

# An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)

Guidance on booster COVID-19 vaccine doses in  
Canada – Update December 3, 2021

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH



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## PREAMBLE

The National Advisory Committee on Immunization (NACI) is an External Advisory Body that 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.

In addition to burden of disease and vaccine characteristics, PHAC has expanded the mandate of NACI to include the systematic consideration of programmatic factors in developing evidence based recommendations to facilitate timely decision-making for publicly funded vaccine programs at provincial and territorial levels.

The additional factors to be systematically considered by NACI include: economics, ethics, equity, feasibility, and acceptability. Not all NACI Statements will require in-depth analyses of all programmatic factors. While systematic consideration of programmatic factors will be conducted using evidence-informed tools to identify distinct issues that could impact decision-making for recommendation development, only distinct issues identified as being specific to the vaccine or vaccine-preventable disease will be included.

This statement contains NACI's independent advice and recommendations, which are based upon the best current available scientific knowledge. This document is being disseminated for information purposes. People administering the vaccine should also be aware of the contents of the relevant product monograph. Recommendations for use and other information set out herein may differ from that set out in the product monographs of the Canadian manufacturers of the vaccines. Manufacturer(s) have sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monographs. NACI members and liaison members conduct themselves within the context of PHAC's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

## INTRODUCTION

On October 29, 2021, NACI published [interim guidance on booster COVID-19 vaccine doses in Canada](#). Since NACI's initial guidance:

- Health Canada has authorized the use of Pfizer-BioNTech Comirnaty 30 mcg (on November 9, 2021) and Moderna Spikevax 50 mcg (on November 12, 2021) as booster doses in those 18 years of age and older at least 6 months after completion of the primary series.
- Cases of COVID-19 are increasing rapidly in various countries with a trend of rising COVID-19 related deaths. Incidence rates of COVID-19 decreased and then increased slightly in some jurisdictions in Canada as of November 24, 2021.
- A new variant of concern (VoC), Omicron (B.1.1.529) has been identified. Information on this VoC is still emerging including its impact, if any, on vaccine effectiveness (VE).
- Evidence has evolved on decreasing protection against SARS-CoV-2 infection and symptomatic illness over time, and some studies have shown decreases in protection against serious disease in some populations since the completion of a COVID-19 primary vaccine series.
- Evidence on the potential benefit and safety of booster doses of mRNA COVID-19 vaccines has evolved and no safety concerns have been noted following the booster doses beyond those recognized after the primary series. The risk of myocarditis/pericarditis after a booster dose of an mRNA vaccine appears to be lower than the already rare risk after the second dose of the primary series but higher than after the first dose.
- On October 28, 2021, the Chief Medical Officers of Health (CCMOH) added goals for the next phase of the Canadian COVID-19 immunization response including to: 1. Minimize serious illness and overall deaths while preserving health system capacity, and 2. Reduce transmission to protect high risk populations.

NACI has reviewed the evolving situation and evidence and has updated evidence-informed recommendations in this new context.

While the term “booster dose” is used in this guidance, NACI continues to monitor the emerging scientific data on whether this dose is indeed a booster dose (to stimulate the memory response once protection has truly waned), or should be considered part of the primary series (to establish strong immune response and memory). NACI will adjust the terminology as required.

NACI continues to recommend a primary COVID-19 vaccine series with an authorized mRNA vaccine in all authorized age groups, and continues to recommend that immunization in those who are eligible but who have not yet received their primary series should remain the top priority. NACI acknowledges the urgency for vaccinating people around the world who have not yet received any COVID-19 vaccine or completed their primary series.

COVID-19 vaccines have been shown to be very effective against symptomatic laboratory confirmed SARS-CoV-2 infection, severe disease, hospitalization, and death from COVID-19 to date. Incidence rates of new SARS-CoV-2 infection as well as rates of hospitalization, ICU admission, and mortality continue to be highest among unvaccinated individuals. In addition, those who have been vaccinated are less likely to become infected, and therefore are less likely to transmit SARS-CoV-2 infection to others.

However, in the context of the circulating Delta (B.1.617.2) variant, evidence is emerging that VE against SARS-CoV-2 infection and COVID-19 decreases with time after the primary series and there may be some decrease in protection against severe illness (especially in older individuals). Decreasing protection against infection could contribute to increased transmission, since infected individuals may be a source of infection for others. Therefore, a booster dose may provide more durable protection to reduce infection, transmission, and in some populations, severe disease.

