults.html#a1>

[#] Milder side effect than the Pfizer and Moderna vaccines. Only one case of anaphylactic reaction reported. It will take time to come up with a firm estimate of how frequently this side effect occurs.

Advice for individuals with taking treatment for tuberculosis (TB) disease or latent TB infection

<http://www.bccdc.ca/health-info/diseases-conditions/covid-19/priority-populations/tuberculosis-and-covid-19>

Nearly everyone will be able to safely receive the COVID-19 vaccine, although a very small number of people may need to avoid vaccination due to severe allergies to parts of the vaccine.

- If you are taking treatment for TB disease or latent TB infection, it is safe to receive the COVID-19 vaccine when it is offered to you.
- If you are not tolerating your TB treatment, you should wait until your treatment is stable before receiving the COVID-19 vaccine. It is not a safety concern, but it is important to separate the side effects of your TB treatment from a potential side effect of the COVID-19 vaccine.

NOTE re: Drug interactions¹⁸

Tuberculin skin testing (TST) or interferon gamma release assay (IGRA)

There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed.

In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. However, re-testing (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of TB infection may be prudent in order to avoid missing cases due to potentially false-negative results.

Advice for immunosuppressed individuals including individuals receiving immunosuppressant therapy

NACI recommends that a complete COVID-19 vaccine series **may be offered** to individuals who are immunosuppressed due to disease or treatment in the authorized age group in this population, if a risk assessment deems that the benefits outweigh the potential risks. **Informed consent prior to vaccination should include a discussion about the absence of evidence on the use of COVID-19 vaccine in this population.**

- Currently, there are no data on COVID-19 vaccination in individuals who are immunosuppressed. Participants in the mRNA COVID-19 vaccine clinical trials only included individuals who were not immunosuppressed, and those not receiving immunosuppressive therapy during the trial.
- In general, **non-replicating vaccines may be administered to immunocompromised people because the antigens in the vaccine cannot replicate.** However, the magnitude and duration of vaccine-induced immunity are often reduced. It is currently unknown whether immunocompromised individuals will be able to mount an immune response to mRNA vaccines.
- The relative degree of immunodeficiency in individuals who are immunocompromised varies depending on the underlying condition, the progression of disease, and use of medications that suppress immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.
- Although inactivated vaccines can be safely administered at any time before, during or after immunosuppression, inactivated vaccines should be administered at least 14 days before initiation of immunosuppressive therapy to optimize immunogenicity.¹⁹
- Active surveillance in these vaccine recipients is strongly encouraged.
- NACI and CTS will monitor the evidence as it evolves, and update these recommendations as needed.

Advice for individuals treated with a biological therapy for Asthma

The two large randomized controlled trials (RCTs) of the mRNA vaccines published in the NEJM ([Pfizer-BioNTech](#) and [Moderna](#)), the [viral vector-based vaccines](#) (Vaxzevria ([Oxford-AstraZeneca](#))) published in the Lancet and ([Janssen – regulatory decision summary](#)) did not include participants on (asthma) biologics. There is no biological rationale as to why anti-IgE, anti-IL5, anti-IL5R or even anti-IL4/13 therapies should place patients at higher risk for adverse events. Of course, many of these patients **ALSO** have a history of severe allergy & anaphylaxis. The COVID-19 vaccine RCTs generally excluded these patients but, in post-emergency use authorization, the incidence of anaphylaxis has been about 1/100,000 vs. 1/1,000,000 for other vaccines. To our knowledge, none have resulted in fatality, and all have responded well to Epi-Pen and/or brief ER management.

Thus, patients with asthma on a biologic therapy should be advised:

- 1) Risks are as above, but that benefits outweigh these;
- 2) **Timing:** the vaccine should not be administered on the same day as a biologic; if possible, time to be vaccinated between doses of the biologic at a site with onsite EMS/physician coverage;
- 3) Those with a history of allergies to advise the vaccination staff, and to have their Epi-Pen – where relevant – with them, current, and visible on the table.

Advice for individuals with an autoimmune condition

NACI recommends that a complete vaccine series with a COVID-19 vaccine **may be** offered to individuals with an autoimmune condition in the authorized age group in these populations if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in these populations.

Responses to Frequently Asked Questions by Patients

This advice is for health care professionals and we cannot answer individual patient queries. Those looking for further information are advised to speak to their physician, who are best placed to answer specific questions.

