

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 Government of Canada [website](#) and the CTS COVID-19 webpage at <https://cts-sct.ca/covid-19/> for updates.

In Canada, there is a lack of knowledge about the rate of vaccination in patients with respiratory diseases. The few studies that include specific uptake rates vary widely, and there is a need for further research that examines vaccine uptake by respiratory disease. However, it is clear from Canadian studies¹⁻⁶ that do address vaccine uptake that individuals with respiratory diseases are not being vaccinated at the optimal rate.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.* Please refer to the Lung Vaccination Working Group white paper entitled '[Optimizing Vaccination Rates in Canadians with Lung Disease](#)' for more details.

Which COVID-19 vaccine is the best?

Vaccination is the single most effective way to reduce deaths and severe illness from COVID-19. **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. 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](#)
- [Oxford-AstraZeneca COVID-19 vaccine: What you should know](#)
- [Janssen COVID-19 vaccine: What you should know](#)

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*)

Summary of efficacy and safety vaccines approved by Health Canada (see summary table on Page 11)

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 94 % efficacy** for preventing symptomatic and severe disease. The duration of follow up has been limited to 2-4 months. Additional clinical trial evidence can be found in [Appendix A](#) and [Appendix B](#) of the PHAC-NACI Recommendations on the use of COVID-19 vaccines report published on September 28, 2021. The authorized mRNA vaccines are safe and efficacious in those with one or more comorbidities (e.g., body mass index ≥ 30 kg/m², chronic pulmonary disease, diabetes mellitus, cardiac disease).

Oxford-AstraZeneca COVID-19 vaccine

The approval for use of the ([Oxford-AstraZeneca](#))¹² COVID-19 vaccine in Canada has shown an effectiveness of over 64% in preventing symptomatic COVID-19 disease ≥ 15 days 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 clinical trial evidence can be found in [Appendix C](#) of the PHAC-NACI report published on September 28, 2021. AstraZeneca COVID-19 vaccine is efficacious in those with one or more mild to moderate and controlled medical conditions (e.g., cardiovascular disease, respiratory disease, diabetes, body mass index ≥ 30 kg/m²).

Janssen COVID-19 vaccine

The [Janssen](#)^{13,14} COVID-19 vaccine is a one dose vaccine with 66% 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. Additional clinical trial evidence can be found in [Appendix D](#) of the PHAC-NACI report published September 28, 2021. The vaccine is safe and efficacious in those with one or more comorbidities 14 days after vaccination, although efficacy is somewhat lower in participants with comorbidities at 28 days post-vaccination.

Efficacy and effectiveness against asymptomatic infection and transmission¹⁵

- Evidence has begun to emerge from post-marketing studies conducted in Israel, the UK, and the US on the effectiveness of COVID-19 vaccines against asymptomatic infection in adults. Estimates of vaccine effectiveness for the Pfizer-BioNTech COVID-19 vaccine against SARS-CoV-2 infection with no reported symptoms was moderate to high after the first dose (depending on time since vaccination) and high after the second dose. Similar results were reported for mRNA COVID-19 vaccines in general (i.e., Moderna and Pfizer-BioNTech). In one UK study, asymptomatic SARS-CoV-2 infections were significantly less likely to be identified in vaccinated participants compared to those who were unvaccinated. There are no results specific to other COVID-19 vaccines yet, but studies are ongoing.
- The clinical trial data demonstrates that the authorized mRNA COVID-19 vaccines are efficacious over the short-term in individuals with or without evidence of prior SARS-CoV-2 infection. However, participants with laboratory-confirmed (using a nucleic acid amplification test, such as RT-PCR) SARS-CoV-2 infection prior to enrollment were excluded from the trials and the number of trial participants with evidence of previous infection (as defined by trial protocol) who had confirmed symptomatic COVID-19 disease during the trials were small; therefore, the efficacy in

this population and how it compares to those without evidence of previous infection is unknown at this time. The efficacy of the Janssen COVID-19 vaccine in those with evidence of prior infection is inconclusive at this time due to small sample size, and this outcome has not been assessed for AstraZeneca COVID-19 vaccine.

