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

Guidance on an additional dose of COVID-19 vaccines in the spring of 2024 for individuals at high risk of severe illness due to COVID-19

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Directives sur l'administration d'une dose supplémentaire de vaccins contre la COVID-19 au printemps 2024 pour les personnes exposées à un risque élevé de maladie sévère en raison de la COVID-19

To obtain additional information, please contact:

Public Health Agency of Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications-publications@hc-sc.gc.ca

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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 July 11, 2023, NACI provided guidance of the use COVID- 19 vaccines in the fall of 2023, with an addendum later published on September 12, 2023. The advice noted that recommendations on the timing of subsequent doses would be provided, if warranted, as the seasonality of SARS-CoV-2 has not been established and the need for routine programs is still unclear. NACI has previously recommended a vaccine program during the fall/winter and spring periods based on an assessment of the need for and potential benefit of additional doses in certain populations, with the spring program being a smaller and more targeted program for individuals at higher risk for severe illness due to COVID-19.

With provinces and territories having resumed other public health programs and activities, NACI guidance is being provided in advance to facilitate planning for a possible spring program.

NACI's recommendations continue to align with the goals of the Canadian COVID-19 Pandemic Response (February 14, 2022):

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

Methods

On October 17 and 31, 2023, the NACI COVID-19 Working Group (WG) reviewed the available information on SARS-CoV-2 epidemiology and seroprevalence, vaccine effectiveness (VE) of bivalent vaccines, including vaccine duration of protection, and the impact of hybrid immunity. Preliminary cost-effectiveness estimates for a spring 2024 campaign were also reviewed.

On November 15, 2023, NACI reviewed the evidence presented to the COVID-19 WG, along with feedback from provinces and territories on their experience with the spring 2023 COVID-19 vaccine program. NACI reached consensus on proposed recommendations, and approved the Statement on December 11, 2023. An early briefing on the recommendations was provided by NACI to provinces and territories on November 23, 2023 and November 30, 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 in the Canadian Immunization Guide (CIG).

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

Overview of Evidence

Information available as of November 15, 2023 is summarized below.

Epidemiology

- The evolutionary trajectory of SARS-CoV-2 remains uncertain and seasonality of SARS-CoV-2 has not been established.
- Recombinant XBB* sub-lineages of SARS-CoV-2 continue to circulate in Canada and globally. From sequencing data up to the week of October 22, 2023, HV.1* and other XBB* sub-lineages comprised nearly all positive cases sequenced across Canada [(3)].
- Older adults continue to be at the highest risk of a severe outcome and are less likely to have experienced previous SARS-CoV-2 infection compared to other age groups.
    - Seroepidemiologic studies have demonstrated high levels of infection-acquired seroprevalence in the Canadian adult population, which decreases with increased age, with older individuals having higher levels of immunity derived from vaccination alone. Approximately 30% of adult blood donors 60 years of age and older did not have infection-acquired seroprevalence as of September 2023 [(4)].
    - Based on seroprevalence data from July 2023 in a recently published study from British Columbia (BC), ~40% of adults 70 to 79 years of age and 80 years of age and older lacked evidence of previous SARS-CoV-2 infection [(5)].
        - As of July 2022, 80% of the eligible population in Lower Mainland, BC had received two doses of COVID-19 vaccine, with more than 85% of individuals 75 years of age and older having received three doses. From July to December 2022, the BC study estimated that 1 in 30, 1 in 100 and 1 in 600 newly infected adults aged 80 years of age and over, 70 to 79 years of age and 60 to 69 years of age, respectively would be hospitalized, in this highly vaccinated population [(5)].

Vaccine protection and hybrid immunity

- As the fall vaccination program proceeds with the XBB.1.5 vaccines and coverage increases, VE estimates will become available. Pre-clinical and clinical data have shown cross-neutralization from the XBB.1.5-containing vaccines against newer circulating subvariants that are descendants of the XBB sublineage. The HV.1 sublineage is antigenically similar to previous XBB sublineages; however, no cross-neutralization data from the XBB.1.5 vaccine against HV.1 was available at the time of the committee's deliberations. No safety issues have been identified to date with the use of the XBB.1.5 mRNA COVID-19 vaccines.
- 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

* Includes all descendant lineages, unless otherwise specified.

summarized evidence demonstrating that previous infection and vaccination may provide superior protection against variants of concern, including Omicron, compared with vaccination alone, or previous SARS-CoV-2 infection without vaccination [6-14]. However, even in the context of hybrid immunity, protection from vaccination and from previous infection has been shown to wane over time.

- Evidence from Canada (previously reviewed by NACI) [15-17] and the US, which has a population with a high prevalence of infection-induced immunity, shows that bivalent, Omicron-containing mRNA vaccines helped to prevent hospitalization in adults due to COVID-19, but effectiveness waned over a 6-month period [18]. Data on immunocompromised individuals showed more variability [18], but in general, this population is at increased risk for complications from SARS-CoV-2 infection and may have lower VE.

