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SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF SEPTEMBER 1, 2022

Recommendations on the use of bivalent Omicron-containing mRNA COVID-19 vaccines

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Également disponible en français sous le titre :

Résumé de la déclaration du Comité consultatif national de l'immunisation (CCNI) du 1 septembre 2022 : Recommandations sur l'utilisation des vaccins à ARNm bivalents contre la COVID-19 contenant le variant Omicron

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OVERVIEW

- On September 1, 2022, Health Canada authorized the use of Moderna Spikevax Bivalent (50 mcg) COVID-19 vaccine as a booster dose in adults aged 18 years of age and older. This represents the first bivalent Omicron (BA.1)-containing mRNA COVID-19 vaccine authorized for use in Canada.

- On September 1, 2022, the Public Health Agency of Canada (PHAC) released recommendations from the National Advisory Committee on Immunization (NACI) on the use of bivalent Omicron-containing mRNA COVID-19 vaccines.

- This guidance updates NACI's June 29 guidance on planning considerations for a fall 2022 COVID-19 vaccine booster program in Canada to include the authorized use of Moderna Spikevax Bivalent (50 mcg) COVID-19 vaccine and the changing epidemiology of COVID-19.

- NACI reviewed clinical trial data on the safety and immune response generated by a booster dose of Moderna Spikevax Bivalent (50 mcg) COVID-19 vaccine, the spread and severity of COVID-19 in the Canadian population, as well as post-market safety on mRNA vaccines pertaining to myocarditis and/or pericarditis.

- **With regards to the product offered for a fall booster dose, NACI makes the following recommendations:**

    - For adults 18 years of age and older who are recommended to receive a fall booster dose, NACI recommends that the authorized dose of a bivalent Omicron-containing mRNA COVID-19 vaccine should be offered. If the bivalent Omicron-containing mRNA COVID-19 vaccine is not readily available, an original mRNA COVID-19 vaccine should be offered to ensure timely protection. (*Strong NACI Recommendation*)

    - For adolescents 12-17 years of age with moderately to severely immunocompromising conditions and/or who have biological or social risk factors that place them at high risk of severe outcomes from COVID-19, NACI recommends that the authorized dose of a bivalent Omicron-containing mRNA COVID-19 vaccine may be offered off-label. (*Discretionary NACI Recommendation*)

- Individuals eligible for fall boosters, especially those at increased risk for severe outcomes from COVID-19, should not delay their planned vaccination in anticipation of a bivalent Omicron-containing COVID-19 vaccine. Individuals choosing to delay a booster dose in anticipation of a new vaccine should carefully consider their individual risk.

- NACI continues to monitor the spread and severity of COVID-19 and the safety, effectiveness and duration of protection of Moderna Spikevax Bivalent (50 mcg) COVID-19 vaccine and will update guidance as needed.

For the full statement, including supporting evidence and rationale, please see NACI Statement: Recommendations on the use of bivalent Omicron-containing mRNA COVID-19 vaccines.

For information on the interim fall booster planning considerations, including the list of individuals considered to be at an increased risk of severe illness from COVID-19, please see NACI Statement: Interim guidance on planning considerations for a fall 2022 COVID-19 vaccine booster program in Canada.

For information on booster doses in children 5 to 11 years of age, please see recent NACI Statement: Recommendations on the use of a first booster dose of Pfizer-BioNTech Comirnaty COVID-19 vaccine in children 5 to 11 years of age.

For more information on NACI's recommendations on the use of COVID-19 vaccines, please refer to the COVID-19 vaccine chapter in the Canadian Immunization Guide (CIG), as well as additional statements on the NACI web page.

WHAT YOU NEED TO KNOW

- On September 1, 2022, Health Canada authorized the use of Moderna Spikevax Bivalent (50 mcg) COVID-19 vaccine as a booster dose in adults aged 18 years and older. This represents the first bivalent Omicron-containing mRNA COVID-19 vaccine authorized for use in Canada

- When developing these recommendations, NACI reviewed the spread and severity of Omicron variants; the level and duration of protection from COVID-19 vaccination, infection, or hybrid immunity (i.e., protection due to a combination of both infection and vaccination) in affected age groups; clinical trial data on the safety, efficacy and immune response of a booster dose of bivalent Omicron (BA.1)-containing mRNA vaccination; and ethical considerations related to COVID-19 vaccination.

- During the summer of 2022, Canada has experienced an increase in COVID-19 activity driven by the BA.5 and BA.4 Omicron subvariants. These subvariants are more infectious relative to previous Omicron subvariants, even among individuals who have been previously infected and/or vaccinated against COVID-19.

- Although the Moderna Spikevax Bivalent vaccine targets the Omicron BA.1 subvariant, clinical trial results suggest this vaccine induces a stronger immune response against the Omicron BA.4/BA.5 subvariants compared to the original Moderna Spikevax COVID-19 vaccine.

