

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

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

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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

Cases of myocarditis/pericarditis have rarely been reported following mRNA COVID-19 vaccines globally, including in Canada, and the National Advisory Committee on Immunization (NACI) has been closely monitoring this vaccine safety signal.

Post-market safety surveillance on mRNA COVID-19 vaccines identified that when myocarditis and/or pericarditis occurs, it occurs usually within a week following vaccination, most frequently in adolescents and young adults (12 to 29 years of age), more frequently in males compared to females, and more frequently after the second dose as compared to the first.

## METHODS

On November 16, 2021, NACI reviewed the recent evidence on myocarditis/pericarditis following COVID-19 vaccination including data from Canada, Israel, the United States (US), France, and Nordic countries (Denmark, Finland, Norway, Sweden). NACI discussed this recent evidence while considering data on the epidemiology of COVID-19 infection, safety, immunogenicity, efficacy/effectiveness of COVID-19 vaccines as well as ethics, equity, feasibility, and acceptability.

Following a comprehensive review, NACI updated and approved its recommendations on the use of the COVID-19 vaccines authorized for use among individuals aged 12 years and older in the context of myocarditis and pericarditis following vaccination on November 16, 2021. NACI continues to review the evidence on the use of COVID-19 vaccines. Recommendations on re-vaccination of individuals aged 12 years and older with a history of myocarditis/pericarditis following a previous dose of an mRNA COVID-19 vaccine is not covered in this document but will be addressed in future updates. Refer to this [link](#) for the full NACI [Recommendations on the use of COVID-19 vaccines among individuals aged 12 years and older](#), and other NACI statements including [Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine \(10mcg\) in children 5 to 11 years of age](#).

Details of NACI's evidence-informed recommendation development process can be found elsewhere <sup>(1, 2)</sup>.

## RECOMMENDATIONS

The previous NACI recommendation continues to be maintained:

- 1. NACI preferentially recommends that a complete series with an mRNA COVID-19 vaccine should be offered to individuals 12 years and older without contraindications to the vaccine. (*Strong NACI Recommendation*)**

In addition, NACI now recommends that:

**1.a. For individuals aged 12 to 29 years receiving an mRNA COVID-19 vaccine primary series:**

- **The use of Pfizer-BioNTech Comirnaty (30 mcg dose) is preferred to Moderna Spikevax (100 mcg dose) to start or continue the mRNA primary vaccine series.**
- **The second dose of mRNA vaccine should be provided 8 weeks after the first dose as a longer interval between doses is associated with higher vaccine effectiveness and potentially lower risk of myocarditis/pericarditis.**

**1.b. For individuals aged 18 to 29 years who are eligible to receive a booster dose of vaccine\*:**

- **The use of Pfizer-BioNTech Comirnaty booster dose (30 mcg dose) may be preferred to Moderna Spikevax booster dose (50 mcg dose).**
- **The booster dose should be provided at least six months after completing the primary vaccine series.**

**1.c. For individuals aged 30 years or older receiving an mRNA COVID-19 vaccine primary series or booster dose:**

- **Either of the mRNA COVID-19 vaccines (Moderna Spikevax or Pfizer-BioNTech Comirnaty) should be used.**
- **The second dose of mRNA vaccine should be provided 8 weeks after the first dose as a longer interval between doses is associated with higher vaccine effectiveness and potentially lower risk of myocarditis/pericarditis.**
- **The booster dose should be provided at least six months after completing the primary vaccine series.**

\*The use of mRNA booster doses is not currently authorized among individuals aged less than 18 years.

NACI will continue to review the evidence as it emerges and update the recommendations as needed.

