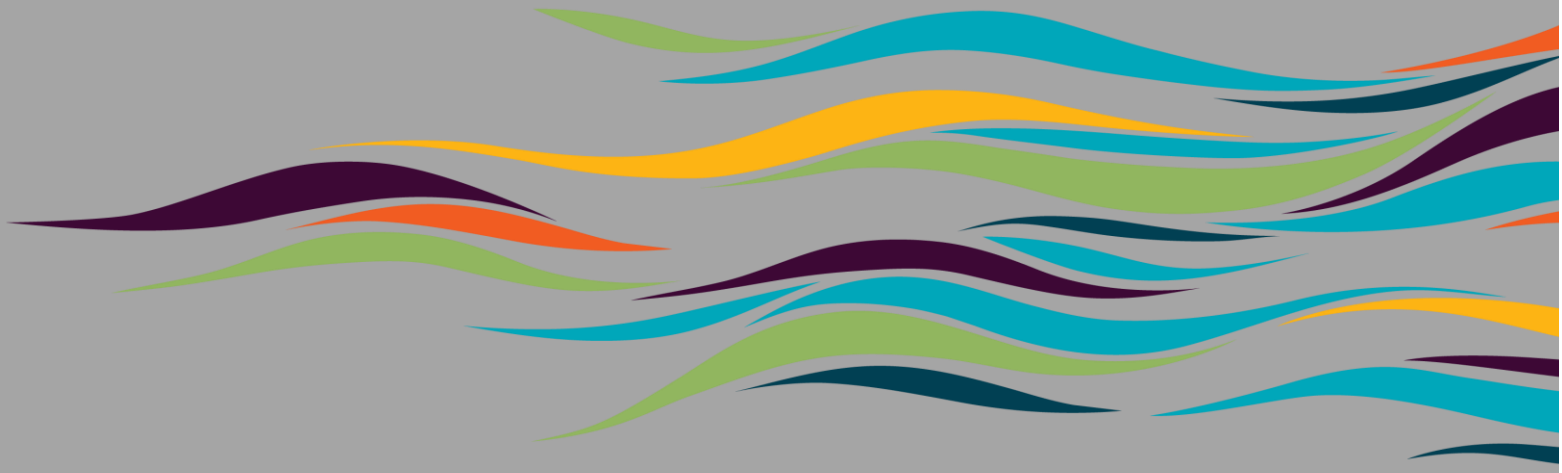
COVID-19 Vaccine FAQs for Health Care Providers

August 2022



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Background

Updated as of July 14, 2022

This FAQ document includes information on COVID-19 vaccines and answers common questions about the vaccines that are currently in use in Yukon.

These FAQs are for your own information, but more importantly are designed to help you counsel patients appropriately about vaccines, to address vaccine hesitancy, to ensure that patients have their questions answered, and to inform their consent to receiving the vaccine.

The most trusted source of vaccine information is a patient's health care provider.

COVID-19 vaccine information is evolving, and as such, this FAQ document will be updated as new information becomes available.

COVID-19 disease

1. What is the epidemiology of COVID-19?

For the most up-to-date data on COVID-19 cases, go to:

- **Global:** https://health-infobase.canada.ca/covid-19/international/
- **National:** https://health-infobase.canada.ca/covid-19/
- **Yukon:** https://yukon.ca/en/health-and-wellness/covid-19-information/case-counts-covid-19

2. Why is COVID-19 vaccination important?

Preventative measures such as physical distancing, frequent handwashing, and wearing a mask help to reduce the risk of exposure and transmission of SARS-CoV-2, but these measures alone are not enough. The combination of COVID-19 vaccination and following prevention measures will provide the best protection against COVID-19.

Ending this pandemic requires all the tools we have available including, most importantly, vaccination. Safe and effective vaccines will reduce the transmission of the virus that causes COVID-19 and associated illnesses and deaths. Over time, widespread immunization will allow Yukoners to live with fewer restrictions.

COVID-19 vaccination protects the person being vaccinated and also the people around them, including those unable to be vaccinated. The level of COVID-19 vaccination coverage required to reach herd immunity will vary based on vaccine effectiveness. For an R_0 of 2.5 to 3.5 (the average number of people who become directly infected by someone with COVID-19), approximately 60-72% of the population would need to be immunized to block the continued transmission of SARS-CoV-2.

3. How do I know if someone has an expected vaccine response or if they should be tested for COVID-19?

While some of the side effects of the vaccine are similar to symptoms of COVID-19 infection, it is important not to assume that symptoms are due to the vaccine. For example, cough or other respiratory symptoms are not side effects of the vaccine and are more likely to be due to a respiratory infection like COVID-19. Symptoms that are multiple and last longer than a few days also could be due to COVID-19. The routine testing recommendations for COVID-19 (July 15, 2020) should be applied in the immediate post-immunization period and to people who are fully immunized against COVID-19.

It is particularly important to test people who present with any of the following symptoms regardless of COVID-19 immunization history: cough, fever/chills, shortness of breath, difficulty breathing, or loss of taste or smell. Regardless of vaccination status, there should be a low threshold for testing anyone who is a contact of a COVID-19 case or returned from out-of-Yukon travel in the 14 days prior, and testing is recommended as soon as possible.

Vaccine development and safety

4. What is NACI (National Advisory Committee on Immunization)?

The National Advisory Committee on Immunization (NACI) is a national advisory committee of experts in the fields of pediatrics, infectious diseases, immunology, pharmacy, nursing, epidemiology, pharmaco-economics, social science, and public

health. NACI has been providing guidance on the use of vaccines currently or newly approved for use in Canada to the Government of Canada since 1964. The Committee reports to the Vice-President of the Infectious Disease Prevention and Control Branch and works with staff of the Centre for Immunization and Respiratory Infectious Diseases of the Public Health Agency of Canada to provide ongoing and timely medical, scientific and public health advice.

NACI makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable diseases for whom vaccination should be targeted. NACI knowledge syntheses, analyses and recommendations on vaccine use in Canada are included in published literature reviews, statements, and updates.

5. How do we know that the COVID-19 vaccines are safe and effective if they were developed so quickly?

The efforts to find a vaccine for COVID-19 have been on a scale that has never been seen before. With so many resources put towards it, these vaccines were developed in record time. Factors that allowed the COVID-19 vaccine to progress quickly include advances in vaccine technology, government funding and purchase commitments, international collaboration to develop the vaccine, rapid recruitment of participants for clinical trials, and streamlined vaccine approval processes by the national drug regulatory organizations, including Health Canada. While the need to deliver the vaccine quickly was important, no steps in Canada's rigorous approval process were missed. Instead, with more resources came faster results

As with all vaccines and treatments, Health Canada reviews all evidence and scientific data before deciding whether to authorize a product for use in Canada. They will only authorize the vaccine when the evidence shows that:

- **The vaccine is safe, effective and of good quality; and,**
- **The benefits outweigh the known and potential risks.**

For example, Health Canada's approval of the Pfizer COMIRNATY vaccine was based on ensuring that the vaccine itself, laboratory studies and three phases of double-blinded randomized clinical trials showed safety, immunogenicity (ability to generate an immune response) and efficacy (ability to prevent COVID-19 disease) in animals, and in adolescents and adults 16 years of age and older. Approximately 44,000 individuals randomized (1:1) to receive either the vaccine or placebo participated in phases 2 and 3 of the clinical trials. This population has been considered sufficient to approve vaccines based on safety and efficacy.