Economics

- Canadian provinces and territories continue to access supply of vaccines that were procured under federal pandemic investments, and therefore the product cost has been assumed by the Government of Canada. This supply is expected to be available at no cost to provinces and territories in the spring of 2024. However, provinces and territories continue to bear the costs associated with providing the vaccination program.
- Modelling and cost effectiveness analyses are underway to inform future COVID-19 vaccine program decisions, and these factors are expected to become more prominent as programs transition to traditional procurement pathways led by provincial and territorial program requirements and budget assessments.

Ethics, equity, feasibility, and acceptability (EEFA)

- Early advice for a spring COVID-19 vaccine program considers both the need for guidance to facilitate program planning and the unknowns that could affect the benefit of and need for a spring program. With the experience and knowledge gained through the pandemic, including the 2023 spring COVID-19 vaccine program, and the continued relevance of the NACI decision-making framework previously used for booster doses, the key considerations that will affect the need for a spring program include:
    - COVID-19 epidemiology (e.g. emergence of new escape variants, levels of local disease circulation),
    - Population level cumulative immunity and vaccine coverage as well as the timing of recent infection and vaccination, and
    - Vaccine characteristics in different groups against circulating strains (i.e. VE of the XBB.1.5 vaccine and duration of vaccine protection).
- A targeted spring COVID-19 vaccination program can promote well-being and minimize the risk of harm to those at high risk of severe illness due to COVID-19. A sufficient supply of XBB.1.5 vaccine has already been federally purchased and is expected to be available to support a spring 2024 campaign. However, a spring program would involve additional resources for implementation, compared to a fall program that can take advantage of the infrastructure of the long-established influenza vaccine program. Resources to mount a

spring campaign may represent opportunity cost, potentially taking resources away from the delivery of other important vaccine programs or public health services.

- Overall vaccine uptake has declined with each additional campaign,but continues to be highest in older adults (particularly those 80 years of age and older). National vaccination coverage between April 1 and June 18, 2023 (i.e. spring 2023) was estimated to be approximately 11% in adults 65 years of age and older [19], however there was variability in how provinces and territories promoted a spring campaign. Coverage estimates for the fall 2023 COVID-19 vaccination program were not available, as the program is ongoing. Public acceptance of future vaccinations and what strategies would lead to the greatest uptake are unknown. There is a potential to impact acceptability of COVID-19 vaccines if a spring 2024 program is strongly recommended, and there is low uptake and/or limited disease circulation in the spring.

Recommendations

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

Starting in the spring of 2024, NACI recommends that the following individuals who are at increased risk of severe illness from COVID-19 may receive an additional dose of XBB.1.5 COVID-19 vaccine:

- **Adults 65 years of age and older**
- **Adult residents of long-term care homes and other congregate living settings for seniors**
- **Individuals 6 months and age and older who are moderately to severely immunocompromised (due to an underlying condition or treatment)**

(*Discretionary NACI recommendation*)

  - The added benefit of a spring COVID-19 vaccine program will depend on a number of factors; information on some of these factors is not yet available and may also vary by jurisdiction. Table 2 identifies factors that support a spring program and considerations that are currently unknown.

Considerations:

- Age and setting are being used as proxies for frailty in older adults, as they are easier to measure and operationalize. The risk of severe illness is highest in adults 80 years of age and older; however, adults 65 years of age and older are being included in the recommendation as an acknowledgement that the risk of severe illness exists along a gradient in older adults and to support consistency in messaging across COVID-19 and other vaccine programs.
- According to the updated NACI guidance on the use of COVID-19 vaccines in individuals who have not been previously vaccinated, unvaccinated individuals who are moderately to severely immunocompromised starting their primary series with an XBB.1.5 vaccine are recommended to receive 2 doses, 4 to 8 weeks apart if 5 years of age and older, and 3 or 4

doses if 6 months to under 5 years of age (depending on the product received). For these individuals who are at higher risk for severe COVID-19, an additional dose of COVID-19 vaccine in the spring of 2024 may further improve or boost the immune response.

    - A wide range of conditions and medications can be immunocompromising, including those that can result in severe immunocompromise (e.g., transplant recipients, such as hematopoietic stem cell transplants). The degree of immunocompromise can vary over time and between individuals with the same condition. Further consultation with a health care provider may assist in more individualized advice regarding COVID-19 vaccination for this heterogenous patient population.