- Three doses of original mRNA COVID-19 vaccines continue to provide strong and sustained protection against severe outcomes following COVID-19 infection. However, the Omicron variant has demonstrated it is partially evasive of immunity from the original COVID-19 vaccines or from previous infection with variants prior to Omicron. The immune evasion exhibited by Omicron subvariants BA.4 and BA.5 may be greater than that exhibited by previous Omicron subvariants, although evidence is still emerging at this time.

- NACI continues to recommend that all older adults (65 years of age and older), and also individuals 12 to 64 years of age who are at increased risk of severe illness from COVID-19, should be offered a fall COVID-19 vaccine booster dose regardless of the number of booster doses previously received. All other individuals 12 to 64 years of age may also be offered a fall COVID-19 vaccine booster dose regardless of the number of booster doses previously received.

- NACI has also provided recommendations for the use of a booster dose with an authorized COVID-19 vaccine for children 5 to 11 years of age, which can be integrated into the fall booster programs.

- Individuals eligible for fall boosters, especially those at increased risk for severe outcomes from COVID-19, should not delay their planned vaccination in anticipation of a bivalent Omicron-containing mRNA COVID-19 vaccine. Individuals choosing to delay a booster dose in anticipation of a new vaccine should carefully consider their individual risk.

- NACI continues to recommend that COVID-19 booster doses may be offered at an interval of 6 months after a previous COVID-19 vaccine dose or SARS-CoV-2 infection, regardless of the product offered. However, a shorter interval of at least 3 months may be warranted in the context of heightened epidemiologic risk, as well as operational considerations for the efficient deployment of the COVID-19 vaccination program. A 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.

- Individuals who are less likely to have been infected during Omicron waves may experience additional benefits from a bivalent Omicron-containing mRNA COVID-19 vaccine to prime the immune response to the Omicron variant. Additionally, previously-infected individuals receiving a bivalent Omicron-containing mRNA COVID-19 vaccine may experience a greater and more rapidly-induced immune response.

- There are currently no data on the efficacy, immunogenicity or safety of Moderna Spikevax Bivalent (50 mcg) COVID-19 vaccine in individuals under 18 years of age. However, the immunological benefits of the inclusion of an Omicron component in Moderna Spikevax Bivalent (50 mcg) COVID-19 vaccine for adolescents at high risk of severe outcomes from COVID-19 may outweigh any potential risks that are unknown at this time due to a lack of data for the use of this vaccine in this age group.

- Post-market surveillance safety data to date have not shown product-specific differences in the risks of myocarditis and/or pericarditis after a booster dose of an mRNA COVID-19 vaccine. Therefore adults 18 to 29 years of age can receive a booster dose with any available mRNA COVID-19 vaccine for which they are currently eligible.

- Informed consent should include discussion regarding what is known and unknown about the benefits and risks of providing a booster dose to affected populations.

- NACI continues to monitor the spread and severity of COVID-19 and the safety, effectiveness and duration of protection of Moderna Spikevax Bivalent (50 mcg) COVID-19 vaccine and will update guidance as needed.

For the full statement, including supporting evidence and rationale, please see NACI Statement: Recommendations on the use of bivalent Omicron-containing mRNA COVID-19 vaccines.

For more information on NACI's recommendations on the use of COVID-19 vaccines, please refer to the COVID-19 vaccine chapter in the Canadian Immunization Guide (CIG), as well as additional statements on the NACI web page.

QUOTES

"Earlier this summer, NACI provided interim guidance on planning considerations for a fall COVID-19 vaccine booster program and highlighted those who will benefit most from a fall booster. With the introduction of the bivalent Omicron-containing mRNA COVID-19 vaccine, NACI is updating its fall booster guidance on the type of mRNA COVID-19 vaccine to be offered. While there are a number of potential benefits to the bivalent COVID-19 vaccine, particularly for the elderly, being able to receive timely protection is also a consideration. The original mRNA COVID-19 vaccine continues to offer good protection against severe COVID-19 illness, and should be offered if the bivalent vaccine is not readily available.

NACI will continue to monitor the evidence, including real world use and monitoring of vaccine safety, to ensure up-to-date guidance is provided on the use of booster doses in all age groups."

- Dr. Shelley Deeks, NACI Chair

"Keeping up-to-date with COVID-19 vaccines, including booster doses, is very important for reducing the risk of hospitalisation and death due to COVID-19. I am pleased to see the authorization of the Moderna Spikevax Bivalent COVID-19 vaccine. This vaccine, which targets more than one strain of COVID-19, is anticipated to provide stronger and broader protection, including against the Omicron variants that have been circulating.

NACI's updated guidance on the use of the original and bivalent mRNA COVID-19 vaccines will help provinces and territories offer timely protection to Canadians, particularly to individuals at high risk for severe outcomes. PHAC, Health Canada and NACI will continue to monitor the safety and effectiveness of the Moderna Spikevax Bivalent COVID-19 vaccine and will update guidance as necessary to provide Canadians with the information and advice they need to make informed decisions."

- Dr. Theresa Tam, Chief Public Health Officer