## METHODS

The evidence pertaining to the need for and benefit of COVID-19 booster doses is rapidly evolving. NACI reviewed this evidence on November 30, 2021 and approved these updated recommendations on December 2, 2021. To date, NACI has published the following evidence-informed guidance on booster doses:

1. [Interim guidance on booster COVID-19 vaccine doses in Canada](#) (October 29, 2021) including a description of NACI’s decision-making framework
2. [Rapid response: Booster dose of COVID-19 vaccine in long-term care residents and seniors living in other congregate settings](#) (September 28, 2021)

The intent of a “booster dose” is to restore protection that may have decreased over time or is no longer sufficient in individuals who initially responded adequately to a complete primary vaccine series. This is distinguished from the intent of an “additional dose” that might be added to the standard primary vaccine series with the aim of enhancing the immune response and establishing an adequate level of durable protection. NACI has also issued the following evidence-informed guidance for an “additional dose” in the primary series for [moderately to severely immunocompromised individuals](#) who may not have mounted an adequate immune response after a standard primary series:

1. [Rapid Response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series](#) (September 10, 2021)

NACI recommendations on the use of COVID-19 vaccines generally are available [here](#).

Data on COVID-19 vaccination coverage and doses administered in various key populations in jurisdictions across Canada is available [here](#).

Further information on [NACI’s process and procedures](#) is available elsewhere <sup>(1, 2)</sup>.

## RECOMMENDATIONS

Please see Table 3 for an explanation of strong versus discretionary NACI recommendations.

***NACI strongly reiterates its previous evidence-informed recommendations for the primary series of COVID-19 vaccines in all authorized age groups.***

Additional details are available in the following statements:

- [NACI statement on Recommendations on the use of COVID-19 vaccines;](#)
- [NACI rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series;](#)
- [NACI statement: Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine \(10 mcg\) in children 5 to 11 years of age;](#)
- [NACI Statement: Recommendation on the use of mRNA COVID-19 vaccines in adolescents 12 to 17 years of age](#) and
- Rapid response: Updated recommendation on the use of authorized COVID-19 vaccines in individuals aged 12 years and older in the context of myocarditis and pericarditis reported following mRNA COVID-19 vaccines

***NACI's evidence-informed recommendations for booster doses of COVID-19 vaccines in adults 18 years of age and older***

NACI acknowledges that the epidemiology of COVID-19 (including the impact of SARS-CoV-2 VoC) and the evidence on booster doses of COVID-19 vaccines are rapidly evolving, and continues to monitor the evidence in the Canadian context and provide additional recommendations as needed. NACI has therefore increased the strength of the recommendations from its [interim guidance on October 29, 2021](#) and expanded the groups for whom booster doses are now recommended.

NACI makes the following evidence-informed recommendations on booster doses of authorized mRNA COVID-19 vaccines based upon emerging evidence on VE, the risks of exposure to SARS-CoV-2 in Canada at this time, the revised objectives of Canada's COVID-19 immunization program, the ongoing risk of severe illness from COVID-19, the societal disruption that results from transmission of infections, and the adverse impacts on health system capacity of the COVID-19 pandemic.

(\*Please refer to the section on "[Options for Vaccine Type and Dose offered for COVID-19 Vaccine Booster Doses](#)" in the context of these recommendations):

1. NACI recommends that a booster dose of an authorized mRNA COVID-19 vaccine\* *should be offered* ≥6 months after completion of a primary COVID-19 vaccine series to adults in the following populations:
  - Adults ≥50 years of age
  - Adults living in long-term care homes for seniors or other congregate living settings that provide care for seniors
  - Recipients of a viral vector vaccine primary series that was completed with only viral vector vaccines (AstraZeneca/COVISHIELD or Janssen COVID-19 vaccine)
  - Adults in or from First Nations, Inuit and Métis communities
  - Adults who are frontline healthcare workers (having direct close physical contact with patients) regardless of the interval between doses in their primary series

*(Strong NACI Recommendation)*

2. NACI recommends that a booster dose of an authorized mRNA COVID-19 vaccine\* *may be offered* ≥6 months after completion of a primary COVID-19 vaccine series to adults 18-49 years of age with consideration of jurisdictional and individual risks.  
(Discretionary NACI Recommendation)

The relative need for a booster dose varies by a number of factors that may differ between jurisdictions and between individuals as summarized in Table 1.

