

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

Guidance on the use of COVID-19 vaccines in the fall of
2023

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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 January 20, 2023, the National Advisory Committee on Immunization (NACI) published [Guidance on COVID-19 vaccine booster doses: Initial considerations for 2023](#), followed by [Guidance on an additional COVID-19 booster dose in the spring of 2023 for individuals at high risk of severe illness due to COVID-19](#) on March 3, 2023.

Since then, the World Health Organization (WHO) has determined that COVID-19 is an established and ongoing health issue and no longer constitutes a public health emergency of international concern ⁽¹⁾. Transition to the long-term management of the COVID-19 pandemic is now needed, but there continue to be uncertainties such as the ongoing epidemiology of COVID-19, duration of protection from current COVID-19 booster doses and previous infection, and vaccine effectiveness (VE) of future vaccines.

On May 18, 2023, the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) released recommendations for updates to COVID-19 vaccine antigen composition ⁽²⁾. An approach recommended by TAG-CO-VAC is a monovalent XBB.1 descendent lineage, such as XBB.1.5 or alternatively XBB.1.16. The International Coalition of Medicines Regulatory Authorities (ICMRA), European Centre for Disease Prevention (ECDC), the European Medicines Agency (EMA), and the US Food and Drug Administration Vaccines and Related Biological Products Advisory Committee (FDA VRBPAC) have also released decisions supporting XBB as a candidate for the COVID-19 vaccine composition update. Manufacturers have indicated that new COVID-19 vaccine formulations are in development and products are forthcoming.

Although seasonality of SARS-CoV-2 has not been established, other respiratory viruses such as influenza and respiratory syncytial virus (RSV) typically increase in the fall and winter months. To help reduce the impact of COVID-19 on the health system while other respiratory viruses are circulating and with the expected availability of a new COVID-19 vaccine formulation, NACI is providing guidance on the use of COVID-19 vaccines to inform planning for a vaccination program starting in fall 2023.

Methods

Following preliminary discussions on April 28, 2023, the NACI COVID-19 Working Group and full NACI membership reviewed, on May 23, 2023 and June 6, 2023 respectively, the available evidence on epidemiology, vaccine protection, hybrid immunity, safety, and concurrent administration of COVID-19 vaccine with the seasonal influenza vaccine. Preliminary modelling data were also considered, as well as equity, feasibility and acceptability considerations for a fall 2023 COVID-19 vaccination program. NACI approved these recommendations on June 26, 2023.

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

Further information on [NACI's process and procedures](#) is available elsewhere ^(3, 4).

Overview of Evidence

Available scientific literature (published or pre-print) as of May 19, 2023 is summarized below.

Epidemiology

- The evolutionary trajectory of SARS-CoV-2, including the emergence of novel variants of concern (VOCs), is uncertain and seasonality of SARS-CoV-2 has not been established.
- Recombinant XBB* sub-lineages continue to circulate in Canada and globally. XBB.1.5* is the most prevalent lineage in Canada but is declining as of May 19, 2023 with increases in other XBB* sub-lineages, such as XBB.1.16⁽⁵⁾.
- Seroepidemiologic studies demonstrate high levels of antibodies to spike antigen attributed to past COVID-19 vaccination and/or SARS-CoV-2 infection in the Canadian population⁽⁶⁾.
- Since the fall of 2022, national surveillance data has shown a surge in COVID-19 cases from late September to November 2022, and a smaller surge in December 2022 and January 2023. Weekly rates and number of cases, hospitalizations and deaths have shown gradual decreases since January 2023, and have been relatively stable up to May 17, 2023⁽⁷⁾.
- Rates of hospitalizations and deaths in Canada continue to be highest for adults 65 years of age and older, with risk increasing with age and highest among those ≥80 years and those who are unvaccinated. Among those under 18 years of age, rates of hospitalizations are highest in children under 1 year of age. Rates of infection and severe disease are lowest for those recently vaccinated⁽⁸⁾ and those with hybrid immunity, particularly if the previous infection was with a more recent Omicron strain⁽⁹⁻¹⁹⁾.
- In addition to age, vaccination status and prior history of SARS-CoV-2 infection, studies looking at risk factors continue to show individuals with comorbidities are at higher risk for severe outcomes due to COVID-19 in adults⁽²⁰⁾. Evidence on risk factors for severe COVID-19 illness in children is limited given the much lower incidence of severe illness in this population⁽²¹⁾.

