



Vaccine Confidence InfoBulletin

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This Special Spring "Booster" Edition aims to provide you with a summary of the latest National Advisory Committee on Immunization (NACI) guidance on booster doses of COVID-19 vaccines.

The latest NACI guidance on booster doses of COVID-19 vaccines

NACI continues to emphasize the importance of completing a primary COVID-19 vaccine series with an authorized mRNA COVID-19 vaccine and receiving a booster dose as soon as individuals are recommended to do so. Evidence shows that being up-to-date with all recommended doses, including boosters, provides strong protection against serious illness, hospitalization and death from COVID-19.

NACL continues to recommend that COVID-19 vaccines should be offered to people who have had a previous COVID-19 infection. While infection alone provides some protection, vaccination after infection helps improve the immune response and may provide better and longer-lasting protection against current and future variants of the virus. NACI has suggested optimal intervals between infection and subsequent vaccination.

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Quick reference - NACI COVID-19 vaccine booster dose recommendations

In general, 6 months or longer is the recommended time between primary series completion and a booster dose, as well as between a first and second booster dose. However, for the second booster dose, NACI states that the 6-month interval may need to be balanced with local and current epidemiology. As a result, shorter intervals may be indicated for those who are recommended to receive a second booster dose. When applicable, timing of recent COVID-19 infection should also be considered.

For individuals who have contracted COVID-19, NACI suggests a 3-month interval between infection and a 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.

For an explanation of strong versus discretionary NACI recommendations in Table 1 click here.

Table 1

| Age | Specific group Assuming sufficient time has passed from the previous dose as noted above | NACI Recommendation 1 st booster | NACI Recommendation 2 nd booster |
|---|--|---|--|
| Specific population at higher risk, 18 years of age and older | Adult residents of long-term care or other congregate living settings for seniors | Strongly recommends | Strongly recommends |
| | First Nations, Métis, and Inuit communities | Strongly recommends | Discretionary recommendation ** (may be offered) |
| | Adult frontline health care providers | Strongly recommends | No NACI recommendation |
| 80 years and older | | Strongly recommends | Strongly recommends |
| 70 to 79 years | | Strongly recommends | Discretionary recommendation (may be offered) |
| 50 to 69 years | Not in a group noted in the "Specific population at higher risk, 18 years of age and older" above | Strongly recommends | No NACI recommendation |
| 18 to 49 years of age | Not in a group noted in the "Specific population at higher risk, 18 years of age and older" above | Strongly recommends | No NACI recommendation |
| 12 to 17 years | Adolescents not listed in the row below | Discretionary recommendation * (may be offered) | No NACI recommendation |
| | Have an underlying medical condition that puts them at high risk of severe illness due to COVID-19, living in congregate setting or belonging to marginalized or racialized groups | Strongly recommends | No NACI recommendation |
| 5 to 11 years | | No NACI recommendation | No NACI recommendation |

^{*} May be offered after the completion of a primary series in the context of heightened epidemiological risk.

^{**} A second booster dose among adults younger than 70 years of age in or from First Nations, Métis, or Inuit communities may be considered. Autonomous decisions should be made by Indigenous Peoples with the support of health care and public health partners in accordance with the United Nations Declaration on the Rights of Indigenous Peoples.

Summary of the latest NACI guidance

NACI's updated recommendations on the use of first COVID-19 booster doses in adolescents and adults

On April 12, 2022, NACI released <u>updated guidance on the use of first COVID-19 booster doses in adolescents and adults.</u>

Summary

- In addition to their strong recommendations for first booster doses in those 50 years of age and over, NACI now **strongly recommends** that the following people receive a first booster dose at least six months after the last dose of their primary series:
 - o all adults 18 to 49 years of age and older; and
 - o high-risk adolescents 12 to 17 years of age, including those who:
 - have an <u>underlying medical condition</u> that puts them at high risk of severe outcomes from COVID-19 (this would be a fourth dose for those who are moderately to severely immunocompromised and had already received 3 doses)
 - are residents of congregate living settings; and
 - belong to racialized and/or marginalized communities disproportionately affected by COVID-19.
- NACI has also added a new discretionary recommendation that all other adolescents 12 to 17 years of age may be offered a first booster at least six months after the last dose of their primary series.

Intervals

- NACI recommends people receive a booster dose at least 6 months after completing their primary vaccine series.
- For people who have experienced a SARS-CoV-2 infection, NACI suggests 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.