**Table 1. Considerations to determine the need for a booster dose of COVID-19 vaccine**

	Assessment of:	Considerations:
<b>Jurisdictional</b>	Local epidemiology	<ul style="list-style-type: none"> <li>• Circulation of virus, including VoC</li> <li>• Evidence of decreasing protection against severe disease, infection, transmission</li> </ul>
	Health system capacity and access	<ul style="list-style-type: none"> <li>• Limited health system capacity to withstand a surge in cases</li> <li>• Reduced access to health care</li> </ul>
	Vaccine coverage of primary series in the population	<ul style="list-style-type: none"> <li>• Lower vaccine coverage at a regional population level leads to lower indirect protection and higher risk of breakthrough infection</li> </ul>
<b>Individual</b>	Risk of increased waning of protection and/or less protection	<ul style="list-style-type: none"> <li>• Shorter interval between doses in the primary series</li> <li>• Longer time since completion of primary series</li> <li>• Moderately to severely immunocompromised individuals</li> <li>• Vaccination with only viral vector vaccines</li> </ul>
	Risk of severe illness from COVID-19	<ul style="list-style-type: none"> <li>• Older age</li> <li>• <a href="#">Underlying medical condition</a> (including those who are immunocompromised and who received a three-dose primary series)</li> <li>• Racialized and marginalized populations who have been disproportionately affected due to a number of intersecting equity factors</li> </ul>
	Risk of transmission to individuals at increased risk of severe illness from COVID-19	<ul style="list-style-type: none"> <li>• Close contact with those at risk for severe disease (e.g., healthcare provider, primary caregiver)</li> <li>• Decreased ability to physically distance (e.g., congregate living settings)</li> <li>• Decreased access to infection prevention and control measures</li> </ul>

### Options for Vaccine Type and Dose offered for COVID-19 Vaccine Booster Doses

NACI has indicated circumstances where specific products and/or doses may be preferred for a booster/additional dose as outlined in Table 2. However, if any of Pfizer-BioNTech Comirnaty (30 mcg), Moderna Spikevax (50 mcg) or Moderna Spikevax (100 mcg) are administered as a booster/additional dose, the dose should be considered valid and therefore would not need to be repeated.

**Table 2. Options<sup>a</sup> and considerations for vaccine types and doses offered for COVID-19 vaccine booster doses for certain populations**

Population	Vaccine type (and dose) for booster doses which may be preferred	Rationale or additional considerations
18 to 29 year olds	Pfizer-BioNTech Comirnaty (30 mcg)	<ul style="list-style-type: none"> <li>• Lower reported rates of myocarditis/pericarditis following vaccination with Pfizer-BioNTech Comirnaty (30 mcg) compared to Moderna Spikevax (100 mcg). [This is based upon data following the second dose in the primary series using Moderna Spikevax (100 mcg). Evidence following the Moderna Spikevax (50 mcg) booster dose is limited.]</li> </ul>
<ul style="list-style-type: none"> <li>• ≥70 year olds</li> <li>• Adults living in long-term care homes for seniors or other congregate living settings that provide care for seniors</li> <li>• Moderately to severely immunocompromised adults<sup>b</sup> (after the recommended 3-dose primary series)</li> </ul>	<p>Either Moderna Spikevax or Pfizer Comirnaty (30mcg) may be considered.</p> <p>If Moderna Spikevax vaccine is being used as the booster product, a 100 mcg dose may be preferred, based on clinical discretion.</p>	<ul style="list-style-type: none"> <li>• Moderna Spikevax (100 mcg) induces somewhat higher antibody levels compared to Pfizer-BioNTech Comirnaty (30 mcg)</li> <li>• Protection (against infection and severe disease) from a primary series with Moderna Spikevax (100 mcg) may be more durable than Pfizer-BioNTech Comirnaty (30 mcg)</li> <li>• These populations may have less robust immune function (elderly) or a diminished immune response to the vaccine (some immunocompromised individuals). It is possible that Moderna Spikevax (100 mcg) may induce a better immune response than Moderna Spikevax (50 mcg), although there is currently no direct comparison of these two dosages as boosters</li> <li>• Currently there are no data comparing the immune responses after a booster vaccination with Moderna Spikevax (100 mcg) and Pfizer-BioNTech Comirnaty (30 mcg) in these populations.</li> <li>• There is heterogeneity among those who are moderately to severely immunocompromised, and risks from COVID-19, as well as the likelihood of a reduced response to vaccines, will vary depending on age and the immunocompromising condition.</li> <li>• It should be noted that Moderna Spikevax (100 mcg) is not currently authorized by Health Canada as a booster dose.</li> </ul>