Health Canada also has processes in place that allow for sharing of information with other countries' regulatory bodies including the US Food and Drug Administration and the European Medicines Agency.

Once approved, vaccine safety and effectiveness are continuously monitored to detect rare, serious, or unexpected side effects.

6. What is the approval process for COVID-19 vaccines in Canada?

The Biologic and Radiopharmaceutical Drugs Directorate (BRDD) is part of Health Canada and supervises all pieces of vaccine production and quality control. When the manufacturer collects enough scientific and clinical evidence of the safety, efficacy, and quality of a vaccine, they file a complete package of information and submit it to BRDD for market authorization. The submission includes data from scientific studies and information about the manufacturing process, including the facility and method. BRDD then reviews the submission to determine if the benefits of a vaccine outweigh any potential risks. BRDD also reviews the procedures for safety monitoring by the manufacturer and any plans to minimize identified risks. BRDD may also visit the manufacturing site to evaluate the process' quality and make sure the manufacturer is completing the necessary quality controls for the vaccine.

The review process was able to be expedited for COVID-19 vaccines because of administrative changes to the process, including the allowance of submission of data when available rather than waiting until the entire data package is complete prior to submission. In addition, Canada and many countries have allowed for a shorter period of follow-up of people enrolled in the phase 3 clinical trials. Clinical trials will continue to accrue cases and safety information for up to two years following immunization and the results of these studies will provide additional information about issues such as duration of protection. For non-pandemic vaccines, the follow-up period is typically over one year.

More Health Canada information can be found at: Vaccines and Treatments for COVID-19: Progress and Interim order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

7. How do we reassure the public that COVID-19 vaccines are safe and effective?

In order to have an effective conversation about COVID-19 vaccines, the conversation must come from a place of compassion and understanding. As mentioned earlier, the most trusted source of vaccine information is a patient's health care provider. Be transparent about the latest information, reassure that there is a robust vaccine safety system in Canada, and emphasize the role vaccines play in the protection of the recipient and people around them. Your willingness to listen to the patients' concerns will be critical in developing trust in you and your recommendations. If the patient has concerns or questions, this doesn't always mean they won't accept a COVID-19 vaccine. Sometimes patients simply want your answers to their questions. Once you've responded to their questions, ensure them that you are open to continuing the conversation. Direct them towards trusted sources of information, like the federal or Yukon government websites. Continue the conversation about COVID-19 vaccination during future visits.

8. How will the safety of the COVID-19 vaccines be monitored in Canada?

Local, territorial/provincial, and national surveillance systems are used to carefully monitor any adverse events following immunization and detect any vaccine safety concerns. Once a vaccine is approved, its safety is continuously monitored as long as it is being used. In most places, health care providers are legally obliged to report all serious and unexpected adverse events following immunization to the medical health officer. Every serious or concerning event is then reported to Yukon Immunization Program. These reports are reviewed at Yukon Immunization Program and also sent to the Public Health Agency of Canada system called the Canadian Adverse Events Following Immunization System (CAEFISS), as are reports from all provinces and territories. Additional monitoring for adverse events is being done through a system called CANVAS (Canadian National Vaccine Safety Network) through which recipients of the vaccine can enroll to self-report adverse events following receipt of the vaccine.

At the international level, the World Health Organization's International Drug Monitoring Program collects reports from over 75 countries and uses these data to monitor for any vaccine safety concerns. In addition, all vaccine manufacturers are required to report serious adverse events of which they become aware, in Canada or internationally, to Health Canada. For COVID-19 vaccines, manufacturers are expected to implement enhanced monitoring.

More information about Canada's vaccine safety surveillance system can be found in the Canadian Immunization Guide: Vaccine safety and pharmacovigilance.

9. How do health care providers report an adverse event following COVID-19 immunization?

Vaccine providers should refer to the Yukon Immunization Manual – Section 13 – Adverse Events Following Immunization for criteria on reporting adverse events following immunization (AEFI), and report AEFIs by entering them into Panorama. If the provider does not have access to Panorama, then notify the Yukon Immunization Program by fax to 867-393-4357.

10. What is VITT (Vaccine-Induced Immune Thrombotic Thrombocytopenia)? Are there any concerns about safety issues with the COVID-19 vaccines?

There have been no confirmed cases of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) with the Pfizer COMIRNATY or Moderna COVID-19 vaccines.

The rate of VITT in Canada appears to be extremely rare (1 in 100,000 doses of AstraZeneca), but ongoing investigations will improve estimation of the rate. VITT (also known as Vaccine-Induced Prothrombotic Immune Thrombocytopenia or VIPIT) is a rare adverse event that can follow adenovirus vector COVID-19 vaccines, including the AstraZeneca and Janssen COVID-19 vaccines. This condition is characterized by thrombosis (blood clots) and thrombocytopenia (low platelet levels) that appear 4-28 days after vaccination.

At this time, we don't know if certain patients are more likely to get VITT because it does not develop through the same process as more common types of bleeding or clotting problems. Most patients who developed VITT have been under 60 years old, and there have been more women than men diagnosed with VITT.

COVID-19 Vaccines in Yukon

11. Which COVID-19 vaccines are currently authorized for use in Canada?

There are currently five COVID-19 vaccines approved for use in Canada. Two are mRNA vaccines:

- **Pfizer COMIRNATY COVID-19 vaccine**
- **Moderna COVID-19 vaccine**

Two are non-replicating viral vector vaccines:

- **AstraZeneca/COVISHIELD vaccine**
- **Janssen vaccine**

One is a recombinant protein subunit vaccine:

- **Novavax Nuvaxovid**

12. How are the COVID-19 vaccines being used in the Yukon?

Ages 6 months to 4 years	
Dose 1 Moderna SPIKEVAX – 25 mcg	**Dose 2** 8 weeks after first dose Moderna SPIKEVAX – 25 mcg

Ages 5 to Under 12			
Dose 1 Pfizer Comirnaty - 10 mcg	**Dose 2** 8 weeks after 1st dose Pfizer Comirnaty - 10 mcg	**Dose 3** For moderately to severely immunocompromised: 28 days after 2nd dose Pfizer Comirnaty - 10 mcg	**Booster dose** 6 months after completion of primary series Pfizer Comirnaty - 10 mcg

Ages 12-17				
Dose 1 Pfizer Comirnaty - 30 mcg	**Dose 2** 8 weeks after 1st dose Pfizer Comirnaty - 30 mcg	**Dose 3** For moderately to severely immunocompromised: 28 days after 2nd dose Pfizer Comirnaty - 30 mcg	**Booster 1** 6 months after completion of primary series Pfizer Comirnaty - 30 mcg	**Booster 2** For moderately to severely immunocompromised: 6 months after Booster 1 Pfizer Comirnaty - 30 mcg

Ages 18 and over
Pfizer Comirnaty (preferred ages 18-29)