Vaccine protection

Duration of vaccine protection of Omicron-containing bivalent mRNA vaccines

- Evidence from the US assessing VE of the BA.4/5 bivalent vaccine show emerging trends in waning vaccine protection against Omicron SARS-CoV-2 infection and hospitalization as was observed with the original monovalent vaccine^(22, 23). Waning protection against severe disease conferred by a bivalent booster dose has also been reported in a Finnish study (pre-print) in adults 65 years of age and older⁽²⁴⁾.
- Preliminary data from Ontario (preprint) demonstrates that short-term (<90 to 119 days) VE against severe outcomes in community dwelling adults 50 years of age and older was similar between those receiving original and bivalent mRNA vaccine booster doses and between the available vaccine products (Moderna Spikevax original or bivalent BA.1 and Pfizer-BioNTech Comirnaty original or bivalent BA.4/5) during a period when BA.5 was the predominant Omicron sub-lineage and BQ.1 was emerging⁽²⁵⁾.
- There are no data available on the duration of vaccine protection of bivalent mRNA vaccines in children and adolescents. The duration of vaccine protection of the original monovalent mRNA vaccines against infection and severe disease in children and adolescents has been very similar to the trends observed in adults.

- Several studies have reported waning VE against Omicron infection or symptomatic infection of original monovalent Pfizer-BioNTech Comirnaty in children 5 to 11 years of age (from approximately 40-70% to 20-40% within two months post vaccination with the primary series) ⁽²⁶⁻³⁴⁾, and of any original monovalent mRNA primary series in adolescents (from approximately 50-80% to 20-60% within two months post vaccination) ^(30, 34-37). Limited evidence has also shown waning VE against severe disease due to Omicron ^(26, 31, 32, 35, 37).
- There is emerging evidence of waning VE against infection following the primary series in children 6 months to under 5 years of age ^(26, 38).
- There is limited evidence that short term VE (1 to 3 months post-booster) against Omicron infection is restored after an original monovalent booster dose in children and adolescents 5 years of age and older ^(30, 33, 37), as well as subsequent waning protection after the booster dose ^(30, 39).

VE in individuals with hybrid immunity

- Hybrid immunity results from ≥ 1 exposure(s) from vaccination and ≥ 1 exposure(s) from SARS-CoV-2 infection (before or after vaccination). Earlier NACI statements have summarized evidence demonstrating that previous infection and vaccination may provide superior protection against VOCs, including Omicron, compared with vaccination alone, or previous SARS-CoV-2 infection without vaccination ⁽⁹⁻¹⁷⁾.
- Data have emerged estimating the relative VE of an Omicron-containing bivalent mRNA booster compared to those who did not receive a bivalent booster during a period when BA.5 was the predominant subvariant and stratified by prior documented infection status ^(18, 19). The studies demonstrate that the bivalent booster provided additional protection relative to the previous original monovalent booster dose in those without previous SARS-CoV-2 infection and in those with more distant previous infection.
 - A study in the Netherlands assessed relative VE of the bivalent BA.1 mRNA COVID-19 vaccine against SARS-CoV-2 Omicron infection among adults 18 to 85 years of age who had previously received primary vaccination and one or two monovalent booster doses. The relative VE of a BA.1 bivalent booster against infection in adults 18-59 years of age was highest in those with an earlier prior (pre-Omicron) infection (44%; 95% confidence interval [CI]: 13 to 64%), followed by those without a prior infection (32%; 95% CI: 14 to 47%), and lowest in those with an Omicron infection (20%; 95% CI: -7 to 40%). This trend was also observed in adults 60 to 85 years of age, with lower relative VE estimates ⁽¹⁸⁾.
 - A study in Italy assessed relative VE of the bivalent BA.4/5 mRNA COVID-19 vaccine against severe COVID-19 disease in adults 60 years of age and older who had previously received one monovalent booster ⁽¹⁹⁾. The relative VE of a BA.4/5 bivalent booster against severe COVID-19 disease was comparable between those with no prior infection (59%; 95% CI: 55 to 63%) and those with earlier prior pre-Omicron or Omicron infection (i.e., prior infection that occurred 27 to 39 weeks earlier and was predominantly BA.1 had a relative VE of 62%; 95% CI: 43 to 74% and prior infection 40 or more weeks earlier and was predominantly original and Alpha strains had a relative VE of 62%; 95% CI: 38 to 76%). Relative VE in those with prior infection occurring 17 to 26 weeks earlier was lowest but also imprecise (10%; 95% CI: -44 to 44%; predominantly BA.5 or BA.2 infection).
 - In the above studies, hybrid immunity from a previous original monovalent booster in the context of a more recent Omicron infection were not improved by a bivalent booster, possibly because protection from hybrid immunity remained high. Protection from hybrid immunity in vaccinated individuals who had an earlier