For all other populations in whom booster doses are recommended that have not been specified above.	Either Moderna Spikevax (50 mcg) or Pfizer-BioNTech Comirnaty (30 mcg) are suitable products as a booster dose	<ul style="list-style-type: none"> <li>Authorized as booster doses by Health Canada</li> </ul>
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<sup>a</sup> A booster dose with a viral vector COVID-19 vaccine (AstraZeneca Vaxzevria or Janssen) should only be considered when other authorized COVID-19 vaccines are contraindicated or inaccessible. Viral vector vaccines are not currently authorized as booster doses in Canada. Vaccine effectiveness against symptomatic infection and severe COVID-19 outcomes has consistently been somewhat lower, and vaccine protection against infection and symptomatic disease decreases more quickly with viral vector vaccines compared to mRNA vaccines when used in a primary series. Viral vector vaccines also have a risk of vaccine-induced immune thrombotic thrombocytopenia (VITT) and other adverse effects that are not concerns with mRNA vaccines.

<sup>b</sup> Moderately or severely immunocompromised adults receiving a booster dose after a primary series of three doses, will receive a total of four doses.

### Additional considerations, summary of evidence and rationale

- NACI discussed the importance of global and domestic equity in this pandemic and has assessed the need for booster doses in this context when making its recommendations. NACI acknowledges the urgency for vaccinating people around the world who have not yet received their primary series of COVID-19 vaccine <sup>(3)</sup>.
- Incidence rates of COVID-19 are increasing and novel VoCs are circulating in various parts of the world. Incidence rates are not increasing as quickly in Canada to date (due, in part, to the preferential use of mRNA vaccines, recommendations for a longer interval between doses in the primary series, indirect protection from high vaccine coverage with 75.5% of Canadians fully vaccinated as of November 20, 2021, and the use of other public health measures). However, increasing incidence rates have been noted in recent weeks in some jurisdictions in Canada. Rising COVID-19 related deaths following increasing incidence rates continue to occur in some countries and jurisdictions.
- Emerging evidence suggests a decrease in post-vaccination COVID-19 antibody levels and VE against SARS-CoV-2 infection over time following completion of the primary series. Although protection against severe COVID-19 outcomes appears to be more durable than protection against asymptomatic or mildly symptomatic infection <sup>(4)</sup>, some studies are showing decreases in protection against serious infection <sup>(5-10)</sup>, and more notably in older adults <sup>(5-9)</sup>. A recent systematic review and meta-analysis of VE studies of WHO Emergency Use Listing vaccines comparing fully vaccinated to unvaccinated people showed the following percentage point declines in VE from 1 to 6 months after full vaccination for all eligible age groups: 18.5% (95% CI: 8.4 to 33.4) for SARS-CoV-2 infection; 25.4% (95% CI: 13.7 to 42.5) for symptomatic COVID-19; and 8.0% (95% CI: 3.6 to 15.2) for severe disease <sup>(11)</sup>.
- In the context of the Delta variant and possibly other highly transmissible variants, increased incidence of breakthrough infections will contribute to transmission, which in addition to spread in unvaccinated populations (particularly in communities with low vaccination coverage), can result in high community rates of SARS-CoV-2. This can have significant impacts, especially on populations at high risk of COVID-19 illness and on, health system capacity.
- Vaccinated individuals subsequently infected with the Delta variant are less likely to develop severe disease than unvaccinated individuals. However, vaccinated individuals infected with this highly transmissible variant can be infectious to others. As vaccine

protection against infection decreases over time, protection against subsequent transmission to other people (vaccinated or unvaccinated) may also decline <sup>(12, 13)</sup>.

