COVID-19 Vaccine FAQ's for health care providers

Updated as of February 15, 2021

Yukon is on track to receive enough Moderna vaccine by the end of the first quarter of 2021 to immunize 75% of the entire adult population. This is the figure based on a national allocation that is based on estimated actual uptake, and that considers all three territories as priority populations. Our goal is to ensure that every Yukon adult willing to accept the Moderna vaccine will have the chance to get it.

Although we are receiving far more vaccine per capita in this first quarter than any jurisdiction south of 60, we will still have limited supply during these first two months. Thus, we are in a position of needing to prioritize vaccine for higher risk populations until we have enough supply to open doors for the public clinics in Whitehorse starting February 10. The mobile teams that visit communities however, will be able to offer vaccine to all adults who are willing to step forward for vaccine, allowing us the opportunity to vaccinate our rural populations rapidly.

These FAQ's are for your own information, but more importantly are designed to help you counsel patients appropriately about vaccine, to address vaccine hesitancy, to ensure that clients have an opportunity to have their questions answered, and to inform their consent to receiving vaccine.

History has repeatedly shown that the most trusted source of vaccine information is a patient's health care provider.

I hope the following do provide some assistance in answering your patients' questions and in helping them to overcome any hesitancy they may have.

Please note that while these conversations are so valuable, they are not a requirement prior to vaccination, as we want to ensure that we maintain our barrier-free approach to vaccination. Instead, these abbreviated conversations will be incorporated into the consent process.

Please find Yukon's vaccine strategy and roll-out schedule online at Yukon.ca.

Additional information sources are listed at the bottom of this document.

Contents

COVID-19 disease

1. What is the epidemiology for 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 from 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 infected by a single case of 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?

Some of the side effects of the vaccine are similar to symptoms of COVID-19 infection. However, it is important to not assume that symptoms are due to 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, longer lasting, also could be due to COVID-19. The routine Testing Recommendation for COVID-19 (July 15, 2020) including the Decision Support Tool (September 16, 2020) should be applied in the immediate post immunization period and to persons who are fully immunized against COVID-19.

It is particularly important to tests persons who present with any of the following symptoms: cough, fever/chills, shortness of breath or difficulty breathing or loss of taste or smell regardless of COVID-19 immunization history.

Any one who is a contact to COVID-19 or returned from out of Yukon travel in the 14 days prior, and received this vaccine, should also have a low threshold for testing, and testing is recommended as soon as possible regardless of immunization history.

Vaccine development and safety

4. How do we know that the COVID-19 vaccine is safe and effective if it was developed so quickly?

The efforts to find a vaccine for COVID-19 have been on a scale that's never been seen before. With so many resources put towards it, this vaccine was 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 among health professionals, researchers, industry and governments to develop the vaccine, rapid recruitment of participants for clinical trials, and streamlined vaccine approval processes by the regulatory body at 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 authorized in Canada, Health Canada reviews all evidence and scientific data before deciding whether to authorize a vaccine. They will only authorize the vaccine when the evidence shows that the vaccine:

- Is safe, effective and of good quality and
- Demonstrates that the benefits outweigh the known and potential risks

For example, Health Canada's approval of the Pfizer-BioNTech vaccine was based on ensuring that the vaccine itself, laboratory studies and three phases of double-blind 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.

5. 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 develops 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 several administrative changes to the process, including 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 shorter period of follow-up of people enrolled into the phase 3 clinical trials. The 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 upwards of 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.

6. 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.

7. 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 provinces and territories, 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.

On an 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.

8. 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 to the Yukon Immunization Program. Information on reporting can also be found in this section of the manual.

COVID-19 Vaccines in Yukon

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

There are currently two COVID-19 mRNA vaccines approved for use in Canada:

- Pfizer-BioNTech COVID-19 vaccine (additional information from manufacturer)

- Moderna COVID-19 vaccine (additional information from manufacturer)

Yukon is using the Moderna COVID-19 vaccine because it can be transported between remote locations relatively easily. This makes it a good fit for Yukon and other northern territories.