infection and/or earlier vaccination with the original monovalent COVID-19 vaccine would have had a longer time to wane, thereby contributing to higher relative VE after receiving a bivalent booster.

Vaccination of individuals who are pregnant

- Studies continue to support vaccination during pregnancy. Vaccination with original mRNA COVID-19 vaccines has been shown to confer protection to the pregnant individual as well as protection against Omicron SARS-CoV-2 infection and hospitalization in infants <6 months of age (who are not yet eligible for vaccination) when compared to infants of individuals who were unvaccinated or did not receive at least one dose (either dose 2 of a primary series or a booster dose) of COVID-19 vaccine during pregnancy ⁽⁴⁰⁻⁴³⁾. Protection in infants was highest in the first two months of life and decreased by four to six months of age ⁽⁴¹⁾.
- Systematic reviews assessing the safety of COVID-19 vaccines during pregnancy have not identified any adverse effects specific to pregnancy.
- No evidence on VE against infant outcomes is available for vaccination with bivalent mRNA vaccines in persons who are pregnant.

Post-COVID-19 Condition

- Post COVID-19 condition (PCC) is a condition in which symptoms following a SARS-CoV-2 infection persist for more than 8 weeks and are present for 12 or more weeks following the acute phase. Emerging evidence suggests that individuals may be less likely to report experiencing PCC symptoms if infected during the Omicron period compared to those infected with a pre-Omicron variant ⁽⁴⁴⁻⁴⁶⁾. Nonetheless it is estimated that approximately 10 to 20% of people who are infected with SARS-CoV-2 develop PCC ^(47, 48).
- To the extent that vaccination prevents infection, it also prevents PCC as those who do not become infected do not develop PCC. In addition, there is evidence that those who are vaccinated with at least two doses of the monovalent original COVID-19 vaccine before becoming infected are less likely to develop PCC than those who are not vaccinated before infection. Estimates of PCC protection from pre-infection vaccination vary between studies with a systematic review noting approximately one-third less PCC among two-dose vaccinated people compared to unvaccinated people (OR, 0.64; 95% CI, 0.45–0.92%) ⁽⁴⁹⁾. A third dose of COVID-19 vaccine may offer additional protection against PCC compared to receiving one to two doses ^(50, 51). Vaccination has not been associated with a higher risk of developing PCC or worsening PCC symptoms.
- Evidence of any positive benefit on PCC from vaccination post-infection is limited ^(44-46, 49).
- There are no studies to date evaluating the effectiveness of bivalent vaccines specifically in reducing the risk of developing PCC.

Safety of Omicron-containing bivalent mRNA COVID-19 vaccines

- The safety profile of the bivalent mRNA COVID-19 vaccine boosters is comparable to that of original mRNA COVID-19 vaccine boosters among individuals in the authorized age group for mRNA booster doses (i.e., those 5 years and older).
- A statistical signal for ischemic stroke among adults 65 years of age and older was detected in the US Vaccine Safety Datalink (VSD) following administration of Pfizer-BioNTech Comirnaty BA.4/5. This signal has weakened over time since it was first detected in October 2022 and is no longer being detected. It was not noted in the VSD for the Moderna bivalent booster ⁽⁵²⁾.
- No evidence of a safety signal has been detected for ischemic stroke with either mRNA COVID-19 bivalent boosters in other US safety surveillance systems (as of April 2, 2023)

⁽⁵²⁾, nor in Canada (as of April 28, 2023) ⁽⁵³⁾, other international regulatory and public health safety monitoring systems, or in global vaccine safety monitoring by Pfizer-BioNTech. A study from England published on June 15, 2023 assessing BA.1 bivalent mRNA vaccines and stroke in adults 50 years of age and older also found no evidence of increased risk of stroke, including among individuals who concurrently received an influenza vaccine ⁽⁵⁴⁾.