- The first dose of the authorized COVID-19 vaccines has been shown to offer at least short-term protection against confirmed COVID-19 disease. For mRNA vaccines, the highest efficacy is seen after the second dose is administered. There is currently no available evidence on medium- and long-term efficacy of the authorized COVID-19 vaccines, however trials are ongoing, and information will be updated as evidence emerges.

Efficacy and effectiveness against severe disease¹⁵

- Emerging real world evidence from studies in the United Kingdom, Israel, the United States, and Canada suggests moderate to high vaccine effectiveness against severe COVID-19 outcomes after the first or second dose of mRNA COVID-19 vaccines in adults, and after the first dose of AstraZeneca COVID-19 vaccine, including in older and frail populations. COVID-19 related hospitalization was the most common severe COVID-19 outcome assessed, while fewer studies provided estimates of effectiveness against severe disease and death. Emerging evidence from Israeli studies suggest high vaccine effectiveness after the second dose of Pfizer-BioNTech COVID-19 vaccine against severe disease, COVID-19 related hospitalization and death.

Efficacy and effectiveness against variants¹⁵

- There is evidence that the Pfizer-BioNTech and AstraZeneca vaccines protect against the B.1.1.7 (Alpha) variants of concern (VOC). While there appears to be reduced protection against acquisition of B.1.617.2 (Delta) after the first dose for both Pfizer-BioNTech and AstraZeneca vaccines as compared with other strains, emerging data suggest that Pfizer-BioNTech offers very good protection and the AstraZeneca vaccine offers good protection against infection with the B.1.617.2 (Delta) VOC after the second dose. In addition, the vaccines offer good protection against hospitalization after the first doses. There are also emerging data on the efficacy or effectiveness of mRNA vaccines against B.1.351 (Beta) VOC. Evidence from the Janssen vaccine clinical trials indicate that it is protective against symptomatic moderate to severe/critical COVID-19 infection in areas where B.1.351 (Beta) VOC and P.2 (Zeta) variant of interest (VOI) are circulating widely. The AstraZeneca clinical trial was conducted when the B.1.351 (Beta) lineage was the predominant strain in South Africa, and vaccine efficacy was not demonstrated against this strain.

Summary of Side Effects and Adverse Events¹⁵

mRNA Vaccines

- Local and systemic adverse events were generally less frequent in older adults (≥ 65 in the Pfizer-BioNTech clinical trial and ≥ 65 in the Moderna clinical trial). There have been reports of myocarditis and/or pericarditis after immunization with mRNA COVID-19 vaccines in Canada and internationally. Cases of myocarditis and/or pericarditis occur more often in adolescents and adults under 30 years of age, more often in males than in females, and more often after a second dose of an mRNA vaccine than after a first dose.
- Post-market preliminary safety data reported by the US Vaccine Safety Database as well as Canadian post-market passive and active surveillance data suggest relatively higher rates of myocarditis/ pericarditis reported after Moderna vaccination compared to Pfizer-BioNTech, although verification of this potential difference is ongoing.

AstraZeneca

- In clinical trials, the majority of local and systemic adverse events with the AstraZeneca COVID-19 vaccine were mild and transient and did not differ by dose administered or age.
- Very rare but serious cases of blood clots, including cerebral venous sinus thrombosis, with concurrent thrombocytopenia have been reported globally following post-licensure use of viral vector COVID-19 vaccines. The exact mechanism by which these vaccines may trigger thrombosis with thrombocytopenia is still under investigation. The case fatality rate typically ranges between 20 and 50%.
- Very rare cases of capillary leak syndrome (CLS) have been reported following immunization with the AstraZeneca COVID-19 vaccine. Of the six cases of CLS that occurred in Europe and the UK, three individuals had a previous history of CLS and one subsequently died.

- Very rare cases of Guillain-Barre syndrome (GBS) have been reported following vaccination with viral vector COVID-19 vaccines, at a higher rate that would normally be expected based on background rates in the general population.
- Anyone receiving the AstraZeneca COVID-19 vaccine should be informed of the risk of thrombosis with thrombocytopenia (also known as TTS or VITT), CLS and GBS and advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.

After a thorough, independent assessment of the currently available scientific data, Health Canada has updated warnings on the label for the [AstraZeneca COVID-19 vaccine](#) and [COVISHIELD](#) vaccine to inform Canadians and healthcare professions of these possible side effects and to provide information about the signs and symptoms and when to seek prompt medical attention following vaccination. For more information, please read the Health Canada alert issued on April 14, 2021: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75389a-eng.php>.