Dose 1 Pfizer Comirnaty - 30 mcg	**Dose 2** 8 weeks after 1st dose Pfizer Comirnaty - 30 mcg* *(*first choice if less than 30years of age)*	**Dose 3 (special populations)** For moderately to severely immunocompromised: 28 days after 2nd dose Pfizer Comirnaty - 30 mcg* *(*first choice if less than 30years of age)*	**Booster 1** 6 months after completion of primary series Pfizer Comirnaty - 30 mcg* *(*first choice if less than 30 years of age)*	**Booster 2** 6 months following 1st booster dose Pfizer Comirnaty - 30 mcg *(*first choice if less than 30 years of age)*
Moderna SPIKEVAX Adult/Adolescent (preferred ages 30+)				
Dose 1 Moderna Spikevax 100mcg	**Dose 2** 8 weeks after 1st dose Moderna Spikevax 100mcg	**Dose 3 (special populations)** For moderately to severely immunocompromised: 28 days after 2nd dose Moderna Spikevax 100mcg	**Booster 1** 6 months after completion of primary series • Ages 18-69 = 50mcg • Ages 70+ = 100mcg	**Booster 2** 6 months following 1st booster dose • Ages 70+ or immunocompromised = 100mcg • Ages 69 and younger = 50mcg
Novavax Nuvaxovid (if unable or unwilling to get mRNA)				
Dose 1 Novavax Nuvaxovid – 5mcg	**Dose 2** 8 weeks after 1st dose Novavax Nuvaxovid – 5mcg	**Dose 3 (special populations)** For moderately to severely immunocompromised: 28 days after 2nd dose Novavax Nuvaxovid – 5mcg	**Booster 1** 5 – 6 months after completion of primary series Novavax Nuvaxovid – 5 mcg	**Booster 2** 5 – 6 months following 1st booster dose Novavax Nuvaxovid – 5 mcg
Fully vaccinated with viral vector vaccine (2 doses of Astra Zeneca or 1 dose Janssen) • booster with mRNA vaccine 6 months after 2nd or last dose Refer to product pages in Section 8 for minimum intervals				

13. What is the recommended COVID-19 vaccines in individuals aged 12 and older in the context of myocarditis and pericarditis?

On December 3, 2021, NACI updated their recommendations on the use of authorized COVID-19 vaccines in people 12 years of age and older in the context of myocarditis and / or pericarditis reported following mRNA COVID-19 vaccination. NACI and Yukon's a/CMOH now

recommend that Pfizer-BioNTech Comirnaty mRNA vaccine (30 mcg) be used preferentially in adolescents and young adults 12 to 29 years of age.

- 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.
- 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) is preferred over the use of the Moderna booster dose (50 mcg).
- 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.

These recommendations are based on new evidence to further minimize the rare risk of adolescents and young adults experiencing myocarditis and/or pericarditis after receiving a COVID-19 mRNA vaccine. 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. In Yukon, the rate of reported myocarditis and pericarditis is extremely low 0.002%. 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.

General questions

14. Will there need to be additional booster doses or a need for a yearly dose as given for influenza?

As of August 19, 2022, NACI recommends that a booster dose of an mRNA COVID-19 vaccine may be offered at least 6 months after completion of a primary COVID-19 vaccine series to people 5 years of age and older..

As of June 29, 2022, the a/MOH recommends a second booster dose should be provided 6 months following the first booster dose, with a minimum interval of 5

months, to all Yukoners 18 years of age or older and to individuals over 12 years of age.

The intent of a booster dose is to restore protection that may have decreased over time to a level that is no longer deemed sufficient in individuals who initially responded adequately to a complete primary vaccine series. In recent studies, a booster dose resulted in about a 10-fold reduction in confirmed infection rates. There is currently limited evidence on the long-term effectiveness of booster doses, with studies suggesting some decrease over time. Ongoing research will continue regarding booster doses for the general public.

NACI's terminology will adjust as they continue to monitor emerging scientific data on whether a dose should be considered a booster dose or part of the primary series. A booster dose is given to stimulate the memory response once protection has truly waned. A primary series dose is given to establish strong immune response and memory.

Alongside a booster dose, NACI provided recommendations on an additional dose to complete a series for certain individuals. A third dose is different then a booster dose and is given to immunosuppressed people so they can develop an adequate immune response. In addition, the third dose is given four weeks after their second shot.

September 2021, NACI recommended that *"for those who have not yet been immunized, moderately to severely immunocompromised individuals in the authorized age groups should be immunized with a primary series of three doses of an authorized mRNA vaccine"* and *"for those moderately to severely immunocompromised individuals in the authorized age groups who have previously received a 1- or 2-dose complete primary series, including those who received a mixed vaccine schedule, should be offered an additional dose of an authorized mRNA COVID-19 vaccine"*. In order to meet the criteria of this definition, the client must have one of the following conditions:

- Active treatment for solid tumor or hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome
- Active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (e.g., a prednisone dose of ≥ 2 mg/kg per day or ≥ 20 mg per day if weight > 10 kg, for ≥ 14 days), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive (e.g., cancer chemotherapy, radiation therapy, cytotoxic drugs, calcineurin inhibitors, biological response modifiers and antibodies that target lymphocytes).

Multiple research and surveillance priorities are occurring with respect to the efficacy, effectiveness, immunogenicity, and safety of the COVID-19 vaccines. These priorities include population effectiveness and medium- and long-term duration of protection of the complete series of the COVID-19 vaccine. The level of protection provided by these vaccines against COVID-19 at one, two, or more years after vaccination will be determined with ongoing surveillance of vaccine effectiveness.

15. Once an individual is vaccinated will they need to continue practicing the recommended public health measures?

Yes. Individuals are still encouraged to practise the Safe 6 for the prevention and control of SARS-CoV-2 infection and transmission. There is currently not enough evidence on the duration of protection of COVID-19 vaccines in preventing infection and reducing transmission of SARS-CoV-2 to recommend discontinuation of public health measures. As we get more information about the impact of vaccination on COVID-19 transmission, there will likely be changes to the current prevention and control measures.

Please refer to Yukon.ca for the most up to date travel guidance.

16. How can I address false information clients have?

When addressing questions related to false immunization information, the first step is to acknowledge your clients' concerns. This helps build a trusting relationship between the client and health care provider.

Ex: "Thanks for bringing this to my attention. There is a lot of false information circulating and it can be difficult to distinguish from fact."

Discuss why the benefits of vaccination greatly outweigh the risks of Covid-19 infection and describe the trustworthiness of Canada's immunization system.

Ex: The vaccines are very effective at preventing severe illness, hospitalization, and death from COVID-19. Health Canada will only authorize a vaccine once the scientific and medical evidence shows the vaccine is safe and effective. The risks of a Covid-19 infection

Address the false information with a fact that is clear and relevant to help the client remember it.

Common concerns:

"I'm worried that these vaccines will change my DNA"

- Vaccines don't change your DNA. The mRNA vaccines cannot alter genetic material, its role is to teach the body to make an immune response against the COVID-19 pathogen.
- mRNA and DNA are different. The mRNA cannot enter the nucleus where DNA is stored and protected. Once the cell receives instructions from the mRNA to provoke an immune response, the mRNA will be destroyed.

“Can I get Covid-19 from the vaccine?”

- The vaccines cannot cause Covid-19 because they don’t contain the virus that causes infection.
- mRNA vaccines do not contain the live virus to trigger an immune response, rather they teach your cells how to make antibodies that help fight off the real virus.

“mRNA vaccines are so new; how do we know they are not experimental?”