- Decreased protection against infection over time has been noted to occur more quickly after the viral vector vaccines than the mRNA vaccines. With the mRNA vaccines, protection with Moderna Spikevax (100 mcg) may be more durable than with Pfizer-BioNTech Comirnaty (30mcg) <sup>(5, 7, 9, 10, 14-17)</sup>. Shorter intervals between the first and second dose for 2-dose COVID-19 vaccine series result in lower initial antibody titres that may result in an earlier decline in protection <sup>(18)</sup>.
- Immunogenicity studies indicate that booster doses of mRNA vaccines given at three or more months after the primary series elicit a robust immune response against the wild type Wuhan strain and the studied VoC, with antibody titres often measuring higher after the booster dose than after the primary series <sup>(19-21)</sup>. A longer interval between the primary series and booster dose may result in higher antibody titres <sup>(18)</sup>.
- A clinical trial <sup>(22)</sup> and real-world VE data suggest that a booster dose provides good short-term effectiveness against SARS-CoV-2 infection <sup>(23-27)</sup> (based on available follow-up periods) and has a safety profile comparable to that observed after the second dose of the vaccine <sup>(22, 28, 29)</sup>. In Israel, rates of myocarditis/pericarditis following the booster dose of Pfizer-BioNTech Comirnaty (30mcg) (given at least five months after the primary series and where the primary series was given using manufacturer recommended intervals in those 12 years of age and over) have been lower than the elevated rates seen after the second dose, but higher than the rates seen after the first dose of Pfizer-BioNTech Comirnaty (30mcg) in the primary series.
- Pregnant or breastfeeding individuals were excluded from clinical trials of mRNA booster doses. However, no maternal or neonatal safety signals have been detected in pregnant or breastfeeding individuals who have received mRNA COVID-19 vaccines <sup>(30)</sup>. Since the beginning of the COVID-19 pandemic, evidence has evolved to indicate that pregnancy is a risk factor for severe outcomes of COVID-19 <sup>(31)</sup>. Pregnant or breastfeeding adults are included as those recommended to receive a booster dose.
- While data on a fourth dose of a COVID-19 vaccine after the recommended three-dose primary series in moderately to severely immunocompromised individuals are currently limited, many of these individuals are at a higher risk of severe outcomes of COVID-19 and also at increased risk of decreasing protection over time since vaccination. Therefore, immunocompromised individuals who already received an additional dose in the COVID-19 vaccine primary series are included in those recommended to receive a booster dose six months from their last dose. If receiving Moderna Spikevax, dosage (i.e., 50 mcg or 100 mcg) should be based on clinical discretion (see [Table 2](#)). There is heterogeneity among those who are moderately to severely immunocompromised, and risks from COVID-19, as well as the likelihood of a reduced response to vaccines, will vary depending on age and the immunocompromising condition.
- Modelling results suggest that booster doses are projected to reduce infections and severe illness in the population, at least over the short-term, and that there is an expected direct benefit associated with booster doses in groups with evidence of suboptimal or waning protection against severe illness <sup>(32)</sup>.
- The COVID-19 pandemic has been ongoing for almost two years, and has caused substantial morbidity and mortality, societal disruption, pressure on the health care and public health systems, and discontinuation and delay of a number of preventive and treatment services in Canada. Vaccines, including the use of booster doses, are a critical component of a multifaceted public health response to control this pandemic. NACI has made these recommendations considering both the evidence and the current pandemic context.

- Informed consent for vaccination with a booster dose should indicate that a booster dose is intended to restore protection against infection that may have decreased over time, however, the effectiveness against virus transmission, and long-term effectiveness against infection and severe disease are currently unknown. In addition, evidence about the rate of myocarditis and pericarditis after a booster dose is limited.

Further information, a summary of evidence, and ethical, equity, feasibility and acceptability considerations are available in NACI's [Interim guidance on booster COVID-19 vaccine doses in Canada](#).

NACI is continuing to monitor the evidence and will update guidance as required.

Refer to NACI's [Recommendations on the use of COVID-19 vaccines](#) for further information on COVID-19 vaccines.

Refer to NACI's [Guidance on the prioritization of key populations for COVID-19 immunization](#) for further information on NACI's initial framework and foundational elements guiding ethical decision-making.

**Table 3. Strength of NACI Recommendations**

<b>Strength of Recommendation</b> <i>based on factors not isolated to strength of evidence</i> (e.g., public health need)	<b>STRONG</b>	<b>DISCRETIONARY</b>
<b>Wording</b>	<i>"should/should not be offered"</i>	<i>"may/may not be offered"</i>
<b>Rationale</b>	Known/anticipated advantages outweigh known/anticipated disadvantages ("should"), OR Known/Anticipated disadvantages outweigh known/anticipated advantages ("should not")	Known/anticipated advantages are closely balanced with known/anticipated disadvantages, OR uncertainty in the evidence of advantages and disadvantages exists
<b>Implication</b>	A strong recommendation applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.	A discretionary recommendation may be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

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