Safety profile

- First booster doses of mRNA COVID-19 vaccines have a good safety profile and no new safety concerns have been identified in adolescents or adults.
- The rare risk of myocarditis and/or pericarditis after vaccination with an mRNA COVID-19 vaccine appears to be somewhat lower after a booster dose compared to after a second dose of a primary series. Most cases have been mild and have resolved quickly with medical care.

Vaccine product recommendations

- Regardless of the vaccine received for the primary series, the Pfizer-BioNTech Comirnaty® (30 mcg) COVID-19 vaccine is preferred as a booster dose in adolescents 12 to 17 years of age and may be preferred as a booster dose in young adults 18 to 29 years of age to further minimize the rare risk of myocarditis and/or pericarditis after receiving a COVID-19 mRNA vaccine in these age groups.
- The Novavax Nuvaxovid® COVID-19 vaccine may be offered as a booster dose for individuals 18 years of age and over who are unable or unwilling to receive an mRNA COVID-19 vaccine.

NACI's initial guidance on the use of second COVID-19 booster doses in older adults

On April 5, 2022, NACI released initial guidance on the use of second COVID-19 booster doses.

Summary

- NACI recommends that provinces and territories prepare to rapidly offer second booster doses
 of COVID-19 vaccines to older adults and residents of long-term care settings, as data suggest
 concerning COVID-19 trends.
- NACI recommends that the following populations at high-risk for severe disease should be prioritized for a second booster dose:
 - o Adults 80 years of age and older living in the community; and
 - o Residents of long-term care homes or other congregate living settings for seniors.
- While the greatest benefit of a second booster dose is expected in people 80 years of age and older at this time, jurisdictions may consider offering a second COVID-19 booster dose to adults 70 to 79 years of age.
- Adults younger than 70 years of age in or from First Nations, Métis, and Inuit communities, may
 also be offered a second booster based on decisions by Indigenous communities, in
 collaboration with health care and public health partners.

Intervals

- In general, jurisdictions should aim to provide a second booster dose 6 months after the previous booster dose, although the local COVID-19 activity should be considered. As a result, shorter intervals between booster doses may be indicated for older adult populations.
- For people who have experienced a SARS-CoV-2 infection, NACI suggests a 3-month interval between infection and COVID-19 booster dose (e.g., three months after symptoms started or testing positive, if no symptoms were experienced) or at least six months from the most recent vaccine dose, whichever interval is longer.

Safety profile

 Preliminary data suggest the safety of a second booster dose of an mRNA COVID-19 vaccine is similar to previous doses. Canadian and international safety data suggest a second booster dose has no additional safety signals.

Vaccine product recommendations

- NACI recommends the use of either the Moderna Spikevax[™] (50mcg) or Pfizer-BioNTech Comirnaty® (30mcg) COVID-19 vaccines for second booster doses in older adults and high risk populations listed above. The use of the Moderna Spikevax[™] COVID-19 vaccine (100mcg) as a booster may also be considered based on clinical discretion in adults 70 years of age and over and residents of long-term care homes or other congregate living settings for seniors.
- The Novavax Nuvaxovid® COVID-19 vaccine may be offered as a booster dose to individuals who are unable or unwilling to receive an mRNA COVID-19 vaccine.

The science of vaccine effectiveness and boosters

*Sharing this relevant information from the February 24th, 2022 issue of the Vaccine Confidence InfoBulletin.

As of April 10, 2022, over 54% of people 12 years of age and older in Canada have rolled up their sleeves for a third dose of a COVID-19 vaccine. Many public health experts are concerned that uptake of booster doses is dropping off. Pandemic fatigue, lower vaccine effectiveness against infection due to Omicron, recent SARS-CoV-2 infection and perceptions that are shifting towards 'living with COVID' may all be playing a part in decreasing individual enthusiasm for another dose. In order to best promote booster doses, it is helpful to understand the benefits of boosting and how it helps to prevent severe disease.

How does the body establish immunity in response to vaccines?

Two types of immune responses are generated towards a pathogen by vaccination or by infection: humoral (antibodies) and cellular (T cells). Long-lived responses are generated by memory B cells (that make antibodies) and memory T cells. Both these types of long-lived immunity are primed by the first exposure and mature over time.