- Vaccines are rigorously tested and reviewed by Health Canada before they are approved for use.
- mRNA vaccines have been studied for years and could be developed faster because they were made in lab using materials that are easily available.
- Most adverse reactions to vaccines emerge within 6 weeks of immunization which is why vaccine manufacturers are required to produce 8 weeks of safety data.

17. Do the COVID-19 vaccines affect fertility and menstrual cycles?

There is misinformation circulating about COVID-19 vaccines and infertility. COVID-19 vaccines do not cause infertility and there is no scientific reason or biological way they would impact fertility.

Some people have reported changes to their menstrual cycle following vaccination. However, it is important to know that a number of factors can impact the menstrual cycle, including sleep, stress, infection, diet, and exercise. In fact, getting COVID-19 itself may impact the menstrual cycle, as more than 35% of individuals noted changes in their menstrual cycle after COVID-19 infection. While studies are taking place to understand this potential impact, we know that other vaccines have not impacted the menstrual cycle. Read more from the Society of Obstetricians and Gynecologists of Canada.

If your client is pregnant or thinking of getting pregnant, getting vaccinated is the safest way to protect themselves and their baby. People who are pregnant are at increased risk of experiencing a severe case of COVID-19 with serious outcomes for them and

their baby, including preterm birth. Learn more about pregnancy and vaccination from the Yukon information sheet

Eligibility

18. Who is eligible and how are priority populations chosen to receive the COVID-19 vaccination?

NACI's Preliminary guidance on key populations for early COVID-19 immunization guides planning for the equitable allocation of COVID-19 vaccines once they are authorized for use in Canada. NACI recommends that key populations in whom vaccine is deemed safe and effective based on clinical evidence available at the time of vaccine availability should be prioritized for COVID-19 immunization. These groups are not mutually exclusive and may overlap. Sequencing of populations and sub-prioritization within these populations will be based on:

- A population-based risk-benefit analysis taking into consideration risk of exposure, risk of transmission to others, risk of severe illness and death, and the safety and effectiveness of vaccine(s) in key populations
- Vaccine supply (number of available vaccine types, number and timing of available doses, number of doses required)
- COVID-19 epidemic conditions when the vaccine(s) become(s) available

COVID-19 mRNA Vaccines

19. What are COVID-19 mRNA vaccines?

mRNA stands for messenger RNA and is the "blueprint" used by cells to synthesize proteins. The two COVID-19 mRNA vaccines approved in Canada use mRNA contained inside a lipid nanoparticle (LNP). The mRNA contains the synthetic nucleotide sequence that codes for the SARS-CoV-2 spike protein. After injection, the

LNP is taken up by the body's immune system cells and, once inside the cell, the mRNA provides the instructions for the cell to manufacture the spike protein. After being manufactured, the spike protein exits the cell and becomes anchored onto the cell's surface. The immune system gets activated to recognize the spike protein as foreign and initiates an immune response. The mRNA is then cleared by the cell's natural mRNA degradation process. The estimated half-life for mRNA after injection is about 8-10 hours before the native RNases (enzymes that break up DNA) complete degradation in the body. The expressed spike protein continues to be present in the body for several days and during this time continues to stimulate the immune response. mRNA vaccines are not live vaccines and cannot cause infection in the host. The delivered mRNA does not replicate, does not enter the cell nucleus, or interact with or alter the recipient's DNA in any way.

Several mRNA vaccines are under development for other infections such as cytomegalovirus, human metapneumovirus, parainfluenza virus type 3, Zika and influenza viruses.

The manufacturing of mRNA vaccines began a decade ago. The process is cell-free, meaning it does not use human or other animal cells, and does not use vectors (like other viruses), animal products, preservatives, or adjuvants.

20. How effective is the Moderna mRNA vaccine against COVID-19 disease?

The estimated vaccine efficacy at least 14 days after Dose 2 was 94.1% (95% CI: 89.3 to 96.8%), with 11 confirmed COVID-19 cases identified among vaccine recipients (n=14,134) compared to 185 confirmed COVID-19 cases among placebo recipients (n=14,073). In the clinical trial involving adolescents between the ages of 12 and 17 (n=3,732), the vaccine was 100% effective against the development of COVID-19 14 days after Dose 2.

When stratified by age, vaccine efficacy against COVID-19 from 14 days after Dose 2 for those:

- **6 months to 23 months = 50.6%** (when Omicron was the dominant variant)
- **2 to 5 years = 36.8%** (when Omicron was the dominant variant)
- **12 to 17 years of age = 100%**
- **18 to 65 years of age = 95.6% (95% CI: 90.6% to 97.9%).**
- **> 65 years of age = 86.4% (95% CI: 61.4 to 95.2%).**
- **> 75 years of age = 100%, however this must be interpreted with caution as there were few cases identified in this group.**

21. How effective is the Pfizer COMIRNATY vaccine against COVID-19 disease?

The estimated efficacy at least 7 days after Dose 2 was 94.6% (95% CI: 89.9 to 97.3%), with 9 laboratory-confirmed symptomatic COVID-19 cases identified among vaccine recipients (n=19,965) compared to 169 cases among placebo recipients (n=20,172). The vaccine efficacy at least 14 days after Dose 2 in this population was comparable. In the clinical trial involving adolescents between the ages of 12 and 15 (n=2,260), the vaccine was 100% effective against the development of symptomatic COVID-19 7 days after Dose 2. In the clinical trial involving children 5 to 11 years of age (n=3,109), the preliminary efficacy of the 10 mcg dose vaccine is estimated to be 90.7% against the development of symptomatic COVID-19 7 days after Dose 2.

When stratified by age, vaccine efficacy against COVID-19 from 7 days after Dose 2 for those:

- **5 to <12 years of age = 90.7%**
- **12 to 16 years of age = 100%**
- **16 to 55 years of age = 95.6%**
- **> 55 years of age = 93.7%**
- **> 65 years of age = 94.7% (95% CI: 66.7 to 99.9%)**
- **> 75 years of age = 100% (95% CI: -13.1 to 100%), however this must be interpreted with caution as there were few cases identified in this group.**
- **In all subgroups stratified by "at-risk" status (presence of 1 or more comorbidities = 91%**

22. How long does it take for immunity to develop following vaccination?

For both the Moderna mRNA vaccine and the Pfizer COMIRNATY vaccine, SARS-CoV-2 binding and neutralizing antibodies were both induced by one dose of the vaccine and boosted by the second dose of the vaccine. Maximal immune response was seen 7 days after the second dose.

23. How long does immunity after vaccination last?

From the initial phase 3 clinical trials, the median period of follow-up of vaccine and placebo recipients was 2 months. Further clinical trials showed consistent efficacy at the 6-month mark.

Recent Canadian studies show that although two doses of mRNA vaccine elicit a strong initial antibody response in LTC residents, a majority of these individuals fail to demonstrate detectable neutralizing antibody titers at six months following the primary series. While the clinical significance of this is unclear, waning antibodies may indicate susceptibility to SARS-CoV-2 infection, while still being protected against severe outcomes.

Additional information about the duration of protection will continue to be gathered in the clinical trials, which will gather data for at least two years after the vaccination.

Vaccine effectiveness information will be gathered from post-marketing surveillance evaluations including studies using the test-negative design in populations being targeted for early vaccination, such as health care workers.