- Receiving a COVID-19 vaccine in the spring is particularly important for individuals at increased risk of severe illness due from COVID-19 who did not receive a dose of XBB.1.5 COVID-19 vaccine during the fall program.
- The recommended interval is 6 months from the last COVID-19 vaccine dose. However, a shorter interval of at least 3 months (i.e., a minimum interval of 3 months) may be used, to support implementation (including timing of the spring campaign relative to previous and future fall campaigns).
    - Individuals will likely be unaware or unsure if they have been recently infected with SARS-CoV-2 as they may have no or mild symptoms, and may not seek testing, which is now generally less available. Those who do have a recent test-confirmed SARS-CoV-2 infection may consider delaying COVID-19 vaccine by the intervals noted above.
- If there is a need for a fall 2024 campaign, jurisdictions may want to consider an end date for the spring 2024 campaign in order to support eligibility for the fall 2024 campaign based on the recommended interval.

NACI will continue to monitor the evidence, including SARS-CoV-2 epidemiology, VE of XBB.1.5 vaccines and duration of vaccine protection, particularly with regard to severe outcomes, to provide recommendations on the timing of subsequent doses if warranted.

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. Factors supporting a COVID-19 vaccine program in the spring of 2024 and current unknowns

	Factors supporting a spring 2024 COVID-19 vaccine program	Current unknowns
COVID-19 epidemiology	• Recently circulating variants continue to be antigenically related to the XBB* sublineage • Older adults continue to be at higher risk for severe illness due to COVID-19	• Circulating strains and extent for SARS-CoV-2 circulation in the spring and summer of 2024
Population level cumulative immunity and vaccine coverage	• Some individuals do not have hybrid immunity (i.e. have never been infected) and rely on vaccine-induced immunity (30-40% of individuals 65 years of age and older may not have been infected with SARS-CoV-2)	• Uptake of the XBB.1.5 COVID-19 vaccine during the fall/winter of 2023-2024
Vaccine characteristics in different groups against circulating strains	• Even in the context of hybrid immunity, protection against infection and severe disease from vaccines and/or prior infection wanes over time, although protection is more sustained against severe COVID-19 illness than against SARS-CoV-2 infection	• Vaccine effectiveness and duration of protection of the XBB.1.5 COVID-19 vaccine

Research priorities

- Continuous monitoring of data on the safety, immunogenicity, efficacy, and effectiveness of COVID-19 vaccines, including with new formulations, through clinical trials and studies in real-world settings, including the degree and duration of protection conferred 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 post-COVID-19 condition.
- Continuous monitoring of COVID-19 epidemiology and VE in special populations at high risk of severe outcomes and on the long-term consequences of infection with SARS-CoV-2.
- 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.

- Continuous monitoring of vaccine acceptance and coverage in Canada, for COVID-19 vaccines and other routine vaccines, including consideration of measures that may reduce the risk of disparities in vaccine confidence and uptake across different sub-populations.
- Continuous monitoring of the epidemiology of COVID-19, including SARS-CoV-2 variants and seasonal trends, to inform future programs.

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NACI members: S Deeks (Chair), R Harrison (Vice-Chair), M Andrew, J Bettinger, N Brousseau, H Decaluwe, P De Wals, E Dubé, V Dubey, K Hildebrand, K Klein, M O'Driscoll, J Papenburg, A Pham-Huy, B Sander, and S Wilson.

Liaison representatives: L Bill / M Nowgesic (Canadian Indigenous Nurses Association), LM Bucci (Canadian Public Health Association), S Buchan (Canadian Association for Immunization Research and Evaluation), E Castillo (Society of Obstetricians and Gynaecologists of Canada), J Comeau (Association of Medical Microbiology and Infectious Disease Canada), M Lavoie (Council of Chief Medical Officers of Health), J MacNeil (Centers for Disease Control and Prevention, United States), D Moore (Canadian Paediatric Society), M Naus (Canadian Immunization Committee), M Osmack (Indigenous Physicians Association of Canada), J Potter (College of Family Physicians of Canada), A Ung (Canadian Pharmacists Association).

Ex-officio representatives: V Beswick-Escanlar (National Defence and the Canadian Armed Forces), E Henry (Centre for Immunization and Respiratory Infectious Diseases (CIRID), PHAC), M Lacroix (Public Health Ethics Consultative Group, PHAC), P Fandja (Marketed Health Products Directorate, Health Canada), M Su (COVID-19 Epidemiology and Surveillance, PHAC), S Ogunnaike-Cooke (CIRID, PHAC), C Pham (Biologic and Radiopharmaceutical Drugs Directorate, Health Canada), M Routledge (National Microbiology Laboratory, PHAC), and T Wong (First Nations and Inuit Health Branch, Indigenous Services Canada).

NACI COVID-19 Vaccine Working Group

Members: S Wilson (Chair), M Adurogbangba, M Andrew, M Baca-Estrada, Y-G Bui, H Decaluwe, P De Wals, V Dubey, S Hosseini-Moghaddam, M Miller, D Moore, J Regan, and M Wallace.

PHAC Participants: N Islam, C Jensen, R Krishnan, SH Lim, R Neves Miranda, M Salvadori, A Tuite, MC Tunis, B Warshawsky, E Wong, R Ximenes, K Young, and J Zafack.

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