Janssen

- Local and systemic adverse events were typically mild and transient, and no safety signals were detected in clinical trials.
- As of September 8, 2021, 46 TTS cases were confirmed after more than 14.5 million doses of Janssen vaccine were administered in the United States.
- Very rare cases of GBS have been reported following vaccination with viral vector COVID-19 vaccines, at a higher rate that would normally be expected based on background rates in the general population.

Guidance on reporting adverse events following immunization¹⁵

In general, any serious (defined as resulting in hospitalization, permanent disability or death) or unexpected adverse event that is temporally related to vaccination should be reported. In addition to provincial or territorial reporting requirements, the Brighton Collaboration has developed a list of Adverse Events of Special Interest that are of particular interest and should be reported. Refer to <https://brightoncollaboration.us/covid-19/> for the list with definitions. There may be additional very rare AEFIs that have not been detected through clinical trials to date.

Refer to [Adverse Events Following Immunization](#) in the CIG, Part 2 – Vaccine Safety for additional information on definitions, reporting, investigating and managing, and causality assessments for AEFIs.

Refer to the [PHAC weekly report for reported adverse events](#) following COVID-19 vaccination in Canada.

Refer to [data on COVID-19 vaccination coverage and doses administered in various key populations in jurisdictions across Canada](#).

NACI recommendations on the use of COVID-19 vaccines¹⁵ (updated September 28, 2021)

These recommendations apply only to COVID-19 vaccines currently authorized for use in Canada (Pfizer-BioNTech COVID-19 vaccine; Moderna COVID-19 vaccine; Oxford-AstraZeneca COVID-19 vaccine; and Janssen COVID-19 vaccine).

They are based on the thorough review of available evidence, as well as the systematic assessment of ethics, equity, feasibility and acceptability considerations as summarized in [NACI's Guidance on Key Populations for Early COVID-19 Immunization](#), NACI makes the following evidence-informed recommendations for public health program level decision-making.

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.

The complete list of NACI recommendations, summary of evidence and rationale and references are available at: <https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/recommendations-use-covid-19-vaccines-en.pdf>

Rec #1 - NACI preferentially recommends that a complete series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine. (*Strong NACI Recommendation*)

Update on authorized age group¹⁶ August 27, 2021: NACI recommends that a complete series with an mRNA COVID-19 vaccine should be offered to adolescents 12 to 17 years of age who do not have contraindications to the vaccine. (*Strong NACI Recommendation*)

Rec #2 - NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, as well as the need to seek immediate medical care should symptoms develop. (*Discretionary NACI Recommendation*)

Refer to the [Table 5](#) of the PHAC-NACI Recommendations on the use of COVID-19 vaccines report published on September 28, 2021 for a summary of considerations for COVID-19 vaccines authorized for use in Canada.

Interchangeability of authorized COVID-19 vaccines in a vaccines series when the first dose is:

mRNA COVID-19 vaccine

NACI recommends that, if readily available*, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available*, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the vaccine series. The previous dose should be counted, and the series need not be restarted. (*Strong NACI Recommendation*)

*readily available = easily available at the time of vaccination without delay or vaccine wastage

AstraZeneca/COVISHIELD COVID-19 vaccine

NACI recommends that while either an AstraZeneca/COVISHIELD COVID-19 vaccine or an mRNA COVID-19 vaccine product may be offered for the subsequent dose in a vaccine series started with an AstraZeneca/COVISHIELD COVID-19 vaccine, an mRNA COVID-19 product is preferred as a subsequent dose, due to emerging evidence, including the possibility of better immune response, and the safety of heterologous schedules. Regardless of which product is offered, a complete two-dose series is important for protection; the previous dose should be counted, and the series need not be restarted. Individuals who receive two doses of the AstraZeneca/COVISHIELD vaccine are considered protected and do not require further vaccination. (*Discretionary NACI Recommendation*)

See [Table 3](#) of the PHAC-NACI Recommendations on the use of COVID-19 vaccines report published on September 28, 2021 for information on recommended intervals for authorized COVID-19 vaccines.