## Rationale and additional considerations

- NACI has reviewed the recent evidence and continues to strongly recommend the preferential use of mRNA COVID-19 vaccines instead of viral vector COVID-19 vaccines in all authorized age groups, due to better effectiveness of mRNA vaccines and the rare risk of other serious adverse events with viral vector vaccines, such as vaccine-induced immune thrombotic thrombocytopenia (VITT).
- The known risks of COVID-19 illness (including complications like myocarditis/pericarditis) outweigh the potential harms of having an adverse reaction following mRNA vaccination, including the rare risk of myocarditis or pericarditis which despite hospitalization, is relatively mild and resolves quickly in most individuals.
- In a context of sufficient vaccine supply and in order to maximize the benefits while minimizing the risks associated with vaccine; among individuals aged 12 to 29 years, the use of the Pfizer-BioNTech vaccine is preferred to the Moderna vaccine because of a lower reported rate of myocarditis/pericarditis following the Pfizer-BioNTech (30 mcg) compared to the Moderna (100 mcg) vaccine. The Pfizer-BioNTech COVID-19 vaccine (30 mcg) should be used to start or complete the mRNA primary vaccine series.
- For the booster dose, the use of the Pfizer-BioNTech 30 mcg booster dose may be preferred to the Moderna 50 mcg (i.e. half of the dose used in the primary series) booster dose among eligible individuals aged 18 to 29 years as a precaution due to the lower reported rate of myocarditis/pericarditis following the Pfizer-BioNTech 30mcg vaccine compared to the Moderna 100 mcg vaccine but data specific to the lower Moderna 50 mcg booster dose are limited. Further data will be assessed as it emerges.
- The use of mRNA booster doses is not currently authorized among individuals aged less than 18 years.
- Moderately and severely immunocompromised individuals may benefit from the slightly higher antibody levels generated and slightly higher vaccine effectiveness provided by the Moderna 100mcg vaccine compared to the Pfizer-BioNTech 30mcg vaccine. Given this potential benefit, administration of a Moderna vaccine may be considered in some immunocompromised individuals aged 12 to 29 years based on clinical judgement. For additional details, consult the NACI [Recommendations on the use of COVID-19 vaccines](#) and [Rapid response on the additional dose of COVID-19 vaccine in immunocompromised individuals following a 1- or 2-dose primary series](#).
- Individuals aged 12 to 29 years who have already received the Moderna 100mcg vaccine do not need to be concerned, as the risk of myocarditis/pericarditis with this vaccine is rare and events usually occur within a week following vaccination.
- Among individuals aged 30 years or older, either mRNA vaccines (Pfizer-BioNTech or Moderna) should be used to start or continue the mRNA vaccine series (primary series or booster dose) given that this age group has a lower risk of vaccine-associated myocarditis/pericarditis. Furthermore, in older age groups, COVID-19 infection is associated with a higher risk of complications (including myocarditis/pericarditis) and older adults may benefit from the slightly higher antibody titres observed with the Moderna 100mcg vaccine compared to the Pfizer-BioNTech 30mcg vaccine. Limited data suggests that protection from Moderna 100mcg may also be more durable compared to Pfizer-BioNTech 30mcg but more research is required.

- Refer to the [NACI updated guidance on booster COVID-19 vaccine doses in Canada](#) (December 3, 2021) for more information.
- Further data on the safety, immunogenicity and effectiveness of mRNA boosters will be assessed as it emerges.
- In all authorized individuals aged 12 years and older, the subsequent vaccine doses (second dose, additional dose among eligible immunocompromised individuals or booster dose among eligible individuals aged 18 years or older) should be provided in accordance with the NACI recommended intervals between doses. For additional details, consult the [NACI publications and statements](#) which include: [Recommendations on the use of COVID-19 vaccines](#), [NACI rapid response: Booster dose of COVID-19 vaccine in long-term care residents and seniors living in other congregate settings](#) and [NACI rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following a 1- or 2-dose primary series](#)