More information about the Moderna COVID-19 vaccine can be found here: Moderna COVID-19 vaccine: What you should know

10. 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 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, and 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 use vectors (like other viruses) or animal products, preservatives or adjuvants.

General questions

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

Currently, there is no evidence for the need for booster doses of the COVID-19 vaccine after the vaccine series is complete. As the first participants in clinical trials were vaccinated at the end of July 2020, and the first vaccines were approved in December 2020, only short-term clinical trail data are available. Clinical trial participants will continue to be monitored for at least two years after vaccination to understand how long immunity lasts.

There are multiple research and surveillance priorities that 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 one, two or more years after vaccination will be determined with ongoing surveillance of vaccine effectiveness.

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

Yes. You will still need to wear a mask in all public indoor spaces and 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.

Eligibility

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

Vaccination will happen in phases. The first groups to get vaccinated include individuals at increased risk of exposure to the virus and those most at risk of serious complications.

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. There will be a limited initial vaccine supply so it is important to prioritize some populations earlier than others. NACI stated that a sequential approach cannot be determined until vaccine characteristics, results of clinical trials, and the number of available doses is known. NACI has therefore provided urgent guidance on the efficient and equitable prioritization of initial doses, to assist with the planning for allocation of the first COVID-19 immunization programs. You can find more information on this guidance in NACI's Guidance on the prioritization of initial doses of COVID-19 vaccine(s).

In Yukon, you are eligible if:

- You have a valid Yukon health-care card
- You live in Yukon, but do not have a Yukon health-care card (further documentation will be required)
- You are a BC resident who normally receives health care in Yukon (for example, residents of Lower Post)

COVID-19 mRNA Vaccines Efficacy

14. How effective is the Moderna mRNA vaccines 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 confirmedd COVID-19 cases identified among vaccine recipients (n=14,134) compared to 185 confirmed COVID-19 cases among placebo recipients (n=14,073).

When stratified by age, vaccine efficacy against COVID-19 from 14 days after Dose 2 for those 18 to < 65 years of age was 95.6% (95% CI: 90.6% to 97.9%). For those > 65 years of age, vaccine efficacy was 86.4% (95% CI: 61.4 to 95.2%). For those > 75 years of age, vaccine efficacy was 100%, however this must be interpreted with caution as there were few cases identified in this group.

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

For the Moderna mRNA 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.

16. How long does immunity after vaccination last?

From the phase 3 clinical trials, the median period of follow up of vaccine and placebo recipients was 2 months. Protection against COVID-19 is expected beyond this period, and 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

17. 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? Should I be concerned if either I or my patients don't get the second shot at 28 days?

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 (28 days for Moderna) 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. We will be using doses as fast as possible to get them out to the highest number of people to ensure access to the first dose, and will depend on subsequent shipments for our follow-up dosing. This could mean that some people will wait longer than 28 days for the second dose. However, no one should wait more than 42 days before their second dose.

NACI tells us that the short-term effectiveness from the first dose is likely very good, and that limited delays up to 42 days will not be expected to affect overall immune response. Vaccine history with other vaccines show us that giving subsequent doses after the recommended interval do 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. (The UK and other countries are allowing up to 12 weeks between doses).

The NACI revision states the following:

- *While efforts should be made to vaccinate according to the recommended schedules outlined in Table 2, some jurisdictions considering vaccine delivery logistics, current 10 epidemiological status and projections, and healthcare system capacity may maximize the number of individuals benefiting from a first dose of vaccine by delaying the second dose, until further supplies of the vaccine become available, preferably within 42 days of receipt of the first dose.*
    - *In the context of limited, uncertain, and sequential shipments of vaccine supply; significant morbidity and mortality due to COVID-19 with overwhelmed healthcare system capacity and ongoing substantial community transmission; jurisdictions are faced with balancing the rapid roll-out of the COVID-19 immunization program to as many individuals as possible with ensuring the completion of a two-dose COVID-19 vaccine series as close as possible to recommended schedules. Options to maximize population health benefits are needed. The Management Options section below summarizes evidence, considerations and guiding principles for jurisdictions to decide on how to roll out the immunization program as efficiently, effectively, and equitably as possible in their local epidemiological and vaccine supply contexts.*

If administration of the second dose of the COVID-19 vaccine is delayed, 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.

