The National Advisory Committee on Immunization (NACI) has issued a new guidance document to address some key issues concerning COVID-19 vaccine.(1)

The NACI noted the evidence on COVID-19 disease and vaccines is evolving and evidence from clinical trials is still quite limited.

Pfizer-BioNTech COVID-19 vaccine: what is known and unknown:(1)

- ***Age range*** This vaccine is authorized for use in Canada for individuals 16 years of age and older.
- ***Efficacy against symptomatic COVID-19 disease*** Clinical trials have shown high short-term efficacy against symptomatic, confirmed COVID-19 disease. Efficacy is similar in adults with one or more comorbidities, as well as in younger adults and older adults, but only limited evidence is available in adults of advanced age (≥ 85 years) and in long-term care facilities. Evidence is currently insufficient regarding differences in vaccine efficacy or safety between individuals with and those without prior evidence of SARS-CoV-2 infection at the time of vaccination.
- ***Efficacy against severe disease*** Evidence is lacking on the vaccine's efficacy in preventing death or hospitalizations; studies are ongoing.
- ***Efficacy against asymptomatic infection and transmission*** Currently, there is no reported evidence on efficacy in preventing asymptomatic infection, reducing viral shedding or in preventing transmission; studies are ongoing.
- ***Peak protection*** The first dose provides some protection, but peak protection begins one week after the second dose of the two-dose series.
- ***Duration of protection*** Evidence is currently insufficient on the duration of protection (i.e., currently there is no available evidence on medium- and long-term efficacy).
- ***Adverse effects*** No serious safety concerns were identified in short-term clinical trials (with a follow-up period of < 14 weeks after the second dose). Adverse events affecting more than 10% of vaccines include pain at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever; most are mild or moderate and transient, resolving within a few days. Fever is more frequent after the second dose. Lymphadenopathy is an uncommon adverse event. Medium- and long-term evidence on vaccine safety is limited; studies are ongoing. The NACI recognizes that the probability of detecting very rare adverse events in clinical trials to date is low because of limited clinical trial population sizes and duration of follow-up; ongoing pharmacovigilance is essential.
- ***Interval between doses*** The vaccine is administered intramuscularly (deltoid muscle) in a two-dose schedule. The second dose is recommended to be given 21 days after the first dose, but can be given a minimum of 17 days after the first dose or 28 days after the first dose. Most participants in the clinical trial received the two doses 21 to 27 days apart. Currently, there is no data on a maximum interval between doses.
- ***Interruption of vaccine series*** Interruption of a vaccine series does not require restarting the series. However, maximum protection may not be attained until the complete vaccine series has been administered.
- ***Patients with a history of anaphylaxis*** The vaccine is contraindicated in individuals with a history of anaphylaxis after previous administration of the vaccine and in those with

proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its container.

- ***Patients with bleeding disorders*** The bleeding disorder should be optimally managed prior to immunization to minimize the risk of bleeding.
- ***Patients receiving anticoagulants*** Individuals receiving long-term anticoagulation are not at higher risk of bleeding complications following immunization. They may be safely immunized without discontinuing their anticoagulant therapy.

NACI key recommendations:(1)

- ***Prioritizing initial doses*** As vaccine supplies are currently limited, 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)*.(2) Initial doses may also be prioritized for those without previously PCR-confirmed SARS-CoV-2 infection.
- ***Following public health measures*** All those vaccinated should continue to practice recommended public-health measures (masks, physical distancing, etc.) for prevention and control of SARS-CoV-2 infection and transmission. This recommendation may change as more evidence becomes available.
- ***Immunosuppressed, pregnancy/breastfeeding, adolescents (12–15 years of age):*** COVID-19 vaccine should *not* be offered to the following populations that were excluded from clinical trials until further evidence is available: immunosuppressed individuals due to disease or treatment or suffering from an autoimmune disorder; pregnant or breastfeeding; and adolescents 12–15 years of age. However, if a risk assessment finds that the benefits of vaccination outweigh the potential risks, and if informed consent includes discussion about the insufficient evidence in these populations, then a complete series of vaccine may be offered to individuals in these populations.
- ***Post-vaccination counselling*** 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. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever), if they occur after vaccination.
- ***Administration with other vaccines*** Currently, COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines, unless another vaccine is required for post-exposure prophylaxis. In the absence of evidence, it would be wise to wait at least 28 days after completing the two-dose COVID-19 vaccine series before administering another vaccine (except when another vaccine is required for post-exposure prophylaxis). It would also be wise to wait for least 14 days after the administration of another vaccine before administering the COVID-19 vaccine.
- ***Giving with convalescent plasma or monoclonal antibodies*** COVID-19 vaccines should generally *not* be given simultaneously with monoclonal antibodies or convalescent plasma. Administering these products close together may result in decreased effectiveness of the COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies because the monoclonal antibodies have high affinity for the spike protein expressed by the vaccines. Expert clinical opinion should be sought on a case-by-case basis.(1)

The NACI document also outlines research priorities to address the numerous outstanding questions about vaccine efficacy, immunogenicity and safety and several issues related to vaccine administration.(1)

References

1. National Advisory Committee on Immunization (NACI). Recommendations on the use of COVID-19 vaccine(s). December 12, 2020. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html?hq_e=el&hq_m=2169386&hq_l=1&hq_v=42f995eed6#a7 (accessed December 16, 2020).
2. National Advisory Committee on Immunization (NACI). Guidance on the prioritization of initial doses of COVID-19 vaccine(s). Modified December 12, 2020. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-prioritization-initial-doses-covid-19-vaccines.html (accessed December 16, 2020).