- Further investigation into the signal in the VSD system revealed that it was seen with concurrent administration of Pfizer-BioNTech bivalent vaccine and high-dose or adjuvanted influenza vaccines, but not with concomitant administration with standard-dose influenza vaccine or when the bivalent Pfizer-BioNTech vaccine was administered alone.
- Recommendations in the US to give concurrent COVID-19 and influenza vaccines have not changed because of the potential signal identified in VSD. Monitoring regarding this safety signal continues.

Concurrent administration with influenza vaccination

- Except for the ischemic stroke potential safety signal from the VSD noted above, no safety concerns have been identified to date with the concurrent administration of COVID-19 vaccines and influenza vaccines ⁽⁵⁵⁻⁵⁷⁾.
- Higher reactogenicity has been observed following concurrent administration of original mRNA COVID-19 vaccines with influenza vaccination compared to influenza vaccination alone, but reactogenicity was comparable to receipt of the COVID-19 vaccine alone ⁽⁵⁵⁾.
- Two studies in health care workers have observed a reduced immunologic response to the Pfizer-BioNTech Comirnaty original vaccine when concurrently administered with a quadrivalent influenza vaccine ^(56, 58). A reduced immunologic response was also noted in a clinical trial assessing concurrent administration of Novavax Nuvaxovid with influenza vaccines ⁽⁵⁹⁾, without an impact on vaccine efficacy for Novavax Nuvaxovid. In another clinical trial, a reduced immune response was not observed in adults aged 65 years and older who received a third dose with Moderna Spikevax original at the same time as a high-dose quadrivalent influenza vaccine ⁽⁶⁰⁾.
- NACI continues to monitor the safety of concurrent administration of COVID-19 vaccines and other vaccines, including the seasonal influenza vaccine.

Ethics, equity, feasibility, and acceptability (EEFA)

- Over the course of the COVID-19 pandemic, many NACI recommendations have been put forward to address the complex vaccine product landscape, reflecting the knowns and unknowns in the available evidence on vaccine protection against SARS-CoV-2-related outcomes, including infection, and symptomatic and severe disease. The transition to a more sustainable approach to the long-term management of COVID-19 includes learning how to manage the COVID-19 vaccine program alongside other public health priorities and longstanding vaccination programs.
- Where possible, simplifying and streamlining the COVID-19 vaccine recommendations for a fall program would facilitate implementation and ease of communication for both provincial and territorial vaccination programs and individual health care providers. However, it continues to be important to highlight specific populations for whom vaccination is particularly important due to biological and/or social risk factors.
- Fewer severe outcomes of COVID-19 have been reported for children (i.e., hospitalizations due to COVID-19, ICU admission, and deaths) compared to older age groups, and COVID-19 vaccine uptake has been low to very low among children under 12 years of age (only 6% of children 6 months to 4 years and 40% of children 5 to 11 years of age have completed a primary series as of June 18, 2023) ⁽⁶¹⁾. While most children may

have mild or no symptoms, some are at higher risk of severe disease due to COVID-19 or developing PCC. Individual benefit-risk assessments may favour vaccination based on factors including a child's health status.

- In the fall of 2023, it is anticipated that jurisdictions will likely combine the COVID-19 and influenza vaccination campaigns for operational and logistical reasons. For all currently vaccine-eligible age-groups (i.e., 6 months of age and older for the primary series; 5 years of age and older for booster doses), concurrent administration of any dose of a COVID-19 vaccine with other vaccines (including the seasonal influenza vaccine) has the potential to increase program efficiency and may also increase vaccine coverage. The clinical significance of somewhat lower immunogenicity noted in some studies with concomitant COVID-19 and influenza vaccine administration is uncertain.
- There may be variability in how each province, territory and community assesses risk and responds to the needs of their respective jurisdictions.