Antibodies can serve several functions to flag and prevent infection, including neutralization of the pathogen before it can enter cells. After the first exposure to an antigen (an immune -priming molecule), the B cells begin to make antibodies and with subsequent exposures, antibody levels increase rapidly followed by a slow decline. Following initial exposure, some of the B cells become memory B cells, which quickly recognize the antigen if it re-enters the body and can rapidly divide and become plasma cells to produce high quality and strongly binding (high affinity) antibodies to quickly fight infection.

Boosting gives the immune system another opportunity to "see" the antigen and develop better antibodies to prevent infection and help respond to infection if it occurs.

With the cellular immune response, when exposed to an antigen, T cells break into different kinds of effector cells that play a role in fighting an infection. Killer T cells destroy infected cells preventing replication of the virus in the host cell. Helper T cells are even more important as they communicate using chemical signals to strengthen killer T cells as well as antibody producing B cells. Like memory B cells, memory T cells are created after an exposure and can be rapidly called into action on subsequent exposures. Humoral and cellular compartments of the immune response work together: antibodies may be called to action quickly to try to prevent cells from becoming infected in the first place and cellular immune responses deal with infected cells that slip through antibody defenses. The T cell response can prevent the infection from becoming widespread or severe.

While neutralizing antibody responses to the Omicron variant have generally been poorer than against other variants, causing a reduction in vaccine effectiveness against infection, T cell responses against Omicron have generally remained strong, providing protection against more severe disease and offering protection for at least several months after a primary series. T cells responses are also better maintained across different variants, even those that are highly mutated like Omicron, and so T cells are more likely to combat emerging future variants. Just like a booster dose helps to develop better antibodies, it can also generate more robust killer T cells that can respond better to an infection.

Why does vaccine effectiveness decrease over time?

Vaccine effectiveness can refer to several different outcomes, such as effectiveness against infection, symptomatic disease, severe disease and death. Initially after two doses of vaccine in a primary series, protection against infection and symptomatic illness for the ancestral (original) virus strain and earlier variants (e.g., Delta) was high but decreases in protection against infection and symptomatic disease occur as antibodies decline over time, as well as with the emergence of immune evasive variants.

The Omicron variant is genetically quite different from previous variants and from the wild-type strain on which the vaccines are based. Vaccines developed using the wild-type strain are not as effective against Omicron infection and symptomatic disease; however, these vaccines are still effective against severe COVID-19 outcomes.

The goal of a vaccination campaign is to minimize harm from a disease, so while infections may still occur, vaccine effectiveness against severe disease and death are the true measures of a vaccine's success.

How do booster doses help?

Booster doses provide a considerable increase in protection against the Omicron variant.^a



Infection/symptomatic disease: As noted, protection against infection and symptomatic disease from the primary vaccine series decreases over time and is limited against Omicron. With a booster dose, protection against infection and symptomatic Omicron disease increases to about 60% (from very low protection 6 months following the second dose), though this protection will also likely decrease over time.

However, as noted above, protection against infection and symptomatic disease are not the primary objectives of a vaccination campaign, which is really aimed at preventing serious disease and death.

Severe disease: Two doses of an mRNA vaccine provide good protection against severe Omicron disease (approximately 65% to 85%, with a wide range of estimates across studies). Protection from severe Omicron disease increases to approximately 90% or more after the booster dose. The duration of protection against severe disease over time is unknown.

Frequently asked questions

Related to booster doses generally

1. What is the difference between a discretionary and strong recommendation?

The National Advisory Committee on Immunization (NACI) provides technical advice to PHAC for use by provinces and territories and health care providers. NACI makes two types of recommendations—strong recommendations and discretionary recommendations. A strong recommendation uses the words "should/should not be offered" while a discretionary recommendation uses the words "may/may not be offered."

^a UK Health Security Agency, "COVID-19 Surveillance Report: Week4," 27 January 2022. [Online]. Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1050721/Vaccine-surveillance-report-week-4.pdf.

A strong recommendation is one that applies to most individuals in a population unless a compelling alternative is available. A discretionary recommendation means that the vaccine may be considered for individuals in a population, but that the decision should be made considering factors, such as individual benefits and risks, or local epidemiology.

