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

Updated guidance on a first booster dose of COVID-19 vaccines in Canada

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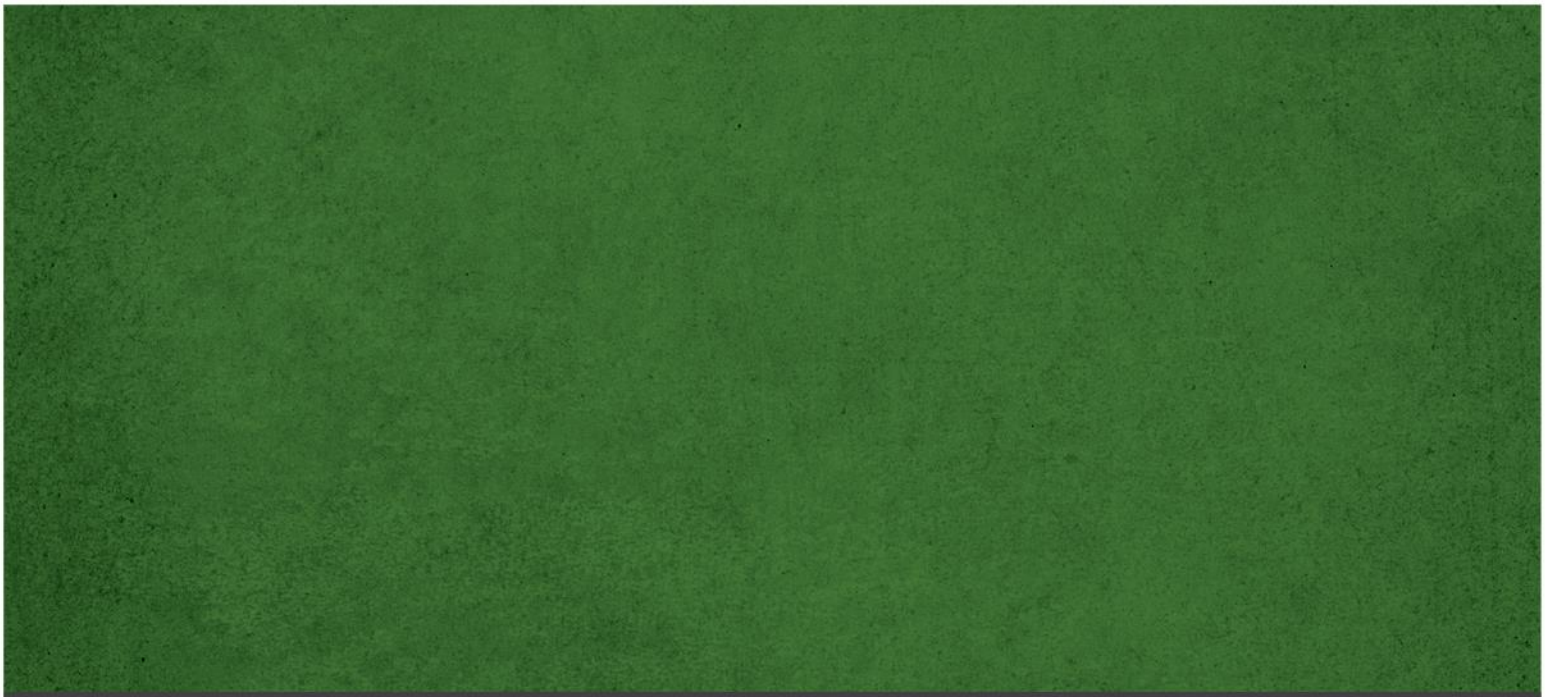

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

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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.