Dosing and Scheduling

24. What if a client presents later than the recommended interval for the COVID-19 mRNA vaccines? How important is the timing for the second dose?

Vaccine history tells us that when further doses are required, the subsequent doses are designed to boost the immune response as well as to confer long-term immunity. NACI has spent a lot of time deliberating on the importance of timing the second dose according to manufacturer recommendations versus waiting for a longer period in order to reach as many people as possible with first doses given the limited supplies.

Our aim is to strike the best balance. On October 22, 2021, NACI recommended an 8 week interval between dose 1 and dose 2 of the COVID-19 vaccine primary series. This change was made in Yukon Immunization Manual shortly after the NACI recommendation.

NACI tells us that the short-term effectiveness from the first dose is likely very good, and that limited delays up to 4 months will not be expected to affect overall immune response. Vaccine history with other vaccines shows us that giving subsequent doses after the recommended interval does not compromise long-term immunity and may even improve it. We can be very confident therefore in the effectiveness of a 4 to 6-week interval between dose #1 and dose #2, and potentially even longer.

If administration of the second dose of the COVID-19 vaccine is delayed (8 weeks or longer), the second dose should still be provided as soon as possible. The series does not need to be restarted. In general, regardless of the time between doses, interruption of a vaccine series does not require the restarting of the series. Delays between doses do not cause a reduction in final antibody concentrations for most other vaccines requiring more than one dose in a series. Maximum protection may not be attained until the complete vaccine series has been administered.

25. What is the minimum interval for the second dose for each of the mRNA vaccines?

For optimal response, immunizers should follow the recommended intervals of 8 weeks between first and second dose as much as possible. Doses given earlier than recommended may still be considered valid and need not be repeated if minimum intervals are observed. Refer to the Yukon Immunization Manual Section 8 Biologic Products specific product pages for minimum intervals,

26. What are the differences in the primary series and booster schedules, doses, and administration between the two COVID-19 mRNA vaccines being used in the Yukon?

Product	Pfizer COMIRNATY Pediatric COVID-19 vaccine	Pfizer COMIRNATY Adolescent/Adult COVID-19 vaccine	Pfizer COMIRNATY Adolescent/Adult COVID-19 vaccine (grey cap)	Moderna SPIKEVAX Adolescent/Adult COVID-19 vaccine	Moderna SPIKEVAX Pediatric COVID-19 vaccine
Authorized for use	5 to less than 12 years of age	12 years of age and older	12 years of age and older	12 years of age and older**	6 months and older***
Primary Dose	0.2 mL (10 mcg*)	0.3 mL (30 mcg*)	0.3 mL (30 mcg*)	0.5 mL (100 mcg)	0.25 mL (25 mcg)
Route	Intramuscular (IM)	Intramuscular (IM)	Intramuscular (IM)	Intramuscular (IM)	Intramuscular (IM)
Primary Series Schedule****	2 doses, 8 weeks apart	2 doses, 8 weeks apart	2 doses, 8 weeks apart	2 doses, 8 weeks apart	2 doses, 8 weeks apart
Booster Dose	0.2 mL (10 mcg of mRNA)	0.3 mL (30 mcg of mRNA)	0.3 mL (30 mcg of mRNA)	0.25 mL (50 mcg of mRNA)*******	Currently not recommended for the age group receiving the product in the Yukon

Booster Dose Schedule	1 dose, 6-month following completion of primary schedule	2 doses, 6-month intervals	2 doses, 6-month intervals	2 doses, 6-month intervals	N/A
Diluent Required	Yes Dilute with 1.3 mL of sodium chloride (0.9% NS)	Yes Dilute with 1.8 mL of sodium chloride (0.9% NS)	No	No	No
Formats available	Multi-dose vial (10 doses) After dilution, vaccine must be used within 12 hours	Multi-dose vial (6 doses) After dilution, vaccine must be used within 6 hours	Multi-dose vial (6 doses) Must be used within 12 hours	Multi-dose vial (10 OR 14 doses) Must be used within 24 hours of first puncture	Multi-dose vial (5 OR 10 doses) Must be used within 24 hours of first puncture

*It is important to note that the dose for this vaccine (0.3 mL and 0.2 mL) is unique compared to that of most routine vaccinations. Special precautions should be taken to ensure the correct dose is taken from the multi-dose vial.

**In the Yukon, the Moderna Current presentation vaccine will only be offered to adults 18 years of age and older.

*** In the Yukon, the Moderna Next Generation presentation vaccine will only be offered to ages 6 months to 4 years.

**** A third dose may be required to complete a series in certain immunocompromised groups.

***** Individuals 70 and older or immunocompromised receive 0.5 mL (100mcg)

27. Can other vaccines be administered at the same time as COVID-19 vaccine?

As of Aug 24, 2021, in the Yukon, COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of inactivated or live vaccines. On Sept 28, 2021, NACI recommended COVID-19 vaccines may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines.

Yukon's CMOH recommends that children 6 mos – 4 years receive the Moderna Spikevax vaccine at least 14 days before or after another vaccine. This is a precaution to help to determine if a side effect that may arise is due to the COVID-19 vaccine or another vaccine. However, there may be circumstances when a dose of a COVID-19 vaccine and another vaccine need to be given at the same time. Clients aged 5 years

and older are eligible to receive concurrent administration of COVID-19 vaccines with other routine (live or inactivated) vaccines.

Administration

28. What if there is remaining vaccine in the vaccine vial after 10 or 14 doses from the Moderna vaccine vial, or 6 or 10 doses from the Pfizer COMIRNATY vaccine vial have been removed?

Some vials have been shown to have an additional dose. If there is enough vaccine left in the vial for a complete dose (0.5 mL Moderna, 0.3mL or 0.2mL Pfizer), another dose can be drawn and administered.

If there is less than a full dose of vaccine remaining in a vial, discard the leftover vaccine. It is not recommended to draw vaccine from two separate vials to make up a full dose.

29. Are the COVID-19 mRNA vaccines interchangeable?

On June 1, 2021, NACI updated their recommendations on the interchangeability of COVID-19 vaccines. These recommendations are based on current scientific evidence and NACI's expert opinion. NACI recommends that people who received a first dose of an mRNA vaccine should be offered the same mRNA vaccine for their second dose. If the same mRNA vaccine is not readily available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series at least 8 weeks after the first dose. This series should be considered valid, without the need to restart a two-dose series with a new product. The spike proteins that encode the authorized mRNA vaccines have the same sequence and are stabilized in the same manner to remain in pre-fusion confirmation. Other vaccine components such as the lipid nanoparticle may be different between the vaccines.

People who received a first dose of the AstraZeneca/COVISHIELD vaccine may receive either an Astra/Zeneca/COVISHIELD vaccine or an mRNA vaccine for their second dose, unless contraindicated. This recommendation considers the risk of severe blood clots with low blood platelets associated with the viral vector vaccine (AstraZeneca)

but not the mRNA vaccines, the possibility of increased short-term side effects when mixing COVID-19 vaccine schedules, and all available data on the immune responses produced by a first dose of the AstraZeneca vaccine follow by a second dose of an mRNA vaccine.

Getting the same vaccine for first and second dose or a mixed schedule are both considered valid options, and both will count as a completed series. More results from ongoing studies, including Canadian data, on mixing vaccine schedules are expected in the coming months.