2. How effective is a first booster and how long does protection last?

Studies show that with a booster, vaccine effectiveness in adults against infection from Omicron is approximately 60% but decreases over time. However, protection in adults against severe illness and hospitalization due to COVID-19 from a primary series remains good and is further improved with a booster dose reaching vaccine effectiveness of approximately 90% or more. Emerging evidence in adolescents on the effectiveness of a booster dose against infection over time shows trends similar to those observed in adults.

There is currently limited evidence on how long protection against severe outcomes of COVID-19 from a first booster dose lasts, with a few studies suggesting some decrease in protection over time and other studies showing sustained protection over the available follow-up time.

Preliminary data indicates that a second booster dose provides additional protection compared to a first booster, including against severe disease. However, the duration of protection is currently unknown.

NACI will continue to monitor the evidence on boosters as data emerge from real-world use and will adjust its recommendations as needed.

3. Are there risks to additional or repeated boosters, especially since a second booster is off-label?

At this time, recommendations for second COVID-19 vaccine booster doses are off-label, as second booster doses are not currently authorized for use by Health Canada. However, it is not uncommon for NACI to make off-label recommendations.

Preliminary data suggest the safety of a second booster dose of an mRNA COVID-19 vaccine is similar to previous doses. Canadian and international safety data suggest a second booster dose is well tolerated and is not associated with any additional safety signals.

NACI, PHAC and Health Canada will continue to monitor additional real-world evidence on the use and safety of second boosters as it becomes available.

4. Will there be a booster for children 5-11 years of age?

At this time, Health Canada has not received a submission for a booster dose for children aged 5 to 11 years of age.

NACI continues to strongly recommend that children 5 to 11 years of age get a primary series of an mRNA COVID-19 vaccine, with an interval of at least 8 weeks between the first and second doses (4 to 8 weeks is the recommended interval between the three doses in the primary series for children 5 to 11 years of age who are considered moderately to severely immunocompromised). The Pfizer-BioNTech Comirnaty® COVID-19 vaccine is preferred to start or continue the primary vaccine series in this age group due to its well-known safety profile. Evidence shows that a primary series provides protection against severe illness and hospitalization, including for the Omicron variant.

NACI will continue to monitor the evidence regarding the need for and effectiveness of booster doses for this age group, and will update guidance as required.

5. Will there be a regular booster schedule in the future?

At this time, evidence is evolving that will help inform whether ongoing repeated boosting for COVID-19 is needed. The Government of Canada continues to monitor the impact of booster doses against emerging variants based on immunologic responses and protection against infection and severe disease.

Related to first COVID-19 booster doses in adolescents and younger adults

6. Is a first booster safe for adolescents, since no vaccines have been approved in Canada as a booster for adolescents?

At this time, recommendations for a first booster dose of a COVID-19 vaccine in adolescents are off-label as COVID-19 vaccines are not currently authorized for use as booster doses in adolescents in Canada. However, it is not uncommon for NACI to make off-label recommendations. NACI's recommendations complement Health Canada's regulatory indications by providing additional context and information on public health strategies based on available and emerging evidence. This means that NACI may provide recommendations that are broader or narrower than the conditions of use approved by Health Canada.

Booster doses with mRNA vaccines have generally been well tolerated in adolescents and adults, and to date, post-market safety data have not identified any additional safety concerns. For adolescent booster doses, safety data is only available for Pfizer-BioNTech Comirnaty® (30mcg).

The rare risk of myocarditis and/or pericarditis after vaccination with an mRNA COVID-19 vaccine appears to be somewhat lower after a booster dose compared to after a second dose of a primary series. Most cases have been mild and have resolved quickly with medical care. In order to further minimize the rare risk of myocarditis and/or pericarditis after receiving a COVID-19 mRNA vaccine, NACI recommends the use of Pfizer-BioNTech Comirnaty® as the booster dose in adolescents 12 to 17 years of age. This is because the risk of myocarditis/pericarditis is lower with Pfizer-BioNTech Comirnaty® than Moderna SpikevaxTM in adolescents and young adults.

7. Given that the protection offered by a booster decreases over time, should adolescents and younger adults get a booster now or wait until the fall, when there could be even more COVID-19 cases?

Given that many areas in Canada are seeing high COVID-19 activity, NACI is strongly recommending a first booster dose be offered to all adults 18 years of age and older and to high-risk adolescents 12 to 17 years of age. NACI has also made a discretionary recommendation that all other adolescents 12 to 17 years of age may be offered a first booster dose in the context of increased COVID-19 activity. It is recommended that individuals receive a first booster dose as soon as they are recommended to do so.