Booster dose in long-term care residents and seniors living in other congregate settings¹⁵

For a primary series, NACI continues to recommend the following for all individuals in the authorized age group, including LTC residents and seniors living in other congregate settings:

NACI preferentially recommends that a complete series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine. (*Strong NACI Recommendation*)

NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, as well as the need to seek immediate medical care should symptoms develop. (Discretionary NACI Recommendation)

Based on ethical considerations, recent trends in COVID-19 epidemiology, and accumulating evidence on waning of COVID-19 vaccine immunogenicity and effectiveness over time, NACI now recommends the following in addition to the above:

For all long-term care residents and seniors living in other congregate settings who have received a primary COVID-19 vaccine series (with a homologous or heterologous schedule using mRNA or viral vector vaccines) NACI recommends that a booster dose of an authorized mRNA COVID-19 vaccine should be offered. This dose should be offered at a recommended interval of at least 6 months after the primary series has been completed. Informed consent for a booster dose should include discussion about what is known and unknown about the risks and benefits, including the off-label status of NACI's recommendation. (Strong NACI Recommendation)

- **A booster dose of an authorized viral vector vaccine should only be considered when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, as well as the need to seek immediate medical care should symptoms develop. (Discretionary NACI Recommendation)**

Concomitant administration with other vaccines¹⁵

NACI recommends that COVID-19 vaccines may be given concomitantly with, or at any time before or after, other vaccines*. (Discretionary NACI Recommendation) * including live, non-live, adjuvanted, or unadjuvanted vaccines

Since COVID-19 vaccine programs were first implemented, evidence on the efficacy/effectiveness, immunogenicity, and safety of COVID-19 vaccines currently authorized in Canada has been accumulating. Combined with the extensive data and experience on the concomitant administration of non-COVID-19 vaccines for routine immunizations, NACI has concluded that a precautionary approach is now no longer necessary and recommends that COVID-19 vaccines may be concomitantly with (i.e. same day), or any time before, non-COVID-19 vaccines (including live, non-live, adjuvanted, or unadjuvanted). The concomitant administration of COVID-19 with non-COVID-19 vaccines will facilitate influenza vaccine programs in the fall and winter months and other routine vaccine programs that were disrupted due to the COVID-19 pandemic.

Informed consent should include a discussion of the benefits and risks given the limited data available on administration of COVID-19 vaccines with other vaccines. Studies to assess the safety and immunogenicity of concomitant administration of COVID-19 vaccines with other vaccines are ongoing.

If more than one type of vaccine is administered at a single visit, they should be administered at different injection sites using separate injection equipment.

Rec #3 – **NACI recommends that jurisdictions should maximize the number of individuals benefiting from the first dose of a COVID-19 vaccine by extending the second dose of COVID-19 vaccine up to four months after the first. With the expansion of COVID-19 vaccine supply in Canada, second doses should be offered as soon as possible, with priority given to those at highest risk of severe illness and death from COVID-19 disease after or concurrent with first doses for all remaining eligible populations. (Strong NACI Recommendation)** This recommendation applies to all two-dose COVID-19 vaccines currently authorized for use in Canada.

Please see NACI's [Statement on Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada \(archived\)](#) in the context of limited vaccine supply for a summary of the evidence and further rationale for this recommendation.

PHAC Webinar: NACI Recommendations on Extended Dose Intervals for COVID-19 Vaccines webinar on May 5, 2021 – link to recording: <https://nccid.ca/webcast/recommendations-of-the-national-advisory-committee-on-immunization-naci-on-extended-dose-intervals-for-covid-19-vaccines/>

Rec #4 - NACI recommends that a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who have had previously PCR-confirmed SARS-CoV-2 infection. (*Discretionary NACI Recommendation*)

Special Populations¹⁵

Individuals previously infected with SARS-CoV-2¹⁵

In studies looking at the immune response of individuals previously infected with SARS-CoV-2, binding and neutralizing antibodies have been shown to persist for at least 6 months post-infection, with only a small proportion of people becoming re-infected for potentially as long as 10 months. Follow-up of cohorts of previously infected individuals have reported high levels of protection against reinfection and were more likely to be asymptomatic (~50%) than cases of primary infection (19%). The risk of re-infection due to VOCs is uncertain. Limited evidence assessing neutralizing activity against VOCs suggests that neutralizing activity is retained against B.1.1.7 (Alpha); correspondingly, the risk of re-infection is similar to the original SARS-CoV-2 strain. There appears to be a reduction in neutralizing activity against B.1.351 (Beta), P.1 (Gamma), and B.1.617.2 (Delta) compared to the original strain, and the risk of reinfection may be higher.