## Summary of Evidence

- There are many potential causes of myocarditis and pericarditis, including both infectious and non-infectious causes, and disease severity can be variable <sup>(3)</sup>.
- Myocarditis can occur as a complication of COVID-19 infection. In Israel, COVID-19 infection has been estimated to cause myocarditis at a rate of 11.0 events per 100,000 persons among individuals aged 16 years and older <sup>(4)</sup>. A retrospective study from the US found myocarditis (or pericarditis or myopericarditis) rates after primary COVID-19 infection to be as high as 45 cases per 100,000 patients in young males aged 12 to 17 years <sup>(5)</sup>.
- Further analyses of Canadian data continue to show that with the primary series, the incidence of myocarditis is rare with either mRNA vaccines, but higher following the Moderna 100 mcg vaccine compared to the Pfizer-BioNTech 30mcg vaccine <sup>(6)</sup>. The product-specific risk is highest following the second dose and among males aged 12 to 29 years. Similar trends were observed in other countries including US <sup>(7-9)</sup>, France <sup>(10)</sup> and Nordic countries (unpublished data from Denmark, Finland, Norway and Sweden) <sup>(11)</sup>. In Canada, as of November 12, 2021, the overall reported rate of myocarditis/pericarditis was 3.0 per 100,000 doses administered following any dose of the Moderna 100 mcg vaccine compared to 1.9 per 100,000 doses administered following any dose of the Pfizer-BioNTech 30 mcg vaccine. The reported rates of myocarditis/pericarditis among males 18 to 29 years after the second vaccine dose were of 15.9 per 100,000 for the Moderna 100 mcg vaccine and 2.6 per 100,000 for the Pfizer-BioNTech 30 mcg vaccine. To date, there has been one case of myocarditis/pericarditis following vaccination with the Moderna 100 mcg vaccine within the 12 to 17 year age group. The reporting rate among males 12 to 17 years after the second vaccine dose was 8.6 per 100,000 for the Pfizer-BioNTech 30 mcg.
- Preliminary unpublished analyses of Canadian data suggest that longer intervals between the first and second vaccine doses of mRNA vaccines are associated with lower reported rates of myocarditis/pericarditis compared to shorter intervals.
- Preliminary data from the US based on assessments by health care providers (n=47) indicate that by 3 months after vaccination, 91% of individuals with myocarditis following

mRNA COVID-19 vaccination had fully (74%) or probably fully (17%) recovered. However, 2% had the same cardiac status as at initial diagnosis and 6% had improved but not fully recovered. Long-term follow up of patients with myocarditis and/or pericarditis following mRNA COVID-19 vaccination is ongoing in the US and in other countries and new data will be assessed as they emerge.

- In Israel where the Pfizer-BioNTech vaccine primary series has usually been administered at a 21-day interval between doses 1 and 2; preliminary results on the safety of a booster dose of Pfizer-BioNTech 30mcg vaccine (usually administered at least 5 months after the primary series) among individuals aged 12 years and older suggest that the incidence of myocarditis after the third dose is lower compared to after the second dose but higher compared to after the first dose. After the booster dose, the highest incidence of myocarditis/pericarditis continues to be reported in males aged 12 to 29 years. As noted above, there are currently limited data on the safety of the Moderna 50 mcg booster dose and the risk of myocarditis/pericarditis with this booster dose is unknown.
- Clinical trial data available to date have shown that both authorized mRNA COVID-19 vaccines are highly efficacious ( $\geq 94\%$ ) in preventing confirmed symptomatic COVID-19 disease in the short term <sup>(12, 13)</sup>. New evidence suggests slightly higher vaccine effectiveness against SARS-CoV-2 infection and/or COVID-19-related hospitalization with the Moderna 100 mcg vaccine compared to the Pfizer-BioNTech 30 mcg primary vaccine series <sup>(14-20)</sup>. Emerging evidence is also suggestive of a more durable immune response being mounted in recipients of the Moderna 100 mcg vaccine <sup>(21-29)</sup>. Studies investigating differences between these two mRNA COVID-19 vaccines are ongoing and new effectiveness and immunogenicity data will be assessed as they emerge.

#### Unknowns:

- The risk of recurrence of myocarditis/pericarditis following receipt of additional doses of any of the authorized COVID-19 vaccines is unknown at this time. Very few cases of revaccination in these individuals have been described in published studies <sup>(30-32)</sup>.
- Investigations into the possible mechanisms of action, risk of recurrence, long-term outcomes, risk following booster doses and identification of potential risk factors of these cases of myocarditis and/or pericarditis continue in Canada and abroad. NACI will continue to review the evidence as it emerges and update the recommendations as needed.

For additional details on myocarditis/pericarditis following COVID-19 vaccination among individuals aged 12 years and older, refer to the [Recommendations on the use of COVID-19 vaccines](#) and [Recommendation on the use mRNA COVID-19 vaccines in adolescents 12 to 17 years of age](#) statements from NACI.

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## TABLES

**Table 1. Strength of NACI Recommendations**

<b>Strength of NACI 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/may not be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

## ABBREVIATIONS

<b>Abbreviation</b>	<b>Term</b>
COVID-19	Coronavirus disease 2019
mcg	microgram
mRNA	Messenger Ribonucleic Acid
NACI	National Advisory Committee on Immunization
PHAC	Public Health Agency of Canada
US	United States
VITT	Vaccine-induced immune thrombotic thrombocytopenia

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