BACKGROUND

On September 28, 2021, NACI published guidance on booster COVID-19 vaccine doses in long-term care residents and seniors living in other congregate settings. On October 29, 2021, NACI published interim guidance on booster COVID-19 vaccine doses in Canada. On December 3, 2021, NACI published updated guidance on booster COVID-19 vaccine doses in Canada for adults 18 years of age and older. The recommendations on booster doses of COVID-19 vaccines were reviewed and reaffirmed in the context of the Omicron (B.1.1.529) variant of concern (VOC) on December 14, 2021. Since that time:

- NACI released advice on the use of booster COVID-19 vaccine doses in adolescents 12 to 17 years of age (January 28, 2022), the timing of COVID-19 vaccination for individuals previously infected with SARS-CoV-2 (February 4, 2022), the use of Novavax Nuvaxovid COVID-19 vaccine (February 17, 2022), the use of Medicago Covifenz COVID-19 vaccine (March 11, 2022), and initial guidance on the use of a second booster dose of COVID-19 vaccines (April 5, 2022);
- The Omicron variant is partially evasive of previous immunity conferred by COVID-19 vaccines or a previous SARS-CoV-2 infection, which supports additional vaccine booster recommendations. The Omicron wave had been abating nationally in Canada, but there is now a rise in cases with an increasing proportion of infections being attributed to the Omicron sub-variant BA.2;
- Vaccine effectiveness data following first and second booster doses have emerged.

NACI continues to monitor rapidly evolving scientific data recognizing that the trajectory of the COVID-19 pandemic remains unclear.

NACI's recommendations are aligned with the goals of the Canadian COVID-19 Pandemic Response that were updated on February 14, 2022:

- To minimize serious illness and death while minimizing societal disruption as a result of the COVID-19 pandemic; and
- To transition away from the crisis phase towards a more sustainable approach to long term management of COVID-19.

METHODS

NACI's recommendations on booster doses are based on the decision-making framework outlined in the published statement entitled Interim guidance on booster COVID-19 vaccine doses in Canada (October 29, 2021). Recommendations are based on evidence of the *need for* (e.g., evidence of decreased vaccine effectiveness against severe illness and/or infection depending on the population) and *benefit of* (e.g., safety and effectiveness) a booster dose in the Canadian context.

On March 1st and March 22nd, 2022, NACI reviewed data on the current epidemiology of COVID-19 nationally and internationally, along with additional evidence included in published scientific literature and preprints, regarding the duration of protection from a COVID-19 vaccine primary series and the efficacy/effectiveness and safety of a first booster dose (i.e., third dose in most individuals) for adults and adolescents. Additionally, NACI reviewed the manufacturer's clinical data available in the regulatory submission to Health Canada to support the expanded indication

of Pfizer-BioNTech Comirnaty (30 mcg) as a booster dose among individuals 16 to 17 years of age. NACI approved these updated recommendations on April 6, 2022.

For further information on NACI's recommendations on the use of COVID-19 vaccines, please refer to National Advisory Committee on Immunization (NACI): Statements and publications and the COVID-19 vaccine chapter in the Canadian Immunization Guide (CIG).

Further information on NACI's process and procedures is available elsewhere [1,2].

RECOMMENDATIONS

NACI's updated recommendations on the use of a first booster dose of COVID-19 vaccine in Canada are presented below, with additional considerations on when to offer the booster dose in light of the current context of the pandemic.

NACI continually assesses the evidence and evaluates recommendations in light of this evidence. Based on strong accumulated real-world evidence, NACI's recommendation for a first booster dose in adults 18-49 years (published December 3, 2021) has been strengthened from "discretionary" to "strong." NACI's recommendation for a first booster dose in adolescents 12-17 years of age (published January 28, 2022) who may be at higher risk of severe outcomes from COVID-19 infection has also been strengthened from "discretionary" to "strong". NACI has also added a new "discretionary" recommendation for a first booster dose in all other adolescents.

Please see Table 1 for an explanation of strong versus discretionary NACI recommendations.

With NACI's updated recommendations, a first booster dose may now be offered to everyone 12 years of age and over. Given the current resurgence in cases due to the increased transmissibility of the Omicron BA.2 sub-lineage and the lifting of public health measures, NACI's updated recommendations may help to further reduce infections and severe disease. Protection is highest soon after the booster dose is given.