Evidence on the safety of COVID-19 vaccination of individuals with prior SARS-CoV-2 infection is available from observational and clinical studies. The occurrence of solicited and unsolicited systemic adverse events after the first or second dose in individuals with prior SARS-CoV-2 infection was slightly higher compared to the SARS-CoV-2 naïve population. However, there was no observed increase in the frequency of more severe adverse events in this population. Two observational studies included less than 100 patients with persistent symptoms from prior COVID-19 infections (long COVID). In this subgroup, receipt of COVID-19 vaccination with either an mRNA or viral vector vaccine was not associated with a worsening of long COVID symptoms or increased reactogenicity following immunization.

Refer to the [Special Population section of the PHAC-NACI Recommendations on the use of COVID-19 vaccines report published on September 28, 2021](#) for additional details on reinfection and immune response.

Immunosuppressed individuals including individuals receiving immunosuppressant therapy¹⁵

Rec #5 - NACI preferentially recommends that a complete COVID-19 vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are immunosuppressed due to disease or treatment. For those who are moderately to severely immunocompromised in the authorized age group who have not yet been immunized, NACI recommends that a primary series of three doses of an authorized mRNA vaccine should be offered. For those who are moderately to severely immunocompromised in the authorized age group who have previously received a 1- or 2-dose COVID-19 vaccine series (with a homologous or heterologous schedule using mRNA or viral vector vaccines), NACI recommends that an additional dose of an authorized mRNA COVID-19 vaccine should be offered. (*Strong NACI Recommendation*)

Moderately to severely immunosuppressed includes individuals with the following conditions:

- Active treatment for solid tumor or hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome
- Active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the CIG for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive.

Rec #6 - NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group who are immunosuppressed due to disease or treatment to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. NACI recommends that the additional dose for those who are moderately to severely immunocompromised be a viral vector vaccine only when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, the need to seek immediate medical care should symptoms develop, the limited evidence on the use of viral vector COVID-19 vaccines in this population, and the lack of evidence on the use of an additional dose of viral vector COVID-19 vaccines in this population. (*Discretionary NACI Recommendation*)

- Individuals should continue to follow recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission.
- A vaccine series should ideally be completed at least two weeks before initiation of immunosuppressive therapies where possible.
- The minimal interval between the 1- or 2- dose initial series and the additional dose should be 28 days. An interval longer than the minimum 28 days between doses is likely to result in a better immune response. However, if a longer interval is being considered, then risk factors for exposure and risk of severe disease should also be taken into account.

Please see [NACI's Rapid Response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series](#) for a summary of the evidence and further rationale for this recommendation.

Refer to [Immunization of Immunocompromised Persons](#) in the CIG, Part 3 – Vaccination of Specific Populations for definitions and additional general information.

Individuals with an autoimmune condition¹⁵

Rec #7 - NACI preferentially recommends that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group with an autoimmune condition. Informed consent should include discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in these populations. (*Strong NACI Recommendation*)

Rec #8 - NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group with an autoimmune condition to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, the need to seek immediate medical care should symptoms develop, as well as the limited evidence on the use of viral vector COVID-19 vaccines in this population. (*Discretionary NACI Recommendation*)

Refer to [Immunization in Persons with Chronic Diseases](#) in the CIG, Part 3 – Vaccination of Specific Populations for additional general information on autoimmune conditions.

Pregnant and breastfeeding women¹⁵

Rec #9 - NACI preferentially recommends that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant or breastfeeding. Informed consent should include discussion about emerging evidence on the safety of mRNA COVID-19 vaccines in these populations. (*Strong NACI Recommendation*)

Rec #10 - NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group who are pregnant or breastfeeding to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, the need to seek immediate medical care should symptoms develop, as well as the limited evidence on the use of viral vector COVID-19 vaccines in these populations. (*Discretionary NACI Recommendation*).

Refer to [Immunization in Pregnancy and Breastfeeding](#), Part 3 – Vaccination of Specific Populations of the CIG for additional general information.

