Public Health Agency of Canada | Agence de la santé publique du Canada

Canada

SUMMARY OF THE NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) RAPID RESPONSE OF DECEMBER 3, 2021

Rapid response: Updated recommendation on the use of authorized COVID-19 vaccines in individuals aged 12 years and older in the context of myocarditis and pericarditis reported following mRNA COVID-19 vaccination

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

OVERVIEW

- On December 3, 2021, the Public Health Agency of Canada (PHAC) released updated guidance from the National Advisory Committee on Immunization (NACI) on the use of authorized COVID-19 vaccines in people 12 years of age and older in the context of myocarditis and pericarditis reported following mRNA COVID-19 vaccination. These recommendations are based on current scientific evidence and NACI's expert opinion.

- Rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the heart lining) following vaccination with COVID-19 mRNA vaccines have been reported in Canada and internationally. Most cases have occurred in males 12 to 29 years of age after a second dose of an mRNA vaccine. Most cases have been mild and resolved quickly.

- NACI has reviewed new Canadian and international data that suggest the rare risk of myocarditis after receiving an mRNA COVID-19 vaccine may be lower with the Pfizer-BioNTech Comirnaty vaccine (30 mcg) compared to the Moderna Spikevax vaccine (100 mcg).

- COVID-19 mRNA vaccines, Pfizer-BioNTech Comirnaty and Moderna Spikevax, continue to have a good safety profile and provide excellent protection against symptomatic illness and severe outcomes from COVID-19. They have been essential in protecting the health of Canadians and reducing hospitalization and death from COVID-19.

After reviewing the latest evidence, NACI continues to:

- **Strongly recommend the preferential use of a complete series of an mRNA COVID-19 vaccine over the use of viral vector COVID-19 vaccines in all authorized age groups.**

Based on new evidence, and in order to further minimize the rare risk of adolescents and young adults experiencing myocarditis and/or pericarditis after receiving a COVID-19 mRNA vaccine, NACI now recommends:

- **Pfizer-BioNTech Comirnaty mRNA vaccine (30 mcg) is preferred in adolescents and young adults 12 to 29 years of age.**

To see the full recommendations, including the evidence and rationale behind these recommendations, please visit NACI Rapid Response: Updated recommendation on the use of authorized COVID-19 vaccines in individuals aged 12 years and older in the context of myocarditis and pericarditis reported following mRNA COVID-19 vaccination.

WHAT YOU NEED TO KNOW

- Infection with SARS-CoV-2, the COVID-19 virus, can cause severe illness and health complications, hospitalization and death.

- The COVID-19 mRNA vaccines, Pfizer-BioNTech Comirnaty and Moderna Spikevax, have been essential in protecting the health of Canadians and reducing hospitalization and death from COVID-19. Both mRNA vaccines have good safety profiles and provide very good protection against symptomatic illness, hospitalization and death from COVID-19.

- There are many potential causes of myocarditis and pericarditis. Myocarditis and/or pericarditis can occur as a complication in people who are infected with SARS-CoV-2, the virus that causes COVID-19.

- Rare cases of myocarditis and/or pericarditis following vaccination with COVID-19 mRNA vaccines have been reported in Canada and internationally.

- Most cases of myocarditis and/or pericarditis following vaccination with an mRNA COVID-19 vaccine have occurred in males 12 to 29 years of age after a second dose of an mRNA vaccine. Most cases have been mild and resolved quickly. Longer-term follow up of patients with myocarditis and/or pericarditis following mRNA COVID-19 vaccination is ongoing in Canada and abroad.

- New Canadian and international data suggest the risk of myocarditis following vaccination with a COVID-19 mRNA vaccine is lower with the Pfizer-BioNTech Comirnaty vaccine (30 mcg) compared to the Moderna Spikevax vaccine (100 mcg), particularly after a second dose in males 12 to 29 years of age.

After reviewing the recent evidence, NACI continues to:

Strongly recommend the preferential use of a complete series of an mRNA COVID-19 vaccine over the use of a viral vector COVID-19 vaccine in all authorized age groups.