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

For optimal response, immunizers should follow the recommended intervals as much as possible. Doses given earlier than recommended may still be considered valid and need not be repeated if minimum intervals are observed.

The recommended minimum intervals between doses for the Moderna COVID-19 mRNA vaccine is 21 days.

19. With the new Shingrix program and more people coming forward for this vaccine, what should I counsel patients about other vaccines during the time they are receiving the 2 doses of COVID-19 vaccine?

The NACI statement remains cautious about simultaneous administration with other vaccines, or in advising vaccine administration with recent or imminent COVID-19 vaccination. Here is the statement:

NACI recommends that COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines due to the potential for immune interference and the need to be able to monitor for potential symptoms of COVID-19 and COVID-19 vaccine adverse events without potential confounding from adverse events following other vaccines.

- *In the absence of evidence, it would be prudent to wait for a period of at least 28 days after the administration of the complete two-dose vaccine series of an mRNA COVID19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response (Precautionary principle). It would be prudent to wait 9 for a period of at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine to prevent erroneous attribution of an AEFI to a particular vaccine.*

- *However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.*

The CMOH advises that COVID-19 vaccine be given priority for the time being over the Shingrix or other vaccines. However, if a patient prefers to get the Shingrix vaccine first, remember that the Shingrix dosing interval is 2-6 months between dose #1 and dose #2. Therefore it would be possible to get a Shingrix vaccine, wait for 14 days, and then get the 2 dose COVID series, and then finish Shingrix. Other vaccines would need to be similarly organized around COVID19 scheduling.

Administration

20. What if there is remaining vaccine in the vaccine vial after 10 doses from the Moderna vaccine vial have been removed?

If there is enough vaccine left in the vial for a complete 0.5 mL dose after 10 doses have been removed from the vial, 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.

21. Are the COVID-19 mRNA vaccines interchangeable?

There is currently no data on the interchangeability of the various COVID-19 vaccines. NACI recommends that the vaccine series be completed with the same COVID-19 vaccine 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.

If the same product is not available for the second dose, the series should be completed with a similar type of COVID-19 vaccine (mRNA vaccine). This series should be considered valid, without the need to restart a two dose series with a new product.

22. 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.

Special Considerations

23. 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 either excluded from, or were represented by small numbers of participants in clinical trials. The recommendations for these groups continues to evolve and more data will be available in the future about both protection from the vaccine and its safety.

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

The latest NACI recommendations (scheduled for publication January 12, 2021) are more permissive than previous regarding COVID-19 during pregnancy, and allow for a fulsome discussion of the benefits vs potential risks of receiving COVID-19 vaccine. NACI's latest statement includes the following:

A complete vaccine series with a 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. (Discretionary NACI Recommendation).

The safety and efficacy profile are expected to be similar to those seen in non-pregnant individuals. However, the potential risks to the fetus and pregnant individual remain unknown until additional data is available. Because pregnant and breastfeeding women were excluded from the vaccine trials, there is no specific trial data on the safety of this vaccine in these populations. However, there is no concerning red flag or hypothesized mechanism for potential harm associated with 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 suggests 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 that while there are many unknowns related to the risks of immunization, the unvaccinated pregnant individual is at risk for acquiring COVID-19 and they are at an increased risk for severe outcomes compared to non-pregnant individuals. They recommend that pregnant individuals who are eligible for the vaccine be able to make an informed decision, based on medical status, risk of exposure and information available regarding risks and benefits. The patient's medical provider is ideally positioned to help patients through this process. The discussion may include an assessment of the following:

