

# Recommendations of the National Advisory Committee on Immunization (NACI) on the use of the Pfizer-BioNTech COVID-19 vaccine

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# Declaration of interests – Dr. Robyn Harrison

- Nothing to declare

# Objectives

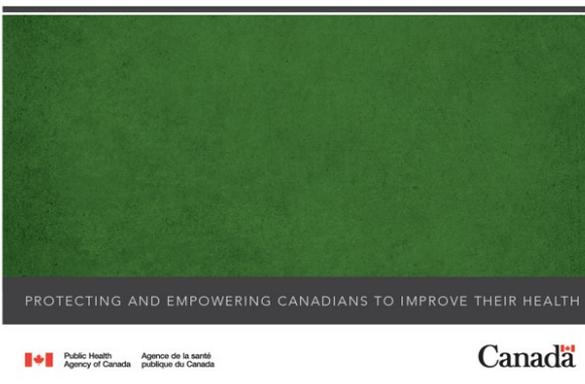
- To summarize the clinical evidence for the Pfizer-BioNTech COVID-19 vaccine
- To summarize the National Advisory Committee on Immunization (NACI) recommendations on the use of the Pfizer-BioNTech COVID-19 vaccine

# Preamble

- The Pfizer-BioNTech COVID-19 vaccine was authorized on December 9, 2020 by Health Canada for use in Canada for individuals 16 years of age and older.
- The following slides summarize the NACI's recommendations on the use of currently available COVID-19 vaccines. These recommendations apply to the Pfizer-BioNTech COVID-19 vaccine, which is the only available COVID-19 vaccine in Canada at the time of this webinar.
- Full details, including supporting evidence and rationale, can be found in the NACI statement, "Recommendations on the use of COVID-19 Vaccine(s)":
  - <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html>

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

Recommendations on the use of COVID-19  
Vaccine(s)



# What is NACI?

- NACI is an external advisory body to the Public Health Agency of Canada that develops evidence-based advice on vaccines approved for use in Canada.
- NACI is comprised of experts in the fields of pediatrics, infectious diseases, immunology, pharmacy, nursing, epidemiology, pharmacoeconomics, social science, and public health.
- NACI's advice is published to the public in the form of NACI statements. All of NACI's statements are synthesized into the Canadian Immunization Guide (CIG).
- More information about NACI can be found at: [www.canada.ca/naci](http://www.canada.ca/naci)

# **Clinical evidence for the Pfizer-BioNTech COVID-19 vaccine**

# Clinical trial characteristics

- Study C4591001 is the pivotal Phase 1/2/3 trial for the Pfizer-BioNTech COVID-19 vaccine.
- Evidence on immunogenicity is available for adults 18 to 55 and 65 to 85 years of age (evidence in 85 years of age and older is limited).
- Evidence on the safety and efficacy of the vaccine is available for adults 16 years of age and older.
- The Phase 2/3 portion of the trial involved approximately 44,000 study participants randomized (1:1) to receive either the vaccine or placebo.
- Trial data available to date are for an interim analysis; therefore the time of follow-up is not consistent but was less than four months after the second dose (maximum of 14 weeks) for all participants.

## Clinical trial characteristics (cont'd)

- Important exclusion criteria in the Phase 2/3 trial include:
  - Pregnancy and breastfeeding
  - Immunocompromised individuals with known or suspected immunodeficiency (including receipt of treatment with immunosuppressive therapy)
  - Previous clinical or SARS-CoV-2 PCR diagnosis of COVID-19
  - Those with a history of adverse reaction associated with a vaccine/component of the study intervention and those who have contraindications to IM injection
  - Receipt of blood/plasma products or immunoglobulin before vaccine administration
- People with chronic conditions were **not** excluded from the study
- People with serological evidence of SARS-CoV-2 infection were **not** excluded
- Participants from long-term care facilities were included but were limited in number

# Clinical evidence

- In clinical trials, the vaccine was efficacious against symptomatic, confirmed COVID-19 disease over the short-term.
  - Vaccine efficacy of 95.0% (95% CI: 90.3–97.6%) in participants without evidence of SARS-CoV-2 prior to 7 days post-dose 2.
- The highest efficacy was seen after the second dose. Peak humoral and specific cellular immune responses occur after the second dose.
- There is currently insufficient evidence on the duration of protection and on the efficacy of this vaccine in:
  - preventing death
  - preventing hospitalization
  - asymptomatic infection
  - reducing transmission of SARS-CoV-2but studies are ongoing.