- mRNA vaccines provide better protection against COVID-19 and are not associated with the risk of experiencing vaccine-induced immune thrombotic thrombocytopenia (VITT), a rare but serious condition of blood clots associated with low levels of blood platelets.

- The benefits of receiving an mRNA COVID-19 vaccine continue to outweigh any potential risks of experiencing a rare or very rare side effect following vaccination with an mRNA vaccine, including the rare risk of experiencing vaccine-associated myocarditis and/or pericarditis.

Based on new evidence, and in order to further minimize the rare risk of adolescents and young adults experiencing myocarditis and/or pericarditis after receiving a COVID-19 mRNA vaccine, NACI now recommends:

For people 12 to 29 years of age receiving an mRNA primary series:

The use of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) is preferred over the use of the Moderna Spikevax COVID-19 vaccine (100 mcg) to start or complete a primary vaccine series. The second dose of a primary series should be provided 8 weeks after the first dose.

- Emerging evidence in adults suggests that a longer interval between the first and second dose of a primary series results in a stronger immune response and higher vaccine effectiveness.

- New data suggest that for mRNA vaccines, longer intervals may also be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.

- Adolescents and young adults 12 to 29 years of age who have already received one or two doses of the Moderna Spikevax vaccine (100 mcg) should not worry as symptoms of myocarditis/pericarditis usually take place within a week of vaccination.

- Based on clinical judgement, the Moderna Spikevax vaccine (100 mcg) may be considered for adolescents and adults 12 to 29 years of age who are moderately to severely immunocompromised given new evidence that the Moderna Spikevax vaccine (100 mcg) may have a slightly higher vaccine effectiveness and may provide longer protection against infection and severe COVID-19 outcomes compared to the Pfizer-BioNTech Comirnaty vaccine (30 mcg).

For people 18 to 29 years of age who are eligible to receive a booster dose of an mRNA vaccine:

The use of the Pfizer-BioNTech booster dose (30 mcg) may be preferred over the use of the Moderna booster dose (50 mcg). A booster dose should be provided at least 6 months after the completion of a primary vaccine series.

- In Canada, booster doses are currently only authorized for use in people 18 years of age and older. The dose of the Pfizer-BioNTech booster is the same as the dose used for the primary series (30 mcg), while the authorized dose of the Moderna booster (50 mcg) is half the dose used for the primary series (100 mcg).

- At this time, NACI recommends that certain populations may be offered a booster dose, at the discretion of provinces and territories. To see NACI's guidance on who may receive a booster dose, please see NACI updated guidance on booster COVID-19 vaccine doses in Canada (December 3, 2021) for more information.

- This recommendation may be revised as more data comparing the use of the Pfizer-BioNTech booster (30 mcg) and the Moderna booster (50 mcg) become available.

For people 30 years of age and older receiving an mRNA primary series and/or receiving an mRNA booster dose:

Either mRNA vaccine (Pfizer-BioNTech or Moderna) should be used. The second dose of a primary series should be provided 8 weeks after the first dose and a booster dose, when recommended, should be provided at least 6 months after the completion of a primary vaccine series.

- Adults 30 years of age and older have a lower risk of experiencing myocarditis and/or pericarditis following vaccination with a COVID-19 mRNA vaccine compared to adolescents and young adults 12 to 29 years of age.

- Everyone who is offered an mRNA COVID-19 vaccine should be informed of the rare risk of experiencing myocarditis and/or pericarditis following immunization and should be advised to seek immediate medical attention if they develop symptoms, including chest pain, shortness of breath, or the feeling of a fast, pounding or fluttering heartbeat after receiving a dose of a COVID-19 mRNA vaccine.

- Cases of myocarditis and/or pericarditis typically occur within a week of vaccination and more commonly after a second dose. Any potential cases should be medically assessed and investigated regardless of the time since vaccination.

- NACI will continue to review the evidence on myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines as it emerges and will update their recommendations as needed.