For those who were recently infected with SARS-CoV-2, NACI continues to suggest receiving a booster dose three months after symptoms started or testing positive (if no symptoms were experienced) or at least six months after completing a primary series, whichever interval is longer.

By getting a booster dose, people in Canada can strengthen their protection against infection and severe disease. Studies show that a booster dose provides very good protection against severe disease and hospitalization from the Omicron variant and may provide better and longer-lasting protection against future variants of the virus. Staying up-to-date on COVID-19 vaccinations provides the best protection against severe outcomes from COVID-19.

Related to second booster doses in older adults

8. What are the recommendations for immunocompromised individuals?

Individuals who are moderately to severely immunocompromised are recommended to receive a three dose primary series, with a 4 to 8 week interval between each dose and a first booster dose 6 months following the completion of the 3-dose primary series (for a total of four doses). While there are not specific second dose booster recommendations for immunocompromised individuals at this time, second booster dose immunization programs for immunocompromised individuals and other high-risk groups as well as the general public may be needed at a later date if data suggest concerning COVID-19 trends, such as the emergence of new variants of concern.

Additionally, a monoclonal antibody product was <u>recently approved</u> for pre-exposure prophylaxis adding to the prevention options for some immunocompromised individuals. NACI will be closely monitoring developments in that area in order to understand the value of additional vaccine booster doses for immunocompromised populations compared to or along with other options, such as prophylactic monoclonal antibodies.

9. Does NACI's guidance mean people 70-79 years of age should get a second booster now or wait until the fall?

It is recommended that individuals receive a second booster dose as soon as they are recommended to do so. The incidence of severe outcomes, including hospitalization and death, is highest among adults 80 years of age and over, and that is why NACI recommends that this age group should be prioritized for a second booster dose, along with those living in long-term care or other congregate settings for seniors.

During the December 2021 to February 2022 Omicron wave in Canada, adults 70 to 79 years of age had the second-highest incidence of severe outcomes, including hospitalization and death. Given this, jurisdictions may also consider offering a second booster dose to adults 70 to 79 years of age living in the community. For those who were recently infected with SARS-CoV-2, NACI continues to suggest receiving a booster dose three months after symptoms started or testing positive (if no symptoms were experienced) or at least six months after completing a primary series, whichever interval is longer.

Staying up-to-date on COVID-19 vaccinations provides the best protection against severe outcomes from COVID-19. Please visit the webpage of your local health authority to find out if and when you are eligible to receive a second booster dose.

Contact Vaccine Confidence

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Have questions or feedback to share? Email us: vaccination@phac-aspc.gc.ca

Please note that any medical questions should be directed to your local health care provider and any urgent medical questions should be directed to 911 or your local emergency department.

Annex

Timeline of NACI COVID-19 vaccine booster dose recommendations

April 12, 2022 - updated guidance on the use of first COVID-19 booster doses in adolescents and adults

 NACI strengthened recommendations for first booster for adults 18 to 49 years of age and adolescents 12 to 17 years of age who may be at higher risk of SARS-CoV-2 infection or severe outcomes from COVID-19. Additionally, NACI added a new discretionary recommendation for a first booster dose for all other adolescents 12 to 17 years of age.

April 5, 2022 - initial guidance on the use of second COVID-19 booster doses for older adults and residents of long-term care settings.

 NACI strongly recommends a second booster dose for adults 80 years of age and older, and adult residents of long-term care or other congregate living settings for seniors. Discretionary recommendation for second boosters for those 70 to 79 years of age and adults younger than 70 years of age who are in or from First Nations, Métis or Inuit communities.

<u>February 4, 2022 - rapid response: updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2.</u>

<u>January 28, 2022 – rapid response: guidance on the use of booster COVID-19 vaccine doses in adolescents 12 to 17 years of age.</u>

<u>December 3, 2021 (ARCHIVED) – updated guidance on booster COVID-19 vaccine doses in Canada (focus on older adults and frontline health care workers).</u>

October 29, 2021 (ARCHIVED) – interim guidance on booster COVID-19 vaccine doses in Canada (focus on older adults and at-risk populations).

<u>September 28, 2021 (ARCHIVED) – rapid response: booster dose in long-term care residents and seniors living in other congregate settings.</u>

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