Other considerations

- TAG-CO-VAC has advised that new COVID-19 vaccine formulations should aim to induce antibody responses that neutralize XBB descendent lineages (such as XBB.1.5 or alternatively XBB.1.16), which are the lineages predominantly circulating globally at present. These sublineages have also been demonstrated to be some of the most immune evasive variants to date, based on neutralizing antibody data from individuals vaccinated with current COVID-19 vaccines. TAG-CO-VAC also advised that future formulations of COVID-19 vaccines should move away from inclusion of the original SARS-CoV-2 virus given that the strain is no longer circulating in humans ⁽²⁾.
- On June 15, 2023, US FDA VRBPAC recommended an update to the COVID-19 vaccine with a monovalent XBB* targeted formulation after reviewing evidence on epidemiology and pre-clinical and clinical data showing that monovalent XBB-targeted vaccines had similar or slightly higher immune responses against XBB-derivatives compared to bivalent XBB-targeted vaccines ⁽⁶²⁾.
- Changes to the vaccine formulations are anticipated; however, the vaccine products that will be available in the coming months have yet to be determined.
- Modelling suggests that an additional vaccine dose offered in the fall of 2023 could be expected to prevent thousands of hospitalizations and deaths across the country over the next year. Modelled estimates are dependent on various assumptions, such as durability of protection from vaccination and/or infection and the possibility of a seasonal resurgence in infections.

Recommendations

Please see [Table 1](#) for an explanation of strong versus discretionary NACI recommendations.

NACI continues to recommend COVID-19 vaccination for those who have not been immunized, as follows:

1. Individuals 5 years of age and older should be immunized with a primary series of an mRNA vaccine. **(Strong NACI recommendation)**
2. Children 6 months to under 5 years of age may be immunized with a primary series of an mRNA vaccine. **(Discretionary NACI recommendation)**

Regarding the product offered, when mRNA vaccines are used for the primary series, the bivalent Omicron-containing vaccines can be used for anyone 6 months of age and older. More information is available in the [NACI interim guidance on the use of bivalent Omicron-containing COVID-19 vaccines for primary series](#).

For **booster doses**, previously NACI has recommended that at least one booster dose should be offered to all adults 18 years of age and over, and adolescents 12 to 17 years of age who are at increased risk of severe illness, along with additional specific population recommendations in the [fall of 2022](#) and [spring of 2023](#).

Additional details including those pertaining to vaccine schedule (e.g., number of doses, interval between doses) and alternative vaccine products, are available in the [COVID-19 vaccine chapter](#) of the Canadian Immunization Guide and NACI [statements and publications](#).

3. **Beginning in the fall of 2023 for those previously vaccinated against COVID-19, NACI recommends a dose of the new formulation of COVID-19 vaccine for individuals in the authorized age group if it has been at least 6 months from the previous COVID-19 vaccine dose or known SARS-CoV-2 infection (whichever is later).**

Immunization is particularly important for those at increased risk of COVID-19 infection or severe disease, for example:

- Adults 65 years of age or older
- Residents of long-term care homes and other congregate living settings
- Individuals with [underlying medical conditions](#) that place them at higher risk of severe COVID-19
- Individuals who are pregnant
- Individuals in or from First Nations, Métis and Inuit communities*
- Members of racialized and other equity-deserving communities
- People who provide essential community services

(Strong NACI Recommendation)

* Autonomous decisions should be made by Indigenous Peoples with the support of healthcare and public health partners in accordance with the [United Nations Declaration on the Rights of Indigenous Peoples](#).