30. Are prophylactic oral analgesics or antipyretics recommended before or at the time of vaccination?

Prophylactic oral analgesics or antipyretics (e.g., acetaminophen or non-steroidal anti-inflammatory drugs such as ibuprofen) should not be routinely used before or at the time of vaccination. While these medications may be used after vaccination, it is not known whether these may blunt the antibody response to vaccine. This phenomenon has been observed in some studies of other vaccines in children, although the clinical significance is still unknown.

If an individual has taken one of these medications before immunization, they should still be immunized.

Oral analgesics or antipyretics may be used for the management of symptoms attributed to the vaccine (e.g., pain, fever, headache, myalgia) if the symptoms cannot be addressed using non-pharmaceutical strategies.

31. Is there a recommendation on the size of needle to be used to dilute the Pfizer COMIRNATY vaccine?

Yes. A 21-gauge needle or narrower is recommended to prevent a larger opening in the vial stopper that may allow the vaccine to leak.

32. When diluting the Pfizer- COMIRNATY vaccine, is there a need to expel air from the vial to equalize the pressure?

Yes. After adding the diluent into the vaccine vial, withdraw 1.8 mL of air (for purple product) or 1.3mL of air (for orange product) from the vaccine vial into the empty diluent syringe prior to removing the needle and attached syringe from the vial. This will prevent loss of vaccine from the vial through forceful expulsion under pressure. The grey product does not require diluent.

Special Considerations

33. Are there groups in which the approved vaccines have not been specifically studied?

People who are pregnant or lactating, immunocompromised, or those with autoimmune disorders were originally not included in large numbers as participants in early clinical trials. Additional evidence is now available from real-world use of COVID-19 vaccines, primarily mRNA vaccines, in these populations. For example, recently published safety analyses included 35,691 pregnant women in the United State who received an mRNA COVID-19 vaccine without any obvious safety signals. This evidence showed that COVID-19 vaccines are safe in these populations so NACI recommendations for these populations are now the same as for the general adult population.

34. How should I counsel my pregnant patients about COVID-19 vaccine?

The latest NACI recommendations states that an mRNA COVID-19 vaccine is preferentially recommended for individuals who are pregnant. NACI's latest statement includes the following:

- ***NACI preferentially recommends that a complete primary vaccine series (2 or 3 doses) and booster (with an mRNA COVID-19 vaccine Pfizer COMIRNATY, Moderna) should be offered to individuals in the authorized age group, including those who are immunosuppressed, have an autoimmune condition, are pregnant or are breastfeeding. If they are not able to receive an mRNA vaccine, for example because of an allergy, another authorized COVID-19 vaccine should be offered.***

- ***mRNA vaccines are preferred for use during pregnancy, 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 Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) during pregnancy, should it occur following the administration of a viral vector vaccine, can be complex.***

There is no concerning red flag or hypothesized mechanism for potential harm associated with the administration of an mRNA vaccine during pregnancy. Other inactivated vaccines have a long history of administration during pregnancy without concern as to adverse effects.

Other considerations should include the potential for more severe COVID-19 disease. The majority of individuals, including pregnant women, who become infected with COVID-19 have mild symptoms or are asymptomatic. However, current data suggest that symptomatic pregnant patients with COVID-19 are at an increased risk of severe illness when compared to their non-pregnant peers. In addition, pregnant patients with underlying co-morbidities such as diabetes or obesity may have an even higher risk of severe illness.*1*

Both the Society of Obstetricians and Gynaecologists of Canada and the American College of Obstetrics and Gynecology have published statements on the use of COVID-19 vaccines in pregnancy. Both medical groups acknowledge the unvaccinated pregnant individual is at risk for acquiring COVID-19 and they are at an increased risk

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1 https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

for severe outcomes compared to non-pregnant individuals. They recommend that pregnant individuals should be offered vaccination at any time during pregnancy or while breastfeeding, if no contraindications exist.

35. My patient is considering pregnancy and wondering about timing vis-a-vis COVID-19 vaccine. What should I advise?

The latest NACI statements also address this question. There are several points that the NACI statement covers to guide advice to your patients considering pregnancy. The following are direct comments from the NACI statement:

- ***Individuals who become pregnant during their vaccine series or shortly thereafter should not be counselled to terminate pregnancy based on having received the mRNA vaccine.***
- ***Vaccine recipients and health care providers are encouraged to report COVID-19 vaccine during pregnancy or breastfeeding to the local public health authority as well as to the vaccine manufacturer for follow-up. Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.***

The Society of Obstetricians and Gynaecologists of Canada recommends that vaccination series should be completed if pregnancy is detected during their vaccine series. Ideally, an individual would be immunized against COVID-19 ahead of conception to benefit from maximal vaccine efficacy throughout the entire pregnancy. **If you're planning to become pregnant, delay conception until at least 28 days have passed after your 2nd dose of the COVID-19 vaccine.**

36. My patient is breastfeeding her young infant. What can or should I advise her about receiving the COVID-19 vaccine?

NACI as of June 1, 2021, states the following key revised recommendations:

- ***NACI recommends that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are breastfeeding. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in this population. (Strong NACI Recommendation)***

There is a long history of safety with inactivated vaccines administered during lactation, as well as there being no biological reason to suspect a safety risk.

37. How should I counsel my immunocompromised patients about receiving the COVID-19 vaccine?

In general, the question is not so much about safety as about effectiveness of the vaccine in an individual who is immunocompromised. The more severe the immunocompromise, the more this may affect the individual's ability to generate immunity from the vaccine. There is also the question of whether individuals who are immunocompromised may be more susceptible to severe COVID-19 disease should they be infected. Surprisingly, according to the CDC, evidence around the severity of COVID 19 and immunocompromised is still not strong.

Immunosuppression from solid organ transplant is more strongly associated with the potential for severe illness, while immunosuppression from other reasons including medical therapy is less certain.

NACI recommends the following:

- ***NACI preferentially recommends that a complete COVID-19 vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are immunosuppressed due to disease or treatment. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines. (Strong NACI Recommendation)***

- ***Individuals who are immunosuppressed from disease or treatment should be informed that they may have a reduced immune response to any authorized COVID-19 vaccine series.***

A complete COVID-19 vaccine series may be offered to individuals in the authorized age group. As of September 10, 2021, NACI recommended an additional dose (3rd dose post 2-dose series, or 2nd dose post 1-dose series) to be offered to moderately to severely immunocompromised individuals that meet certain criteria.

38. My patient has an autoimmune condition. What advice should I be providing regarding COVID-19 immunization?

The decision may be influenced by the presence of other co-morbid conditions, the patient's age, the patients' general attitude towards COVID-19 and risk factors for acquisition, and the severity of the chronic condition. Also, the spectrum of autoimmune conditions is wide, with varying degrees of autoimmunity, disease progression, and varying use of medications that affect immune function. Specialist advice may also be helpful.

The latest NACI statement advises the following:

- ***NACI preferentially recommends that a complete vaccine series with an mRNA COVID19 vaccine should be offered to individuals in the authorized age group with an autoimmune condition. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in these populations. (Strong NACI Recommendation)***

The Canadian Rheumatology Association (CRA) released a position statement on the COVID-19 vaccine on May 20, 2021, stating that they recommend COVID-19 vaccination in persons with autoimmune rheumatic disease as the potential benefits outweigh the potential risks.

