

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

Addendum to the guidance on the use of COVID-19
vaccines in the fall of 2023

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Addenda aux directives sur l'utilisation des vaccins contre la COVID-19 à l'automne 2023

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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.

Use of the XBB.1.5-containing formulation

- On July 11, 2023, the National Advisory Committee on Immunization (NACI) [Guidance on the use of COVID-19 vaccines in the fall of 2023](#) was published. This advice was developed to support provinces and territories in preparing for a fall program. It describes anticipated updates to the COVID-19 vaccines, and frames the recommendations in relation to the new formulation of COVID-19 vaccines expected to become available in fall 2023.
- On September 12, 2023, Health Canada authorized an XBB.1.5-containing mRNA COVID-19 vaccine for use in individuals 6 months of age and older. Submissions for two other updated COVID-19 vaccines are still under review by Health Canada.
- NACI reaffirms the July 11, 2023 recommendation, now specifically using the XBB.1.5-containing COVID-19 vaccine as follows:

Beginning in the fall of 2023 for those previously vaccinated against COVID-19, NACI recommends a dose of the XBB.1.5-containing 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)

* It should be noted that booster vaccination using shorter intervals (i.e. 3 months to < 6 months) following previous vaccination or infection has not been shown to pose a safety risk, though evidence shows that the antibody response is higher with longer intervals between infection and vaccination and with longer intervals between vaccination doses

** 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](#).

For additional details, please see [NACI Guidance on the use of COVID-19 vaccines in the fall of 2023](#).

Epidemiology and the XBB.1.5-containing COVID-19 vaccine

- Recombinant XBB* sub-lineages continue to circulate in Canada and globally. From sequencing data up to the week of August 6, 2023, XBB.1.9.2* is the most prevalent lineage in Canada, and is expected to become the dominant lineage group in the following

weeks ⁽¹⁾. EG.5* is a sub-lineage of XBB.1.9.2*. Its prevalence has been steadily increasing in Canada, and is the most prevalent lineage group globally as of the week of July 30.

- Individuals vaccinated with the updated XBB.1.5-containing COVID-19 vaccine are expected to benefit from a better immune response against currently circulating strains, compared to earlier formulations. Preliminary clinical data demonstrated that a booster dose of a monovalent XBB.1.5-containing COVID-19 vaccine generated similar immune responses against XBB* sub-lineages XBB.1.5, XBB.1.16 and XBB.2.3.2 ⁽²⁾.

Use of the XBB.1.5-containing COVID-19 vaccines

- Health Canada has authorized the XBB.1.5-containing COVID-19 vaccine for use in those not previously vaccinated (previously referred to as the primary series) and those previously vaccinated (previously referred to as the booster dose).

Considerations for those who have been previously vaccinated (i.e. completed a primary series)

- This is the first time an additional dose of the COVID-19 vaccine has been authorized for children 6 months to less than 5 years of age who have been previously vaccinated with a primary series (i.e., a booster dose is now authorized for this age group). While most children under 12 years of age may have mild or no symptoms when infected with SARS-CoV-2, some are at higher risk of severe disease due to COVID-19; and post-COVID-19 condition can occur in children. Individual benefit-risk assessments may favour vaccination based on factors including a child's health status and local epidemiology. For additional information on epidemiology in children, please see [NACI Guidance on the use of COVID-19 vaccines in the fall of 2023](#).
- NACI will continue to monitor the evidence, including SARS-CoV-2 epidemiology and duration of vaccine protection, particularly regarding severe outcomes, to provide recommendations on the timing of subsequent doses if warranted. It is currently unclear whether there should be an annual COVID-19 vaccination program, similar to annual influenza vaccine programs.

Considerations for those not previously vaccinated

- NACI's fall guidance outlines recommendations to support provinces and territories with fall 2023 program planning for those previously vaccinated against COVID-19.
- NACI acknowledges the use of the XBB.1.5 formulation and changes to the vaccine schedule for individuals who have not been previously vaccinated in the product monograph.
- In the coming months NACI will assess the available COVID-19 vaccine formulations and products, optimal number of doses of COVID-19 vaccines and other considerations for individuals who have not been previously vaccinated in various populations (e.g., by age and for those who are immunocompromised). This will be particularly relevant for the youngest populations, some of whom may not yet have been exposed to the SARS-CoV-2 virus.
- In the interim, XBB.1.5-containing vaccine can be used to initiate the series and the current NACI recommendations on vaccine interchangeability can apply to XBB.1.5-containing COVID-19 vaccines if used to complete a primary series started with a different

formulation (either original monovalent wild type-containing or bivalent vaccine). Regardless of which product is offered to start a primary series, the previous dose should be counted and the series need not be restarted.

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](#) in the [Canadian Immunization Guide \(CIG\)](#).

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.

Acknowledgments

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