NACI continues to strongly reiterate previous evidence-informed recommendations for the primary series of COVID-19 vaccines in the authorized age groups. Additional details are available in the COVID-19 vaccine chapter in the Canadian Immunization Guide and NACI Statements and publications (see Table 2).

Details on options and considerations for vaccine types and timing of administration among certain adult populations for the primary series and booster dose were last updated in Table 4 of NACI statement: Recommendations on the use of Medicago COVID-19 vaccine (Covifenz).

1. **NACI recommendation for a first booster dose of COVID-19 vaccine in adults:**

   NACI recommends that a first booster dose of an authorized COVID-19 vaccine[1,2] should be offered ≥6 months after completion of a primary COVID-19 vaccine series to adults ≥18 years of age. An mRNA COVID-19 vaccine dose is preferred for the booster dose.

   (Strong NACI recommendation)

   [1]The use of Pfizer-BioNTech Comirnaty (30 mcg) booster dose may be preferred to Moderna Spikevax (50 mcg) booster dose for those 18 to 29 years of age due to the lower risk of myocarditis/pericarditis with Pfizer-BioNTech Comirnaty compared to Moderna Spikevax.

   [2] If Moderna Spikevax is used for the booster dose, the 100 mcg dose may be preferred for the following groups: adults 70 years of age and over, adults living in long-term care or other congregate living settings that provide care for seniors, and those who are moderately to severely immunocompromised (based on clinical discretion).

2. **NACI recommendations for a first booster dose of COVID-19 vaccine in adolescents:**

   2.1 For the following groups, the NACI recommendation has been strengthened from "discretionary" to "strong". NACI now recommends that a booster dose of an mRNA COVID-19 vaccine[3] should be offered ≥6 months after completion of a primary COVID-19 vaccine series to adolescents 12 to 17 years of age:

   - **with an underlying medical condition that puts them at high risk of severe illness due to COVID-19** (Note: this would be a fourth dose for those who are moderately to severely immunocompromised and who received a 3-dose primary series);
   - **who are residents of congregate living settings** (e.g., shelters, group homes, quarters for migrant workers, correctional facilities);
   - **who belong to racialized and/or marginalized communities disproportionately affected by COVID-19**.

   (Strong NACI recommendation)

The above-mentioned adolescents may experience biological and/or social risk factors that may intersect, and some may experience systemic barriers to accessing health care.

For all other adolescents, a new recommendation has been added:

2.2 NACI recommends that a booster dose of an mRNA COVID-19 vaccine[3] may be offered ≥6 months after completion of a primary COVID-19 vaccine series to all other adolescents 12 to 17 years of age in the context of heightened (ongoing or novel) epidemiological risk.

(Discretionary NACI recommendation)

[3]The use of Pfizer-BioNTech Comirnaty (30 mcg) booster dose is preferred to Moderna Spikevax (50 mcg) booster dose as there are currently no data on the use of Moderna Spikevax (50 mcg) booster dose in adolescents 12 to 17 years of age.

Considerations on when to offer the first booster dose:

- NACI recommends at least a 6-month interval between completion of the primary series and the booster dose, as more time between doses may result in a better response.
- For individuals previously infected with SARS-CoV-2, timing of recent SARS-CoV-2 infection should also be considered. NACI has suggested a 3-month interval between infection and COVID-19 booster dose (i.e., 3 months after symptom onset or positive test if asymptomatic) or 6 months from the most recent vaccine dose, whichever is longer.
- Protection from the booster dose is highest in the period following administration, with the level and duration of protection against infection and severe disease expected to vary based on the immune evasive characteristics of the circulating SARS-CoV-2 strain.
- Due to waning of protection over time, the net benefits of a booster dose are highest when there is considerable viral circulation and may be limited during a time of low disease incidence, particularly if there is an extended period of time before the next wave of SARS-CoV-2.
- Beyond this current wave dominated by Omicron BA.2, the future trajectory of the COVID-19 pandemic remains uncertain. It is possible that, consistent with other respiratory viruses, incidence of COVID-19 will decrease in the summer and increase again in the fall and winter seasons
- There will be variability in how each province, territory and community assesses risk and responds to the needs of their respective jurisdictions, with a focus on protecting those at highest risk for serious outcomes from COVID-19 infection.