Children and adolescents¹⁵

Rec #11 - NACI recommends that a complete series with an mRNA COVID-19 vaccine should be offered to adolescents 12 to 17 years of age who do not have contraindications to the vaccine. Informed consent should include discussion about very rare reports of myocarditis and/or pericarditis following administration of mRNA vaccines. (*Strong NACI Recommendation*)

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 6 months and older and more data will be available in the coming months.

Please see [NACI's Recommendation on the use of mRNA COVID-19 vaccines in adolescents 12 to 17 years of age](#) for a summary of the evidence and further rationale for this recommendation.

Advice for organ transplant recipients

Data from a recent prospective cohort study suggest that a substantial proportion of transplant recipients likely remain at risk for COVID-19 after 2 doses of mRNA vaccine.¹⁷ Patients should continue to observe public health guidelines and other preventive measures to decrease risk of virus transmission. Also read the advice from the Canadian Society of Transplantation website here:

- [National Transplant Consensus Guidance on COVID-19 Vaccine \(revised on May 18, 2021\)](#)

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 \(revised on September 27, 2021\)](#)

Advice for individuals with alpha-1 antitrypsin deficiency

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

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 interactions¹⁵

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 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](#) ([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 that risks are as above, but that benefits outweigh these. Health care professionals should engage their patients in a shared decision-making process to discuss risks and benefits of receiving a COVID-19 vaccine

Timing Considerations for Biologic Therapy and COVID-19 Vaccination*

- The COVID-19 vaccine should not be administered on the same day as a biologic for asthma where possible.
- Patients with asthma should ideally receive a COVID vaccine 72 hours apart from their regular biologic, to make it easier to tell what injection may have caused a problem if the patient has a reaction.
- Individuals with a history of reaction to injectable medications, or a previous COVID-19 vaccine must advise the staff at the vaccination site.

* Guidance to 'hold' a therapy is made based on the assumption that the patient has well-enough controlled disease to allow for a temporary interruption; if not, decision-making should be determined on a case-by-case basis, considering the circumstances involved. These recommendations do not cover non-asthma biologics, such as used in rheumatology, etc.

Click [here](#) to view the **CTS-Canadian Society of Allergy and Clinical Immunology Infographic on Biologic Therapy and COVID-19 vaccine – advice for individuals with asthma**

Side by side comparison of COVID-19 Vaccines approved in Canada* (as of September 28, 2021)