- Local COVID-19 epidemiology (where relative risk of acquisition in the community is low, although importation risk associated with travel outside Yukon remains relatively high)
- The possibility for work-related acquisition (e.g. transmission within a work place, or if breach of PPE in a health care setting combined with exposure to a COVID-19 infected patient)
- Individual risks for COVID-19 related morbidity, including pre-existing conditions
- Gestational age
- Individual beliefs and personal risk tolerance

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

25. 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 or who may have received vaccine inadvertently while pregnant, or who become pregnant between dose 1 and dose 2. The following are direct comments from the NACI statement:

- *There is currently no evidence to guide the time interval between the completion of the COVID-19 vaccine series and conception. In the face of scientific uncertainty, it would be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose vaccine series of an mRNA COVID-19 vaccine. An mRNA COVID19 vaccine may be administered anytime after pregnancy, taking into account whether an individual is breastfeeding.*
- *Eligible individuals should be offered a complete vaccine series with an authorized COVID-19 vaccine post-partum (taking into account whether an individual is breastfeeding) and prior to attempting pregnancy so that the recommended interval between completion of the vaccine series and conception is maintained.*
- *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.*
- *If pregnancy is determined after initiation of the vaccination series, completion of the series may be delayed until after pregnancy, unless risk factors for increased exposure or severe COVID-19 are present and informed consent for vaccination is obtained as above. NACI also encourages additional research and surveillance of COVID-19 vaccination in pregnancy.*
- *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.

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

Again clinical trial data does not help us specifically in this area as the mRNA vaccine trials did exclude breast-feeding participants. However, there is no reason to believe that these vaccines should pose a risk, based on the long history of safety with inactivated vaccines administered during lactation, as well as there being no biological reason to suspect a safety risk.

Again the recent NACI statements should help with your patients determining acceptability of vaccine during the breast feeding period. NACI as of January 12, 2021 states the following key revised recommendations:

- *It is unknown whether the vaccines are excreted in human milk, but there are no data on outcomes in breastfeeding individuals or their breastfed infants. There have been no theoretical concerns about these vaccines in breastfeeding individuals or their breastfed infants.*

Despite the reassuring statements, an informed consent conversation is still recommended including a benefit/risk discussion similar to that for pregnant patients. Consideration for administering the COVID-19 vaccine to this population would involve an assessment and discussion of risks versus benefits similar to that in a pregnant individual.

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

Again a benefit-risk discussion is advised, with the knowledge that this group was also excluded from the clinical trials for the mRNA vaccines. In general, the

question is not so much about safety as about effectiveness of the vaccine in a subject with immunocompromise. 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 with immunocompromise may be more susceptible to severe COVID-19 disease should they be infected. Surprisingly, according the CDC, evidence around severity of COVID 19 and immunocompromised is still not strong.

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

However, as the mRNA vaccines are inactivated, there is no reason to suspect adverse effects other than those that may occur in others. Again the revised NACI statement is more permissive, stating the following:

- *NACI recommends that a complete COVID-19 vaccine series may be offered to individuals who are immunosuppressed due to disease or treatment in the authorized age group if a risk assessment deems that 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. (Discretionary NACI Recommendation)*

A complete COVID-19 vaccine series may be offered to individuals in the authorized age group if a risk assessment deems that 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 these populations. If an immunocompromised individual presents for immunization and indicates that they have had this discussion with their care provider and they understand the benefits and risks and absence of evidence on the use of COVID-19 vaccine in these populations, this would be sufficient for the immunizer to proceed with vaccination.

People living with stable HIV that are considered immunocompetent may receive the COVID-19 vaccine.