NACI continues to monitor and assess the evidence as it emerges and will update its recommendations as needed.

SUMMARY OF EVIDENCE

Evolving epidemiology

- Surveillance data from March 2022 indicate regional variability in COVID-19 activity across Canada, with previous decreases in case incidence stabilizing at elevated levels or showing signs of resurgence in some jurisdictions (weekly rolling average of cases up 7% as of March 23rd, 2022, compared to the previous week), which is consistent with reported increases in wastewater surveillance and other surveillance methods that are less dependent on varying testing capacity across Canadian jurisdictions [(3)].

- The highest incidence of cases during the first Omicron wave occurred in individuals 18-29 years of age followed closely by individuals 40-49 years of age and 30-39 years of age, respectively. The Omicron wave had a smaller proportion of severe cases compared to the previous waves.
- Severe outcomes from COVID-19 continue to disproportionately affect the unvaccinated, with unvaccinated adults ≥18 years of age having a hospitalization rate between 7 (18-39 years of age) and 11 (60-79 years of age) times higher than adults of the same age groups vaccinated with a primary series plus a booster dose [(3)].
- There may continue to be a high burden of disease as public health measures are lifted and as the Omicron variant spreads. There remains considerable uncertainty with regard to the likelihood, timing and severity of any potential future wave of COVID-19 in Canada and this will be influenced by circulating strains/VOC or the emergence of new variants.
- For the most up to date information on the epidemiology of COVID-19 in Canada, please refer to the COVID-19 daily epidemiology update.

Coverage and protection from recent infection

- Given high rates of Omicron infection in younger individuals, a proportion of the population may have boosted their immune response following exposure and infection with the VOC of the virus. This can be considered when planning booster doses for those individuals, recognizing NACI's suggested interval between infection and a booster vaccine dose is 3 months after symptom onset or positive test (if asymptomatic) and provided it has been at least 6 months from completing the primary series.
- Approximately 53% of eligible individuals ≥12 years of age have received an additional dose of a COVID-19 vaccine after their primary series as of March 20, 2022. Additional dose coverage is lowest in the younger age groups, with 14%, 35%, 42% and 51% of individuals 12-17, 18-29, 30-39 and 40-49 years of age receiving an additional dose, respectively. In recent weeks, there has been a reduction in uptake, and booster dose coverage is plateauing at lower levels than first and second dose coverage.

Vaccine effectiveness (VE) against infection/symptomatic disease over time following a primary series

- While VE against SARS-CoV-2 infection following the completion of a primary series was originally demonstrated to be high (>90%) against the ancestral strain and earlier variants (e.g., Delta), VE against Omicron infection and symptomatic disease after an mRNA primary series is substantially lower and decreases with time from the second dose; protection is minimal by six months since the second dose in adults.
- In adolescents, protection against Omicron infection waned from 76% (95% CI: 71 to 81%) at <14 days to 46% (95% CI: 18 to 65%) [(4)] at 42 to 48 days after the primary series of Pfizer-BioNTech vaccine in a study from New York State. Waning protection against symptomatic Omicron infection was also noted in a UK study with VE against symptomatic disease in 16 to 17 year olds falling from 76.1% (95% CI: 73.4 to 78.6%) at 7 to 13 days after the primary series of Pfizer-BioNTech to 22.6% (95%CI: 14.5 to 29.9%) at 70 days [(5)]. VE against Omicron infection was 62% (95% CI: -28 to 89%) at ≥150 days after a Pfizer-BioNTech primary series in a US study [(6)].