Other applications of mRNA technologies for the treatment of cancer required anti-self immune response, which raised a theoretical concern that mRNA vaccines for infectious diseases would behave similarly. Previous mRNA vaccine technologies may have elicited inflammation and theoretically exacerbated existing autoimmune disease. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk.

A complete COVID-19 vaccine series may be offered to individuals in the authorized age group. As of September 10, 2021, NACI recommended an additional dose (3rd dose post 2-dose series, or 2nd dose post 1-dose series) to be offered to moderately to severely immunocompromised individuals that meet certain criteria.

39. What if my patient has had a previous COVID-19 infection?

There is no contraindication to receiving COVID-19 vaccination in an individual who has previously had a natural COVID-19 infection. What is uncertain still is the duration of natural immunity. We also do not have information on the expected duration of vaccine-induced immunity, or which will provide the stronger or more lasting protection in the context of evolving variants. Clients are currently recommended to wait 3 months/90days post infection prior to receiving an additional COVID-19 vaccine dose.

40. Is the COVID-19 vaccine recommended for children?

Yes, there is a COVID-19 vaccine recommended for children. On November 19, 2021, Health Canada approved Pfizer COMIRNATY (10 mcg) pediatric product for children 5-11 years of age.

For adolescents 12 years of age and older, the Pfizer COMIRNATY (30 mcg) and Moderna COVID-19 vaccines have been approved for use. However, in the Yukon only Pfizer product will be administered to children and adolescents.

On July 14, 2022, Health Canada approved Moderna SPIKEVAX infant presentation for children 6 months of age and older. In the Yukon, this vaccine will only be administered to children between the ages of 6 months to 4 years old.

41. Can the COVID-19 mRNA vaccines be given simultaneously with blood products or human immunoglobulin?

There is currently insufficient evidence on the receipt of both a COVID-19 vaccine and anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention. The timing of administration and potential interference between the two products are currently unknown. Administration of these products close together may result in decreased effectiveness of a COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies because the monoclonal antibodies have a high affinity for the spike protein expressed by the vaccines.

Any individual who received monoclonal antibodies or convalescent plasma for treatment of COVID-19 should wait for 90 days to elapse prior to vaccination with a COVID-19 vaccine. A second infection is unlikely to occur in that time period, and a period of 90 days or more will lower the risk of blunting of the vaccine-induced immune response, accounting for the estimated half-life of these treatments.

Those receiving other antibody therapies that are unrelated to COVID-19 treatment (e.g., IVIG, RhoGAM) may receive the mRNA COVID-19 vaccine at the same time or

any interval before or after these therapies. They are unlikely to interfere with the immune response to the vaccine.

Allergic event following a dose of COVID-19 vaccine

42. What are the potential allergens in the COVID-19 vaccines that are known to cause type 1 hypersensitivity reactions?

Both COVID-19 mRNA vaccines are contraindicated in individuals with a history of anaphylactic reaction to a previous dose of the vaccine or to any component of the vaccine (e.g., polyethylene glycol (PEG)).

Both COVID-19 mRNA vaccines contain polyethylene glycol (PEG) which can be found in various products such as bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skincare products and as an additive in some food and drinks. No cases of anaphylaxis to PEG in foods or drinks have been reported.

43. What if there is a suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components?

Consultation with an allergist is advised if there is suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components. If there is a specific concern about a possible allergy to a component of the vaccine being administered, the individual should wait for a 30 minute extended period of observation post-vaccination. Alternatively, the vaccine could be administered in an emergency room setting, also with a prolonged observation period.

Clinical trials excluded individuals with a history of severe adverse reactions associated with a vaccine and/or severe allergic reactions to any component of the vaccine.

Pediatric COVID-19 mRNA Vaccine

44. What COVID-19 vaccines are available for children 5 to 11 years in the Yukon?

On November 19, 2021, Health Canada approved Pfizer COMIRNATY vaccine (10 mcg) for use in children 5-11 years of age. The National Advisory Committee on Immunization (NACI) recommends that a complete series with Pfizer COMIRNATY vaccine (10 mcg) may be offered to children 5-11 years of age who do not have contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose. On August 19, 2022, NACI recommended a booster dose be offered at least 6 months since completion of the primary series or SARS-CoV-2 infection.

45. What is the rationale for immunizing children 5-11 years of age?

Most children present mild or asymptomatic infection from COVID-19, however the benefits of vaccination greatly outweigh the risks. Children are at risk of developing multi system inflammatory syndrome in children (MIS-C) following infection with COVID-19. MIS-C is a rare but serious condition and has been reported in this age group following infection. Myocarditis can occur following COVID-19 infection, however, is very rare in children. The broader harms of the pandemic have caused disruptions to school, reduced access to extra-curricular activities, and social isolation, which have a profound impact on the physical and mental well being of children and their families.

46. How was the decision for the pediatric 10 mcg formulation made?

The Pfizer-BioNTech pediatric dose is 10 micrograms of mRNA, one third of the 30 microgram dose given to adults and adolescents aged 12 and older. During the phase 1 study, a total of 48 children 5 to 11 years of age received 10 mcg, 20 mcg, or 30 mcg of the Pfizer-BioNTech (BNT162b2) COVID-19 vaccine (16 children at each dose

level). On the basis of reactogenicity and immunogenicity, a dose level of 10 mcg was selected for further study.

47. How do you complete the series for an 11-year-old who received a 10-mcg dose for the first dose and turned 12 before the second dose is due?

Children who receive the 10 mcg Pfizer COMIRNATY vaccine for their first dose and who have turned 12 years of age by the time the second dose is due may receive the 30 mcg Pfizer COMIRNATY vaccine that is authorized for individuals aged 12 years and older to complete their primary series. If the second dose of 10 mcg is given, the dose should still be considered valid and the series complete.

48. Are there any special precautions for children receiving a COVID-19 vaccine?

Individuals diagnosed with Multisystem Inflammatory Syndrome in Children (MIS-C) should delay COVID-19 vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C.

Additional doses of a COVID-19 vaccine should be deferred in those who experienced a physician-diagnosed myocarditis or pericarditis event following a previous dose of a COVID19 mRNA vaccine with no other cause identified, until further information about the risk of recurrence is available. Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines and are no longer being followed by a medical professional for heart issues.

49. Were any safety concerns seen in the clinical trials?

No allergic events or anaphylactic reactions were reported after either dose. No serious adverse events (SAE) related to the vaccine, no cases of multisystem inflammatory syndrome in children (MIS-C), myocarditis/pericarditis or deaths were reported. Given the clinical trial was limited to 3,109 participants randomized to receive the Pfizer-

BioNTech vaccine, it is unlikely that any adverse events occurring at a frequency less often than 1 in 1,000 would be detected.

50. What COVID-19 vaccines are available for children under 5 years old in the Yukon?

On July 14, 2022, Health Canada approved Moderna SPIKEVAX (blue cap) presentation of their mRNA vaccine (25 mcg) for use in children 6 months and older. The National Advisory Committee on Immunization (NACI) recommends that a primary series of two doses of Moderna Spikevax (25 mcg) COVID-19 vaccine may be offered to children 6 months to 4 years of age who do not have contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose. A primary series of three doses of Moderna Spikevax (25 mcg) COVID-19 vaccine may be offered to children 6 months to 4 years of age who are moderately to severely immunocompromised, with an interval of 4 to 8 weeks between each dose.