- For additional details on myocarditis and/or pericarditis following COVID-19 mRNA vaccination, please see the latest NACI Recommendations on the use of COVID-19 vaccines and NACI Recommendations on the use mRNA COVID-19 vaccines in adolescents 12 to 17 years of age.

To see the full rapid response, including the evidence and rationale behind these recommendations, please visit NACI Rapid Response: Updated recommendation on the use of authorized COVID-19 vaccines in individuals aged 12 years and older in the context of myocarditis and pericarditis reported following mRNA COVID-19 vaccination.

QUOTES

"NACI has been carefully watching for rare cases of myocarditis or pericarditis following mRNA vaccination, and we have been communicating about these cases as the evidence has been emerging. We now have sufficient compelling evidence that the risks of myocarditis or pericarditis can be reduced in adolescents and young adults by choosing to provide the Pfizer-BioNTech Comirnaty vaccine, which has shown lower rates of myocarditis in those 12 to 19 years of age compared to Moderna Spikevax 100 mcg vaccine. This complements the recent NACI recommendations to provide vaccine doses at least 8 weeks apart, which is also expected to further reduce myocarditis and pericarditis risks while increasing vaccine effectiveness. For adults 30 years and older, a product preference is not necessary between the two mRNA vaccines. In some young people who are immunocompromised, the Moderna Spikevax 100mcg vaccine can be considered in consultation with their clinicians since they may have a lower immune response to COVID-19 vaccination and this vaccine may have a slightly higher vaccine effectiveness.

As a precaution, a booster dose of Pfizer-BioNTech Comirnaty may be preferred over a booster dose of Moderna Spikevax (i.e. 50 mcg dose) for adults 18 to 29 years of age who are recommended to receive a booster dose.

NACI has been able to make these recommendations because of the strong safety surveillance systems here in Canada, and also internationally, that help us refine the vaccine program over time to continually reduce very rare risks as we learn more about them. We will keep watching this space closely, and will update advice as needed."

- Dr. Shelley Deeks, NACI Chair

"Based on careful review of the latest accumulated data from ongoing vaccine safety monitoring systems in Canada and internationally, this update from NACI provides further guidance to help maximize the benefits of COVID-19 vaccination while minimizing any potential risks.

NACI reaffirms that the benefits of receiving an mRNA COVID-19 vaccine continue to outweigh any potential risks of experiencing rare side effects following vaccination with an mRNA vaccine, including the rare risk of vaccine-associated myocarditis and/or pericarditis most often seen in males aged 12 to 29 years.

New Canadian and international data suggests the rare risk of myocarditis after receiving an mRNA COVID-19 vaccine may be lower with the Pfizer-BioNTech Comirnaty vaccine (30 mcg) compared to the Moderna Spikevax vaccine (100 mcg) and that a longer interval between the first and second dose in the primary series results in stronger immune response and higher vaccine effectiveness. As well, evidence suggests that longer intervals may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.

Accordingly, for adolescents and adults aged 12 to 29 years, NACI preferentially recommends the use of Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) over the use of the Moderna Spikevax COVID-19 vaccine (100 mcg) to start or complete a primary vaccine series. NACI

further recommends that the second dose of a primary mRNA vaccine series should be provided 8 weeks after the first dose.

As always, PHAC, Health Canada and NACI will continue to monitor the safety and effectiveness of COVID-19 vaccines used in Canada and around the world and will update guidance as necessary to provide Canadians with the best possible protection."

- Dr. Theresa Tam, Chief Public Health Officer

NACI FORWARD AGENDA

NACI continues to actively review emerging evidence on COVID-19 vaccines. Upcoming recommendation may include new advice on:

- Additional advice on booster COVID-19 vaccine doses
- Advice on vaccination for individuals with a history of myocarditis/pericarditis after a previous dose of vaccine
- Recommendations on the use of the Moderna COVID-19 vaccine in children, pending a regulatory decision by Health Canada
- Recommendations on the use of the Novavax COVID-19 vaccine, pending a regulatory decision by Health Canada
- Recommendations on the use of the Medicago COVID-19 vaccine, pending a regulatory decision by Health Canada