VE against outcomes of clinical importance including severe disease over time following a primary series

- In adults, protection from a primary series against severe outcomes, such as hospitalization and deaths, has been more durable than protection against infection, with VE against severe disease estimated at approximately 65 to 85% with some decrease over time reported in some studies but not in others.
- In adolescents, protection against Omicron emergency department/urgent care clinic visits ranged from 34 to 45% (depending on the age of the adolescent) within 14 to 149 days of two-dose vaccination with Pfizer-BioNTech, but there was no observable protection at ≥150 days from the primary series (<5%). VE against hospitalization in the same study ranged from 92 to 94% within 14 to 149 days after the primary series and was 73 to 88% at ≥150 days [(7)]. In a New York State study based on surveillance data, VE against hospitalization in 12 to 17 year olds was maintained at ≥73% (95% CI: 53 to 87%) over the course of the study [(4)].
- Surveillance data from the US have reported high VE for the Pfizer-BioNTech Comirnaty (30 mcg) COVID-19 vaccine (2 dose series) in adolescents 12 to 18 years of age against multisystem inflammatory syndrome in children (MIS-C) (VE 91%; 95% CI: 78-97%) [(8)], however this study was conducted prior to the predominance of the Omicron variant, and it is unknown whether and to what extent protection wanes over time.

Vaccine effectiveness over time following a first booster dose

- VE in adults against infection/symptomatic disease for Omicron from a booster of mRNA vaccine is approximately 65% and in most studies, decreases over time since vaccination [(9-12)].
- Vaccine protection in adults against severe disease and hospitalization due to COVID-19 has been more durable than protection against symptomatic disease or infection, and is approximately 10 to 20% higher following a third dose (or first booster) compared to those who have only completed a primary series, reaching approximately 90% or more.
- Evidence regarding the duration of protection of a booster dose against severe disease is limited, with a few studies suggesting some decrease over time [(13,14)]. As an example, VE against hospitalization was 78% (95% CI: 67 to 85%) at ≥4 months in one US study [(14)].
- There are no data assessing the protection of a booster dose specifically against MIS-C or post-COVID-19 condition.
- There are emerging data on the VE of a booster dose against infection/symptomatic disease over time in adolescents showing similar trends as observed in adults [(15)].

Safety of a first booster dose

- A booster dose with an mRNA vaccine [(16)] or recombinant subunit [(17)] vaccine in the authorized aged groups have generally been well tolerated, and to date post-market safety data [(18-22)] have not identified safety concerns following booster doses beyond those recognized after the primary series.
- For the 2-dose primary series, male adolescents 12 to 17 years of age and male adults 18 to 29 years of age are groups at highest risk for the rare event of myocarditis/pericarditis following mRNA vaccine [(23-25)]. Most of the preliminary post market data suggests that incidence of myocarditis/pericarditis after mRNA vaccine booster is lower compared to dose 2 of the primary series [(19-22)]. Safety data reviewed in adolescents who received a booster dose were for Pfizer-BioNTech Comirnaty (30mcg) only.
- Evidence monitoring is ongoing.

Ethics, equity, feasibility, and acceptability (EEFA)

- Some populations are at increased risk of exposure to the SARS-CoV-2 virus (e.g., due to living settings) and/or at increased risk of severe COVID-19 disease (e.g., hospitalization and death) due to various biological (e.g., pre-existing medical conditions) and social (e.g., low socioeconomic status) factors that may intersect. Current evidence is limited with respect to biological and/or social risk factors associated with severe outcomes from COVID-19 in adolescents 12 to 17 years of age.
- For maximum benefit of the COVID-19 vaccination program, enhancing the uptake of the primary series remains of utmost importance, with the benefit enhanced by subsequent booster doses.
- NACI continues to acknowledge the importance of domestic as well as global vaccine equity to address the pandemic impact even as global vaccine supply increases, recognizing that challenges in access and distribution persist. The World Health Organization calls on individual countries to make vaccine booster dose policy decisions that balance the public health benefits to their population with support for global equity in vaccine access.
- NACI continues to recommend the following elements to guide ethical decision-making, as outlined in NACI's guidance on the Prioritization of Key Populations for COVID-19 Immunization:
    - Efforts should be made to increase access to immunization services to reduce health inequities without further stigmatization or discrimination, and to engage systemically marginalized populations and racialized populations in immunization program planning.
    - Jurisdictions should ensure close and rapid monitoring of safety, coverage and effectiveness of the vaccines in different key populations, as well as effective and efficient immunization of populations in hard-to-reach, remote and isolated communities.
    - Efforts should be made to improve knowledge about the benefits of vaccines in general and of COVID-19 vaccines as each becomes available, address misinformation, and communicate transparently about COVID-19 vaccine decisions.