51. What is the rationale for immunizing children <5 years of age?

Most children ≤ 5 years of age infected with SARS-CoV-2 have mild disease severity and are infrequently hospitalized; however, some children experience severe disease, including previously healthy children. Children are at risk of developing multi system inflammatory syndrome in children (MIS-C) following infection with COVID-19. MIS-C is a rare but serious condition and has been reported in this age group following infection. Myocarditis can occur following COVID-19 infection, however, is very rare in children. The broader harms of the pandemic have caused disruptions to community, reduced access to extra-curricular activities, and social isolation, which have a profound impact on the physical and mental well being of children and their families.

Novavax Nuvaxovid COVID-19 recombinant protein subunit vaccine

52. What is the COVID-19 recombinant protein subunit vaccine?

Novavax is the first COVID-19 recombinant protein subunit vaccine authorized in Canada as of February 17, 2022. It is offered as an option for people 18 and older who are unable or unwilling to receive an mRNA vaccine. This vaccine contains 5mcg of the SARS-CoV-2 recombinant spike protein from the original (Wuhan) strain and is co-formulated with 50mcg of Matrix-M adjuvant.

Methods

The spike protein is made by inserting genetic instructions into a baculovirus; a virus that infects insects. The baculovirus is used to infect moth cells causing spike proteins to replicate, the proteins are then extracted and purified. This vaccine contains no live or inactivated virus, or genetic material, only proteins. This method differs from mRNA vaccines because it uses premade spike protein that are synthesized outside the body, whereas mRNA vaccines instruct the cells to produce spike proteins. This technology used to develop Novavax is similar to the methods used to develop influenza and HPV vaccines.

Matrix-M is a new adjuvant for vaccines, the adjuvant is composed of 40 nanometer particles based on saponin extracted from the Quillaja saponaria Molina bark, also known as the soap bark tree.

Mechanism

The immune system recognizes the spike protein and makes antibodies in response. Spike proteins on their own are harmless and cannot cause COVID-19. The adjuvant is an ingredient that helps stimulate a stronger immune response to the vaccine, creating more antibodies while using a smaller dose of spike protein.

53. How effective is the Novavax vaccine against COVID-19 disease?

Clinical trials showed that beginning 1 week after the second dose, Novavax Nuvaxovid COVID-19 vaccine was 90% effective in protecting trial participants aged 18 and above (n=14,039) against COVID-19 in the short-term.

- **Overall vaccine efficacy = 89.7% (95% confidence interval [CI] 80.2-94.6)**
- **Vaccine efficacy against the alpha variant = 86.3% (95% CI: 71.3-93.5)**
- **Vaccine efficacy against non-alpha variants = 96.4% (95% CI: 73.8-99.5)**

These trials were conducted before the emergence of Delta and Omicron, and there is very limited evidence to demonstrate what level of protection Novavax offers against the Omicron variant.

54. Are there groups in which Novavax has not been specifically studied?

Novavax Nuvaxovid clinical trials did not include the following populations: individuals with previous SARS-CoV-2 infection, immunocompromised due to disease of treatment, pregnant or breastfeeding, and autoimmune conditions. Therefore, the safety and efficacy of Novavax have not been established in these populations, however vaccination is still advised (Preferably with mRNA vaccine).

The Society of Obstetricians Gynaecologists of Canada released the following statement regarding Novavax vaccination in pregnancy:

"There is no theoretical reason why the Novavax Nuvaxovid or the Medicago Covifrenz vaccines should not be administered to pregnant or lactating women, although safety and efficacy data specific to pregnancy is not yet available. Following informed discussion, these vaccines could be considered as an alternative for pregnant and lactating women who cannot use the mRNA vaccine platform due to side effects or those who are opposed to using an mRNA vaccine platform."

Informed consent should include discussion that there is currently limited evidence on the use of the Novavax Nuvaxovid in these populations, while there is evidence on the safety profile and effectiveness of mRNA COVID-19 vaccines in these populations based on real world use

with large numbers of individuals. NACI will continue to monitor the evidence and update recommendations as needed.

For individuals with serious polyethylene glycol (PEG) allergy or previous serious allergic reaction to an mRNA vaccine, Novavax Nuvaxovid may be the preferred product for vaccination, based on consultation with an allergist or healthcare provider.

55. Is the Novavax vaccine interchangeable with other COVID-19 vaccines?

There is evidence that Novavax Nuvaxovid is safe and immunogenic after receiving a first dose of either Pfizer-BioNTech Comirnaty (30 mcg) or AstraZeneca/COVISHIELD. There is currently no data on the use of Novavax Nuvaxovid in a mixed series with Moderna Spikevax (100 mcg) or Janssen COVID-19 vaccines. Given the limited data available on mixed schedules with Novavax Nuvaxovid, informed consent should include a discussion of the benefits and risks of the interchangeability of COVID-19 vaccines.

56. Can other vaccines be administered at the same time as the Novavax vaccine?

On February 17, 2022, NACI advised that administering Novavax Nuvaxovid alone could assist with the assessment of any adverse event following immunization (AEFI) if to determine if a side effect is due to the COVID-19 vaccine or another vaccine. If vaccines are being provided simultaneously, then informed consent should include a discussion of the benefits and risks of simultaneous vaccine administration given the limited data available on administration of the Novavax Nuvaxovid simultaneously with other vaccines.

57. Summary of the primary series schedule, doses and administration of Novavax:

Product	Novavax Nuvaxovid
Authorized for use	18 years of age and older

Dose	0.5 mL (5 mcg SARS-CoV-2 recombinant spike protein)
Route	Intramuscular (IM)
Primary Series Schedule* **	2 doses, 8 weeks apart
Diluent Required	None
Formats available	Multi-dose vial (10 doses) Must be used within 6 hours of first puncture

Additional Resources

58. What are some additional resources for me or my patients?

- **Yukon Immunization Manual https://yukon.ca/en/immunization-manual**
- **Moderna product monograph: https://www.modernacovid19global.com/ca/product-monograph.pdf**
- **Pfizer-BioNTech product monograph: https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf**
- **Government of Canada COVID-19 vaccine information: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/covid-19-vaccine-treatment.html**
- **Government of Yukon COVID-19 information: https://yukon.ca/en/covid-19-information**
- **Government of Yukon vaccine strategy: https://yukon.ca/sites/yukon.ca/files/hss/hss-imgs/yukon_vaccine_strategy_fnl.pdf**
- **Government of Yukon common questions about the vaccine: https://yukon.ca/this-is-our-shot#common-questions**
- **Current NACI statements: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html**
- **CANVAX: https://canvax.ca/covid-19-vaccine-questions-and-answers-healthcare-providers**
- **Society of Obstetrics and Gynaecology of Canada (SOCG) statement on COVID-19 vaccination in pregnancy: https://www.sogc.org/en/-COVID-19/en/content/COVID-19/COVID-19.aspx?hkey=4e808c0d-555f-4714-8a4a-348b547dc268**

- American College of Obstetrics and Gynecology (ACOG) guidance on COVID-19 vaccination in pregnancy: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

- Government of Canada immunization in pregnancy guide: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-3-vaccination-specific-populations/page-4-immunization-pregnancy-breastfeeding.html