# Safety

- Approximately 37,700 trial participants completed a median follow-up time of 2 months after dose 2 (~18,800 trial participants with at least 2 months of follow-up after dose 2).
- No serious safety concerns have been identified to date in clinical trials; however, studies are ongoing.
- Some adverse events were very common (particularly after the second dose) and they were reported to affect more than 10% of people who receive the vaccine. However, they were mild or moderate and transient, resolving within a few days.
  - These included: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. Some adverse events were more frequent after the second dose.
- There is currently minimal evidence to inform on differences in vaccine safety or efficacy between those with and those without prior evidence of SARS-CoV-2 infection at the time of vaccination.

# **NACI recommendations on the use of COVID-19 vaccine(s)**

## Recommendations – Main

**NACI recommends that a complete vaccine series (i.e., 2-doses) of COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine. In the context of limited vaccine supply, initial doses of COVID-19 vaccine should be prioritized for the key populations outlined in NACI's [Guidance on the Prioritization of Initial Doses of COVID-19 Vaccine\(s\)](#). (*Strong NACI Recommendation*)**

### Rationale

- Pfizer-BioNTech COVID-19 vaccine is highly efficacious in the short-term against COVID-19 disease and there are no significant safety concerns.
- The pivotal clinical trial was conducted in people 16 years of age and up, and this is the authorized age indication for the vaccine in Canada.
- Medium- and long-term follow-ups are needed and will be done.

# Recommendations – Public health measures

**NACI recommends that all individuals should continue to practice recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time. (*Strong NACI Recommendation*)**

## Rationale

- Insufficient evidence on the duration of protection of COVID-19 vaccines and the effectiveness of COVID-19 vaccines in preventing asymptomatic infection and reducing transmission of SARS-CoV-2.
- No evidence on the use of COVID-19 vaccine for post-exposure prophylaxis.

## Recommendations – Previous infection

**NACI recommends that a complete series of COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who have had previously PCR-confirmed SARS-CoV-2 infection. In the context of limited vaccine supply, initial doses may be prioritized for those who have not had a previously PCR-confirmed SARS-CoV-2 infection. (*Discretionary NACI Recommendation*)**

### Rationale

- Lack of evidence in this group, but level of protection from previous infection unknown.
- Testing for previous SARS-CoV-2 infection is **NOT** needed prior to COVID-19 vaccination.
- Vaccination may be delayed for 3 months following a PCR-confirmed infection, as reinfections reported to date have been rare within the first 3 months following the first infection.
- All symptoms of an acute illness should be completely resolved before vaccinating.

# Recommendations – Immunosuppressed

**NACI recommends that COVID-19 vaccine should not be offered to populations who are immunosuppressed due to disease or treatment or those with an auto-immune disorder until further evidence is available. *(Strong NACI Recommendation)***

**However, a complete series of COVID-19 vaccine may be offered to individuals in the authorized age group in this population if a risk assessment deems the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. *(NACI Discretionary Recommendation)***

## **Rationale**

- Immunosuppressed were excluded from trials. There is a lack of evidence on efficacy and safety in this group.
- People living with HIV that are considered immunocompetent may be vaccinated.

# Recommendations – Pregnancy & breastfeeding

**NACI recommends that COVID-19 vaccine should not be offered to individuals who are pregnant until after completion of pregnancy, until further evidence is available (Strong NACI Recommendation). However, a complete series of COVID-19 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 absence of evidence on the use of COVID-19 vaccine in this population. (*NACI Discretionary Recommendation*)**

**Same recommendation for breastfeeding.**

## **Rationale**

- Anyone who was pregnant or breastfeeding at time of vaccination were excluded from trials. There is a lack of evidence on efficacy and safety in this group.

## Recommendations – Children & adolescents

**NACI recommends that COVID-19 vaccine(s) should not be offered to individuals who are not in the authorized age group. (*Strong NACI Recommendation*)**

**However, a complete series of Pfizer-BioNTech may be offered to individuals 12-15 years of age who are at very high risk of severe outcomes of COVID-19 (e.g., due to a pre-existing medical condition known to be associated with increased risk of hospitalization or mortality) AND are at increased risk of exposure (e.g., due to living in a congregate care facility) if informed consent with the individual and the parent or guardian includes discussion about the insufficient evidence on the use of COVID-19 vaccines in this population. (*NACI Discretionary Recommendation*)**

### **Rationale**

- Small number of adolescents 12 to 15 years of age were included in trial at a later start date, but were not included in efficacy evidence.

