National Advisory Committee on Immunization (NACI)

Summary of Updated NACI COVID-19 Vaccine Statement of May 3, 2021

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

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

Canada

Overview

- COVID-19 vaccination is essential to ending the pandemic. NACI encourages all Canadians to get vaccinated with a complete series of COVID-19 vaccine to protect themselves, their families, and their communities from illness, hospitalizations and deaths from COVID-19.

- NACI has updated its Recommendations on the use of COVID-19 vaccines to include advice on the use of the Janssen COVID-19 vaccine. NACI has also reaffirmed its recommendation on COVID-19 vaccination during pregnancy.

- The Janssen COVID-19 vaccine is a single dose, viral vector vaccine authorized for use in Canada for adults 18 years of age and over. Health Canada has determined that it is a safe and effective vaccine.

- NACI assesses how best to use an authorized vaccine to achieve the greatest public health benefits. It analyzes the spread of COVID-19 in Canada and the risks for population subgroups; it applies data on the safety and effectiveness of COVID-19 vaccines from studies of their real-world use and develops advice on the equitable use of vaccines in immunization programs given vaccine supplies.

- At this time and based on current evidence, NACI recommends the Janssen COVID-19 vaccine may be offered to individuals 30 years of age and older without contraindications, if the individual does not wish to wait for an mRNA vaccine and if the benefits outweigh the risk for the individual.

- NACI recognizes that public health benefit-risk analyses for the use of the Janssen vaccine may vary between jurisdictions based on their unique circumstances, including local COVID-19 epidemiology; local vaccine supply and logistics; and equity considerations. These factors change over time.

- As a single dose vaccine, the Janssen vaccine may be better suited for populations that are harder to schedule for a second dose (e.g., mobile populations and certain hard to reach populations).

- NACI continues to preferentially recommend authorized mRNA COVID-19 vaccines due to the excellent protection they provide and the absence of safety signals of concern. NACI notes that Canada has procured and is expecting enough mRNA vaccines to fully vaccinate the currently eligible Canadian population before fall 2021.

- NACI recommends that a complete vaccine series, preferably with an mRNA COVID-19 vaccine, may be offered during pregnancy, if the benefits outweigh the risks for the individual and the fetus. An mRNA vaccine is preferred due to recently published data indicating the safety of mRNA vaccines during pregnancy, and concerns about the treatment of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) during pregnancy, should it occur following the administration of a viral vector vaccine.

- NACI also reaffirms that, until further evidence emerges, those previously infected with SARS-CoV-2 be offered a complete series with a COVID-19 vaccine.

- Public health measures remain the foundation of the pandemic response while vaccines continue to roll out across the country. It is important that everyone, regardless of vaccination status, continue to follow recommended public health measures.
- To see the full update, please visit Recommendations on the use of COVID-19 vaccines.

Background

Main Recommendation

- NACI has updated its Recommendations on the use of COVID-19 vaccines to include advice on the Janssen COVID-19 vaccine, a viral vector vaccine.
- Health Canada authorized the Janssen COVID-19 viral vector vaccine for individuals 18 years of age and older on March 5, 2021. It is a single dose vaccine that can be kept at refrigerated temperatures.
- NACI assesses how best to use authorized vaccines to achieve the greatest public health benefits. It analyzes the spread of COVID-19 in Canada and the risks for population subgroups; it applies data on the safety and effectiveness of COVID-19 vaccines from studies of their real-world use and develops advice on the equitable use of vaccines in immunization programs given vaccine supplies.
- NACI met on March 16, 25 and April 13, 26, 2021, to review the most up to date clinical trial data and effectiveness evidence from the real-world use of the Janssen vaccine. NACI also considered Canada's rapidly changing COVID-19 epidemiology; Canada's COVID-19 vaccine supply, including the specific qualities that make a particular vaccine best suited for certain populations or age-groups; and principles of ethical decision-making. NACI continues to review evidence as it evolves.
- Clinical trial data available to date demonstrate the single dose Janssen vaccine is 67% efficacious against moderate to severe symptomatic COVID-19 infection across all age groups, at least two weeks after receiving the vaccine. The vaccine was also highly efficacious in preventing critical illness and hospitalization.
- In addition, preliminary evidence suggests the Janssen vaccine offers protection against the B.1.351 variant of concern first identified in South Africa, and the P.2 variant of interest first identified in Brazil. There is no data on the P.1 variant of concern first identified in Brazil.
- There have been confirmed reports of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) after administration of the Janssen viral vector vaccine, as seen with the AstraZeneca viral vector vaccine. NACI weighed the benefits of the Janssen vaccine in saving lives and protecting populations against serious complications of COVID-19 against the risk of developing VITT.
- At this time and based on current evidence, NACI recommends a complete series with viral vector COVID-19 vaccine (AstraZeneca, Janssen) may be offered to individuals 30 years of

age and older without contraindications if the individual prefers an earlier vaccine rather than wait for an mRNA vaccine and if the following conditions apply:
    - A benefit-risk analysis determines that the benefit of earlier vaccination with the viral vector COVID-19 vaccine outweighs the risk of the individual getting COVID-19 while waiting for an mRNA COVID-19 vaccine;
    - The individual provides informed consent once the benefits and risks of VITT compared to COVID-19 are clearly outlined, including how long the individual will have to wait for an mRNA vaccine and public health measures the individual is able to take to minimize their exposure to the COVID-19 virus; and
    - The individual will have to wait in order to receive an mRNA vaccine.

- This recommendation provides provinces and territories with guidance on how to optimize the use of the Janssen vaccine in their jurisdictions to achieve the greatest public health benefit.

- The public health benefit-risk analysis for the use of the vaccine may vary between jurisdictions. Provinces and territories adapt NACI's recommended age threshold based on their unique circumstances, including local COVID-19 epidemiology, local vaccine supply and logistics and equity considerations. Health officials can refer to a Risk Assessment Tool for the use of the Janssen vaccine included in NACI's updated statement.

- Healthcare professionals should be aware of VITT, including how to diagnose and treat the condition. Individuals who receive the Janssen vaccine should monitor their health and immediately seek medical attention if they develop symptoms of VITT.

- NACI continues to preferentially recommend authorized mRNA COVID-19 vaccines due to the excellent protection they provide and the absence of any safety signals of concern. NACI notes that Canada has procured and is expecting enough mRNA vaccines to fully vaccinate the eligible Canadian population before fall 2021.

Recommendation on COVID-19 Vaccination During Pregnancy

- NACI recommends that a complete vaccine series with a COVID-19 vaccine (preferably with an mRNA vaccine) may be offered to pregnant individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the evidence of the use of COVID-19 vaccines in this population.

- mRNA vaccines (Pfizer-BioNTech, Moderna) are preferred for use in pregnant individuals due to recently published data from a study in the United States indicating the mRNA COVID-19 vaccines are safe in pregnant women. In addition, treating VITT in pregnant individuals, should it occur following the administration of a viral vector vaccine, is complex. Based on current evidence, VITT does not seem to be associated with the use of mRNA vaccines.

Recommendation on COVID-19 Vaccination for People Previously Infected with SARS-CoV-2 Virus

- NACI continues to recommend that people previously infected with the SARS-CoV-2 virus be offered a complete series of a COVID-19 vaccine.

- In the absence of one-dose vaccine effectiveness data in people who were previously infected and limited second-dose safety data, people with previous SARS-CoV-2 infection should continue to receive a complete vaccine series, regardless of the severity of their previous infection.

- NACI will continue to closely monitor the evolving data on COVID-19 vaccines and will update its recommendations as needed.

To see the full update, please visit Recommendations on the use of COVID-19 vaccines.