Other considerations

- There is uncertainty regarding the duration of protection and the effectiveness of the current vaccines against new VOCs. Manufacturers are working on new COVID-19 vaccines, including multivalent vaccines and vaccines specifically targeting VOCs, although their exact composition and when they might be available is not yet known.
- Maximizing the benefit of protection of a booster dose will be affected by the interval between doses. Longer time between doses may result in a better response after any subsequent dose, as this allows time for the immune response to mature in breadth and strength. A longer interval may however also increase the chance of a period with waning (lower) protection while awaiting a next dose.
- The benefit of protection gained from booster doses will be affected by the evolving dynamics of the COVID-19 pandemic.

RESEARCH PRIORITIES

1. Continuous monitoring of data on the safety, immunogenicity, efficacy, and effectiveness of the COVID-19 vaccines, including booster doses, through clinical trials and studies in real-world settings. The research should include consideration of clinical implications of previous SARS-CoV-2 infection, MIS-C, post-COVID-19 condition, or myocarditis or pericarditis in adult, adolescent, and pediatric populations.
2. Further evaluations of the optimal interval between administration of booster doses, as well as further evaluations of the optimal interval between previous SARS-CoV-2 infection and booster dose administration.
3. Vigilant monitoring and reporting of adverse events of special interest, including myocarditis and pericarditis, in order to accurately inform potential risks associated with a booster dose and potentially subsequent booster doses.
4. Continuous monitoring of the emergence of SARS-CoV-2 VOCs at the provincial/territorial, national, and international level.
5. Continuous monitoring of COVID-19 epidemiology and VE in special populations (e.g. those with high-risk medical conditions) and the long-term consequences of COVID-19 in these populations.
6. Further evaluation of the optimal timing and trigger for the initiation of potential future booster dose recommendations, as well as evaluation of potential risks associated with providing booster doses earlier than necessary.
7. Continuous monitoring of vaccine uptake, particularly according to the socioeconomic status, and with consideration of measures that may reduce the risk of socioeconomic disparities in vaccine confidence and uptake.
8. Further evaluation on the optimal immunization schedule for COVID-19 vaccines (e.g., primary series and booster doses) for pregnant women.

Table 1. Strength of NACI Recommendations

Strength of NACI Recommendation *based on factors not isolated to strength of evidence* (e.g., public health need)	**STRONG**	**DISCRETIONARY**
Wording	"*should/should not be* offered"	"*may/may not be* offered"
Rationale	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
Implication	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 considered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

Table 2. NACI statements and publications on recommendations on the use of COVID-19 vaccines as a primary series in the authorized age groups

General population	NACI statement: 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 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 Summary of NACI advice on vaccination with COVID-19 vaccines following myocarditis (with or without pericarditis) NACI rapid response: Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2
Adults	NACI statement: Recommendations on the use of Novavax Nuvaxovid COVID-19 vaccine NACI statement: Recommendations on the use of Medicago COVID-19 vaccine (Covifenz)
Adolescents	NACI statement: Recommendation on the use of mRNA COVID-19 vaccines in adolescents 12 to 17 years of age
Pediatric	NACI statement: Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) in children 5 to 11 years of age NACI updated recommendations on the use of COVID-19 vaccines in children 5 to 11 years of age NACI statement: Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 to 11 years of age

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