Vaccine	Type	Dose	Age	Efficacy one dose 'Symptomatic disease' Mild	Efficacy two dose 'Symptomatic disease'		Variants of Concern (VOC)*	Side Effects¶	Storage
					Mild	Severe**			
Pfizer-BioNTech (Cominarty)	mRNA	2♦	12 (+)	<ul style="list-style-type: none"> >88% (16+ years old) 75% (12-15 years old) 	<ul style="list-style-type: none"> ≥94% (16+ years old) 100% (12-15 years old) 	>88% after one dose (16+ years old)	<ul style="list-style-type: none"> Protects against the B.1.1.7. (Alpha) Offers very good protection against symptomatic illness of B.1.351 (Beta) after 2nd dose Offers very good protection against infection of B.1.617.2 (Delta) after 2nd dose 	≥ 12 years old Common and very common side effects after Dose 1 and Dose 2 : fatigue, headache, muscle pain, chills, joint pain, fever, diarrhea and nausea/vomiting. Note: nausea/vomiting was reported as uncommon side effect after Dose 1 in adults	<ul style="list-style-type: none"> Frozen vials: -25°C to -15°C for up to 2 weeks Thawed under refrigeration: 1 month at +2°C to +8°C Thawed at room temperature: 2 hours up to +25°C
Moderna (Spikevax)	mRNA	2♦	12 (+)	<ul style="list-style-type: none"> 92% (18+ years old) 	<ul style="list-style-type: none"> ≥94% (18+ years old) >93% (12-15 years old) 	100% after two doses (18+ years old)	<ul style="list-style-type: none"> Protects against the B.1.1.7. (Alpha) Offers very good protection against symptomatic illness of B.1.351 (Beta) after 2nd dose 	≥ 12 years old Common and very common side effects after Dose 1 and Dose 2: fatigue, headache, muscle pain, chills, joint pain, fever, diarrhea and nausea/vomiting. Note: fever was reported as an uncommon side effect after Dose 1 in adults	<ul style="list-style-type: none"> 2-8°C up to 30 days, or +8°C to +25°C for up to 24 hours
Oxford-Astra-Zeneca && (Vaxzevria)	Adenovirus based (virus vector)	2♦	30 (+)	<ul style="list-style-type: none"> 64 to 71% after Dose 1 but before Dose 2 (18+ years old) 	<ul style="list-style-type: none"> >62% ≥15 days after vaccination (18+ years old) 	Hospitalization (18+ years old) <ul style="list-style-type: none"> >87% after Dose 1 No data for after Dose 2 	<ul style="list-style-type: none"> Protects against the B.1.1.7. (Alpha) Offers good protection against infection of B.1.617.2 (Delta) after 2nd dose Does not offer protection against B.1.351 (Beta) 	Adults Common and very common side effects after Dose 1 and Dose 2: Fatigue, headache, muscle pain, chills, joint pain, fever, feverishness, nausea/vomiting. Note: vomiting was reported as an uncommon side effect after Dose 2	At 2°C to +8°C for at least 6 months
Janssen (Johnson & Johnson)	Adenovirus based (virus vector)	1	18 (+)	18+ years old <ul style="list-style-type: none"> 66.9% ≥14 days post-vaccination and 66.1% ≥28 days post-vaccination 		18+ years old <ul style="list-style-type: none"> 76.7% ≥14 days post-vaccination and 85.4% ≥28 days post-vaccination 	<ul style="list-style-type: none"> Protects against symptomatic moderate to severe/critical COVID-19 infection in areas where B.1.351 (Beta) VOC and P.2 (Zeta) VOI are circulating widely 	Adults Common and very common side effects after Dose 1: Fatigue, headache, muscle pain, fever, nausea/vomiting	At 2°C to +8°C until the expiration date

** Efficacy "symptomatic SEVERE COVID-19" may be defined differently from one study to the other.

♦ Based on emerging evidence, NACI recommends that in the context of 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.

&& Very rare cases of a specific syndrome that involves serious blood clots associated with thrombocytopenia have been reported after vaccination with viral vector vaccines more information at: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75389a-eng.php>

*Details provided in [Table 5 from the PHAC-NACI-Recommendations on the use of COVID-19 vaccines published on September 28, 2021](#)

¶ For all vaccines, some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine recipients. However, they are mild or moderate and transient, resolving within a few days. These include pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. In clinical trials of mRNA vaccines, some adverse events, including fever, are more frequent after the second dose; this was not the case with the AstraZeneca COVID-19 vaccine. Data provided in [Tables 27 and 28 from the PHAC-NACI-Recommendations on the use of COVID-19 vaccines published on September 28, 2021](#)

Contraindications and Precautions¹⁵

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.

As for the routine administration of all vaccines, COVID-19 vaccines should be administered in settings capable of managing anaphylaxis. Refer to [Anaphylaxis and other Acute Reactions Following Vaccination](#) in the CIG, Part 2 – Vaccine Safety for information on the management of anaphylaxis post-vaccination.

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>

Rare anaphylactic reactions have been reported following immunization with mRNA COVID-19 vaccines.

[Table 4](#) of the PHAC-NACI-Recommendations on the use of COVID-19 vaccines published on September 28, 2021 lists potential non-medicinal ingredients in authorized COVID-19 vaccines that have been associated with allergic reactions in other products. These reactions have occurred rarely and ranged from mild cutaneous reactions to anaphylaxis. Anaphylaxis is typically a rare, severe, life-threatening allergic reaction usually with a rapid onset that involves multiple organ systems and can progress rapidly. Symptoms and signs of anaphylaxis may include, but are not limited to: generalized urticaria; wheezing; swelling of the mouth, tongue, and throat; difficulty breathing; vomiting; diarrhea; hypotension; decreased level of consciousness; and shock. It is important to note that other, less serious reactions may mimic allergic reactions (e.g., vasovagal syncope) and vaccination is not contraindicated in these cases.

Refer to [Anaphylaxis and other Acute Reactions following Vaccination: Canadian Immunization Guide](#) in the CIG, Part 2 – Vaccine Safety for information on the management of anaphylaxis post-vaccination.