1) Can I have a flu vaccination or the pneumococcal vaccination at the same time as a COVID vaccine?

NACI recommends that COVID-19 vaccines should not be given simultaneously with other vaccines (live or inactivated). Currently, no data exist on the simultaneous administration of COVID-19 vaccine with other vaccines. In the absence of evidence, attempts should be made to avoid simultaneous administration to maximize benefits of COVID-19 vaccination while minimizing any risks of harm, including the potential for immune interference or the erroneous attribution of an adverse event following immunization to a particular vaccine. However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.

In the absence of evidence, it would be prudent to wait for a period of at least 28 days after the administration of the complete two-dose vaccine series of an mRNA COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response.¹⁸ It would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administering a COVID-19 vaccine to prevent erroneous attribution of an adverse event following immunization to a particular vaccine.¹⁸

Refer to [Simultaneous administration with other vaccines](#)¹⁸ and [Timing of Vaccine Administration in the Canadian Immunization Guide, Part 1 - Key Immunization Information](#) for additional information on simultaneous administration of other vaccines in general.

2) Which COVID vaccine should I have?

The vaccines that are currently approved by Health Canada are effective and safe. However, many more vaccines will be approved over time. We will learn more about differences on the efficacy and safety profile of each of these vaccines. Based on updated knowledge from clinical trials and real life evidence from large population being vaccinated, it is possible that Health Canada makes changes and public health authorities consider making recommendations of preferable use of certain vaccines by age groups or for population with specific medical conditions. Due to suggested superior efficacy, mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications, especially in those at highest risk of severe illness and death and highest risk of exposure to COVID-19 who are prioritized for early COVID-19 immunization.

3) Should I receive the vaccine and is the vaccine going to work considering I am immunocompromised?

Non-replicating vaccines may be administered to immunocompromised people because the antigens in the vaccine cannot replicate. However, the magnitude and duration of vaccine-induced immunity are often reduced. It is currently unknown whether immunocompromised individuals will be able to mount an immune response to mRNA vaccines.

4) Should I stop taking any of my medications (such as immunosuppressive medications) to make sure the vaccine works well?

You should not stop any of your medications. Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. The Canadian Immunization Guide recommends inactivated vaccines be administered at least 14 days before initiation of immunosuppressive therapy to optimize immunogenicity.

5) I have been suffering from “Long COVID” – does this mean I shouldn’t have the vaccine?

A prior SARS-CoV-2 infection may not provide adequate protection for reinfection, therefore, vaccination against COVID-19 is recommended. However, in setting of limited vaccine supply, doses may be prioritized for those who have not had previously PCR-confirmed SARS-CoV-2 infection.

6) What is the rationale for changing the interval between first and second doses?

The NACI statement on vaccine administration and timing of vaccine administration can be found here: <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#b4>

Useful Links

Canadian Thoracic Society



- [COVID-19: Information for Healthcare Professionals & the Respiratory Community](#)
- [COVID-19 Vaccination Information for health care professionals](#)

AMMI Canada (Association of Medical Microbiology and Infectious Disease Canada)

Educational webinars: <https://www.ammi.ca/?ID=183&Language=ENG>

American Thoracic Society

[COVID-19 vaccination materials for professionals](#)

British Thoracic Society

[COVID-19 information for the respiratory community](#)

Canadian Agency for Drugs and Technologies in Health (CADTH)

[COVID-19 mRNA Vaccines for People with Cancer](#)

Canadian Cancer Society

[Cancer and COVID-19](#)

Canadian Pharmacists Association

[COVID-19 information and Resources](#)

Canadian Society of Allergy & Clinical Immunology

<https://csaci.ca/covid19-resources/>

Canadian Paediatric Society

Online CME module re: [Our best shot at beating COVID-19: Overcoming vaccine hesitancy in 2021](#)

The module covers all ages and is accredited for specialists

CANVAX

[COVID-19 Vaccine Questions and Answers for Healthcare Providers](#)

[COVID-19 resources on immunization](#)

COVID-19 Respiratory Roundtable

Information for people with lung disease: <https://cts-sct.ca/wp-content/uploads/2021/02/COVID-19-Respiratory-Roundtable-Website-URLsv2.docx>

Immunize Canada

[COVID-19 Immunization Information and Q&A](#)

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