Rationale and additional considerations:

- A booster dose starting in the fall of 2023 is expected to increase protection against SARS-CoV-2 infection and COVID-19 symptomatic and severe disease that has waned since the last booster vaccination or SARS-CoV-2 infection. Increased protection will help to reduce the impact of COVID-19 on the health system while other respiratory viruses, including influenza and RSV are circulating in the fall and winter of the 2023-2024 respiratory virus season.
- Prior infection along with vaccination (hybrid immunity) offers greater protection against infection and severe disease than vaccination or prior infection alone, particularly when hybrid immunity is in the context of a recent Omicron infection. For this reason, an additional dose of vaccine starting this fall is particularly important for those who have not been previously infected and have protection from vaccination alone. However, even with hybrid immunity, protection against infection will decrease over time and the duration of protection against severe disease varies between studies and is unknown in the context of currently circulating variants. There are no known safety risks with receiving a vaccine after a recent SARS-CoV-2 infection, although evidence shows that the antibody response is higher with longer intervals between infection and vaccination.
- Vaccination of individuals at higher risk for severe COVID-19 will help to reduce their risk of severe disease that could potentially result in hospitalization and death; thus it is particularly important for these individuals to receive a booster dose starting in the fall of 2023.
- Vaccination of individuals at lower risk for severe disease may provide additional benefit to those at higher risk through indirect protection, particularly shortly after vaccination and in the context of hybrid immunity when protection from infection is greatest. There could also be other benefits such as reducing the risk of PCC, but the extent and duration of the benefits are uncertain. Vaccination of health care providers and others who provide essential community services is expected to be important in maintaining health system capacity.
- Booster doses in the fall will be formulations updated to target more recent, immune-evasive SARS-CoV-2 variants. Individuals vaccinated with the updated formulation are expected to benefit from a better immune response against these variants compared to current vaccines.
- mRNA vaccines remain the preferred COVID-19 vaccine product. A Novavax Nuvaxovid booster should be offered to those 18 years of age and over who are unwilling or unable to receive an mRNA vaccine if it has been at least 6 months from the previous COVID-19 vaccine dose or SARS-CoV-2 infection (whichever is later). Individuals waiting for a new formulation of Novavax Nuvaxovid should assess their individual risk if choosing to delay vaccination.
- COVID-19 vaccines may be given concurrently (i.e., same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines).

- NACI will continue to monitor the safety and effectiveness of COVID-19 vaccines, including the safety of concurrent administration with other non-COVID-19 vaccines, such as the seasonal influenza vaccine.

NACI will review available information on the new vaccine formulations expected for the fall of 2023 and update recommendations as needed. NACI will continue to monitor the evidence, including SARS-CoV-2 epidemiology and duration of vaccine protection, particularly with regard to severe outcomes, to provide recommendations on the timing of subsequent booster doses if warranted.

RESEARCH PRIORITIES

1. Continuous monitoring of data on the safety, immunogenicity, efficacy, and effectiveness of COVID-19 vaccines, including with the new formulation, through clinical trials and studies in real-world settings, including the degree and duration of protection conferred by each booster dose against circulating variants. The research should also consider the clinical implications of previous SARS-CoV-2 infection; repeated immunization; and outcomes after infection such as PCC.
2. Further evaluations of the optimal interval between dose administration, as well as further evaluations of the optimal interval between previous SARS-CoV-2 infection and vaccine dose administration.
3. Vigilant monitoring and reporting of adverse events of special interest, including myocarditis and/or pericarditis, to accurately inform potential risks associated with any future booster doses. Global collaboration should be prioritized to enable data sharing so decision makers around the world can weigh benefits and risks of additional booster doses of COVID-19 vaccines.
4. Continuous monitoring of COVID-19 epidemiology in children, including risk factors for severe outcomes and long-term consequences of infection with SARS-CoV-2.
5. Continuous monitoring of COVID-19 epidemiology and VE in special populations at high risk of severe outcomes or long-term consequences of infection with SARS-CoV-2.
6. Further evaluations on the safety, immunogenicity, and effectiveness on the concurrent administration of COVID-19 vaccines with other vaccines across different age groups, including concurrent administration with high dose or adjuvanted influenza vaccine.
7. Further evaluation on 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.
8. Continuous monitoring of vaccine coverage in Canada, for COVID-19 vaccines and other routine vaccines, particularly in the context of COVID-19 vaccine booster doses and including consideration of measures that may reduce the risk of disparities in vaccine confidence and uptake across different sub-populations.
9. Continuous monitoring of epidemiology, SARS-CoV-2 variants, and seasonal trends to inform future programs.

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	<i>“should/should not be offered”</i>	<i>“may/may not be offered”</i>
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.

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