COVID-19 Vaccine FAQ's for health care providers

Updated as of January 10, 2021
Office of the Chief Medical Officer of Health, Yukon

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.

1. 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).*

Some of the key points to keep in mind as you discuss with your patients include:

- 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:

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

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

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

Additional information available from:

- Society of Obstetrics and Gynaecology of Canada (SOCG): https://www.sogc.org/en/content/featured-news/SOGC_Statement_on_COVID-19_Vaccination_in_Pregnancy.aspx
- American College of Obstetrics and Gynecology (ACOG): https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

2. 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 COVID-19 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.*

3. **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.

Additional information again is available from:

- Society of Obstetrics and Gynaecology of Canada (SOCG): https://www.sogc.org/en/content/featured-news/SOGC_Statement_on_COVID-19_Vaccination_in_Pregnancy.aspx
- American College of Obstetrics and Gynecology (ACOG): https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

4. 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, evidence around severity of COVID 19 and immunocompromised is still not strong. According to CDC, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

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)

For more info, see the following:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/underlying-conditions.html

5. 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 COVID-19 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.

Additional recommendations and information can be found at: https://rheum.ca/wp-content/uploads/2020/12/CRA-Position-Statement-on-COVID-19-Vaccination-v2-FINAL.pdf

6. 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)

7. 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, my add) 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)

8. 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 COVID-19 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*

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.*

I would advise 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 COVID-19 scheduling.

9. What about the scheduling for the second dose of COVID-19? 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*

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.*

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

FAQ's on vaccine for the public are available at https://yukon.ca/this-is-our-shot. Current NACI statements are available here:

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html

The Yukon vaccine strategy and the roll out schedule are best accessed on the Yukon.ca website here https://yukon.ca/en/covid-19-information

CANVAX is a national website with some COVID-19 content:

https://canvax.ca/covid-19-vaccine-questions-and-answers-healthcare-providers

CDC as always has numerous sections that may be helpful:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/underlying-conditions.html