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

This is yet another area where information is incomplete, and where clinical trial data is not sufficient to guide us firmly. The trials did include some participants with autoimmune conditions (without immunosuppression) but they comprised only a very small proportion of trial participants and a narrow range of autoimmune conditions. This is an area where we will get more information and evidence with time. Patients need to understand that evidence is limited but that the decision rests with them after an informed discussion. 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 revised NACI statement advises the following:

- *NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to individuals with an autoimmune condition in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccine in these populations. (Discretionary NACI Recommendation)*

The Canadian Rheumatology Association (CRA) released a position statement on the COVID19 vaccine on 31 December 2020. They have published

recommendations for the use of COVID-19 vaccine for patients under the care of a rheumatologist:

- Patients > 70 years old are considered to be high risk for severe illness and therefore vaccination should be considered regardless of underlying diagnosis or treatment.
- Patients < 70 years old, vaccination should be assessed on an individual basis, considering possible risk factors including occupation.
- Patients at higher risk for more severe illness with COVID-19, including those on corticosteroids, vaccinations should be considered.
- Currently, there is no data to make a recommendation of whether DMARDs should be withheld during COVID-19 vaccination.

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 if a risk assessment deems that 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 these populations. If an immunocompromised individual presents for immunization and indicates that they have had this discussion with their care provider and they understand the benefits and risks and absence of evidence on the use of COVID-19 vaccine in these populations, this would be sufficient for the immunizer to proceed with vaccination.

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

There is no contraindication to receiving COVID-19 vaccination in an individual who has previously had 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. The NACI statement supports our ability to provide vaccine to these recipients. In a context of limited vaccine supply, these individuals would be a lower priority than others, due to at least some short term protection. In our context, these individuals may as well be vaccinated when they have an opportunity, either through a community mobile tour or through the normal booking process in Whitehorse. The NACI wording is as follows:

- *NACI recommends that a complete series with a 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)*

30. What about children? Should they always be excluded?

The currently available mRNA vaccines are not currently authorized for children. A clinical trial for the Moderna vaccine in the 12-17 age group is in the planning stages. Some of the next available vaccines may allow us to open up public vaccination for children and we will learn more in the weeks to come about future expected products and indications.

There are exceptional circumstances where COVID-19 vaccines in children can be considered and we will just have to manage these on a case-by-case basis with our pediatric and other specialist colleagues.

- *NACI recommends that COVID-19 vaccine(s) should not be offered to individuals who are not in the authorized age group. (Strong NACI Recommendation).*
- *8a. However, a complete vaccine series with a Pfizer-BioNTech* (and presumably Moderna, according to CMOH) *may be offered to individuals 12-15 years of age, without contraindications to the vaccine, 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 a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent with the individual and the parent or guardian includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in this population. (Discretionary NACI Recommendation)*

31. 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 or 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 monocloncal antibodies because the monoclonal antibodies have 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 od 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.

Contraindications

32. What are the contraindications to the COVID-19 mRNA vaccines?

The Moderna COVID-19 mRNA vaccine is 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)).

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

For a list of components in the vaccine and packaging, consult the Moderna COVID-19 mRNA vaccine product monograph.

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

The Moderna COVID-19 mRNA vaccine contains 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, skin care products and as an additive in some food and drinks. No cases of anaphylaxis to PEG in foods or drinks have been reported.

34. 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.

Vaccine storage and handling

35. Why do the COVID-19 mRNA vaccines need to be administered within first punctured?

The vaccine doesn't contain any preservatives to prevent microbial contamination.

36. Where can I find information on the specific vaccine storage and handling requirements for the mRNA vaccines?

The Moderna product monograph contains more information. You can also find more information at the Health Care Practitioner Guide or on the COVID-19 Vaccine Storage and Handling Guide.

Additional Resources

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

- Moderna product monograph: https://www.modernacovid19global.com/ca/product-monograph.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/content/featured-news/SOGC_Statement_on_COVID-19_Vaccination_in_Pregnancy.aspx
- 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