Rare cases of VITT have been reported following immunization with viral vector COVID-19 vaccines. Investigations are ongoing and the recommendations will be updated as evidence becomes available. For more information, refer to [Appendix C](#) and [Appendix D](#).

For additional vaccine product-specific information, consult the product leaflet or information contained within the product monograph available through [Health Canada's Drug Product Database](#). Refer to [Vaccine Administration Practices](#) in the Canadian Immunization Guide (CIG), Part 1 - Key Immunization Information for additional general information.

For a complete list of contraindications, please consult the [Contraindications and Precautions section](#) of the PHAC-NACI-Recommendations on the use of COVID-19 vaccines published on September 28, 2021.

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 may be given concomitantly with, or at any time before or after, other vaccines*. (*Discretionary NACI Recommendation*)

*** including live, non-live, adjuvanted, or unadjuvanted vaccines**

Since COVID-19 vaccine programs were first implemented, evidence on the efficacy/effectiveness, immunogenicity, and safety of COVID-19 vaccines currently authorized in Canada has been accumulating. Combined with the extensive data and experience on the concomitant administration of non-COVID-19 vaccines for routine immunizations, NACI has concluded that a precautionary approach is now no longer necessary and recommends that COVID-19 vaccines may be concomitantly with (i.e. same day), or any time before, non-COVID-19 vaccines (including live, non-live, adjuvanted, or unadjuvanted). The concomitant administration of COVID-19 with non-COVID-19 vaccines will facilitate influenza vaccine programs in the fall and winter months and other routine vaccine programs that were disrupted due to the COVID-19 pandemic.

Informed consent should include a discussion of the benefits and risks given the limited data available on administration of COVID-19 vaccines with other vaccines. Studies to assess the safety and immunogenicity of concomitant administration of COVID-19 vaccines with other vaccines are ongoing.

It is currently not known if the reactogenicity of COVID-19 vaccines is increased with concomitant administration of other vaccines. While no specific safety concerns have been identified for various other vaccines with concomitant administration regimens, there is potential for increased reactogenicity with concomitant administration of COVID-19 vaccines with other vaccines, particularly those known to be more reactogenic, such as newer adjuvanted vaccines.

If more than one type of vaccine is administered at a single visit, they should be administered at different injection sites using separate injection equipment.

Refer to [Section 4.7 – Concomitant Administration with Other Vaccine, page 32 of the PDF version of the PHAC-NACI Recommendations on the use of COVID-19 vaccines](#) report published on September 28, 2021.

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. 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. (refer to NACI recommendations 1 and 2 on page 5 of this guide)

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. **For those who are moderately to severely immunocompromised in the authorized age group who have previously received a 1- or 2-dose COVID-19 vaccine series (with a homologous or heterologous schedule using mRNA or viral vector vaccines), NACI recommends that an additional dose of an authorized mRNA COVID-19 vaccine should be offered.** (*Strong NACI Recommendation*)

Refer to [NACI's Rapid Response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series](#) for a summary of the evidence and further rationale for this recommendation published on September 10, 2021.

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. Refer to the Special Population Section of the [PHAC-NACI Recommendations on the use of COVID-19 vaccines report published on September 28, 2021](#) for additional details starting on page 38.

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](#)

American Thoracic Society

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

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

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

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

[Clinical guidance for youth with myocarditis and pericarditis following mRNA COVID-19 Vaccination](#)

[COVID-19 vaccine for children](#)

CANVAX

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

[COVID-19 resources on immunization](#)

Centers for Disease Control and Prevention – Morbidity and Mortality Weekly Reports

[COVID-19 Vaccine Effectiveness and Safety](#)

CoVaRR-Net – [Coronavirus Variants Rapid Response Network](#)

A network of interdisciplinary researchers from institutions across the country created to assist in the Government of Canada’s overall strategy to address the potential threat of emerging SARS-CoV-2 variants.

COVID-END

[COVID-19 Evidence Network to support Decision-making](#)

COVID-NMA Initiative

[A living mapping and living systematic review of Covid-19 trials](#)

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 for HealthCare Providers](#)

Public Health Agency of Canada

[Coronavirus disease \(COVID-19\)](#)

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