# Contraindications

- The Pfizer-BioNTech COVID-19 vaccine is contraindicated in individuals with a history of anaphylaxis after previous administration of the vaccine.
- Individuals with a history of severe allergic reaction to a component of the Pfizer-BioNTech COVID-19 vaccine should not receive the vaccine.
  - Polyethylene glycol is a potential allergen in the vaccine known to cause type 1 hypersensitivity reactions.
- In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, investigation is indicated which may lead to immunization in a controlled setting. Consultation with an allergist is advised.
  - If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted.

## Precautions

- In individuals with bleeding disorders, the condition should be optimally managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy.
- As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, it would be prudent to wait until all symptoms of an acute illness are completely resolved before vaccinating with an authorized COVID-19 vaccine.

## Precautions (cont'd)

- Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, in order to avoid attributing any complications resulting from infection with SARS-CoV-2 to vaccine-related AEFI and to minimize the risk of COVID-19 transmission at an immunization clinic/venue.
- If any persons are identified with symptoms on arrival at the venue, they should be instructed to follow current local public health measures.

# Vaccine administration

- The Pfizer-BioNTech COVID-19 vaccine is administered intramuscularly in a 2-dose schedule.

Immunization schedule	Dose volume	Minimum interval	Authorized interval	Alternate interval
2-dose schedule	0.3 mL	19 days	21 days	28 days

- The same vaccine product should be used to complete the vaccine series.
- Serologic testing is not needed before or after receipt of a COVID-19 vaccine to assess susceptibility to SARS-CoV-2 or immune response to the vaccine.
- COVID-19 vaccines should not be given simultaneously with other vaccines (live or inactivated) at this time, unless other vaccines are required for post-exposure prophylaxis.
- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

# Post-vaccination counseling

- NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination.
  - There is currently no evidence on the benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.
- Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.

# NACI membership

- **Members:** Dr. C Quach (Chair), Dr. S Deeks (Vice-Chair), Dr. J Bettinger, Dr. N Dayneka, Dr. P De Wals, Dr. E Dube, Dr. V Dubey, Dr. S Gantt, Dr. R Harrison, Dr. K Hildebrand, Dr. K Klein, Dr. J Papenburg, Dr. C Rotstein, Dr. B Sander, Ms. S Smith, and Dr. S Wilson.
- **Liaison representatives:** Dr. LM Bucci (Canadian Public Health Association), Dr. E Castillo (Society of Obstetricians and Gynaecologists of Canada), Dr. A Cohn (Centers for Disease Control and Prevention, United States), Ms. L Dupuis (Canadian Nurses Association), Dr. J Emili (College of Family Physicians of Canada), Dr. D Fell (Canadian Association for Immunization Research and Evaluation), Dr. R Gustafson (Council of Chief Medical Officers of Health), Dr. D Moore (Canadian Paediatric Society), Dr. M Naus (Canadian Immunization Committee), and Dr. A Pham-Huy (Association of Medical Microbiology and Infectious Disease Canada).
- **Ex-officio representatives:** Dr. D Danoff (Marketed Health Products Directorate, HC), Ms. E Henry (Centre for Immunization and Respiratory Infectious Diseases [CIRID], PHAC), Ms. M Lacroix (Public Health Ethics Consultative Group, PHAC), Ms. J Pennock (CIRID, PHAC), Dr. R Pless (Biologics and Genetic Therapies Directorate, Health Canada), Dr. G Poliquin (National Microbiology Laboratory, PHAC), Dr. V Beswick-Escanlar (National Defence and the Canadian Armed Forces), and Dr. T Wong (First Nations and Inuit Health Branch, Indigenous Services Canada).

# NACI High Consequence Infectious Disease Working Group

- **WG Chair:** Caroline Quach
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- **Project management support:** Veronica Ferrante, Michelle Matthieu-Higgins

# Additional resources

- [Research priorities for COVID-19 vaccines to support public health decisions](#)
  - NACI guidance to inform clinical trials of candidate COVID-19 vaccines.
- [Preliminary guidance on key populations for early COVID-19 immunization](#)
  - NACI guidance to plan for the efficient, effective, and equitable allocation of an eventual COVID-19 vaccine when limited initial vaccine supply will necessitate the immunization of some populations earlier than others.
- [Guidance on the prioritization of initial doses of COVID-19 vaccine\(s\)](#)
  - NACI guidance for the efficient and equitable prioritization of initial doses of COVID-19 vaccines to assist with the planning for allocation of the first COVID-19 immunization programs.