

MEMORANDUM TO: Regional Health Authorities, Medical Officers of Health, Physicians, and Nurse Practitioners

MEMORANDUM FROM: Dr. Janice Fitzgerald, Chief Medical Officer of Health

Date: January 5, 2021

SUBJECT: Considerations on the use of COVID-19 vaccines in individuals in priority groups who are pregnant, breastfeeding, immunosuppressed, or have an autoimmune condition

Dear colleagues,

Newfoundland and Labrador's [COVID-19 immunization program](#) is following the recommendations from the [National Advisory Committee on Immunizations \(NACI\)](#) on the use of vaccines for individuals who are pregnant and/or breastfeeding, immunosuppressed, or have an autoimmune condition, including those in the current [priority groups](#) for receipt of the initial limited supply of vaccine. NACI recommends that COVID-19 vaccine should not be routinely offered to these individuals as there is absent or very limited data on the use of the vaccines in these populations; however, their recommendations do not exclude individuals from being vaccinated if a risk assessment deems that the benefits outweigh the potential risks and if informed consent includes discussion about the insufficient or absent evidence in these populations. It is anticipated that Health Canada and NACI will issue further guidance when information from ongoing clinical trials becomes available. At the present time, the number of cases of COVID-19 in the province is low and there is no evidence of community transmission.

Pregnancy and/or breastfeeding

Currently, there are no data on COVID-19 vaccination in pregnancy or during breastfeeding as these groups were not included in clinical trials. There is also no evidence to guide the time interval between vaccination and conception. NACI has updated their recommendations to advise that "it would be prudent to delay pregnancy by 28 days or more" after the two-dose vaccine series. In the interim, the program supports individuals making an informed decision with their health care provider concerning whether or not to receive the vaccine in the absence of any available data at this time.

The [Society of Obstetricians and Gynaecologists of Canada \(SOGC\)](#) issued a consensus statement that for "...individuals who are at high risk of infection and/or morbidity from COVID-19...that the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding and vaccination should be offered."

Immunosuppression and autoimmune conditions

Currently, there are no data on COVID-19 vaccination in individuals who are immunosuppressed and very limited data in individuals who have an autoimmune condition. For individuals with immunosuppression, there may be a diminished immune response to the vaccine. For individuals with an autoimmune condition, there is a theoretical concern that the vaccine might exacerbate autoimmune diseases, though the technology has been optimized to reduce this risk. In the interim, the program supports individuals making an informed decision with their health care provider concerning whether or not to receive the vaccine.

Recommendations

1. Individuals in priority groups who are pregnant and/or breastfeeding, immunosuppressed, or have an autoimmune condition are advised to consult with their health care provider for an individualized discussion on potential risks and benefits of having the vaccine. Informed consent includes a discussion about the absent or very limited evidence on use of the vaccine in these situations.
2. We recommend that individuals in current priority groups who are seeking the vaccine in the absence of safety and efficacy data be well-informed prior to booking and arriving for their immunization. Individuals who wish to proceed will be asked at the time of their appointment to complete a consent form and to indicate that they have made an informed decision based on current recommendations.
3. At this time, there is no available evidence to guide whether pregnancy should be delayed after receiving the vaccine. We recommend that individuals receiving the vaccine be advised as a precaution to delay pregnancy by 28 days or more after receiving the second dose of the vaccine. This recommendation will be updated when more information becomes available.
4. Public health measures including wearing a mask, physical distancing, handwashing in addition to the recommendations from Occupational Health and Safety for health care and other workers on appropriate precautions and Personal Protective Equipment will continue to be a mainstay in reducing risk regardless of vaccination status. Until the vaccine has been widely implemented across the province and demonstrated to have been effective in controlling disease transmission, public health measures will be the primary means of protection of individuals who may be at risk of exposure.

For more information on COVID-19 vaccination in these populations and other guidance for health care providers:

1. Appendix 1. Considerations when discussing the risks and benefits of the COVID-19 vaccine (enclosed)
2. Appendix 2. Excerpt from the NACI recommendations on pregnancy and breastfeeding (enclosed)
3. Appendix 3. Excerpt from the NACI recommendations on immunosuppression (enclosed)
4. Appendix 4. Excerpt from the NACI recommendations on autoimmune conditions (enclosed)
5. COVID-19 Immunization Plan for Newfoundland and Labrador: <https://www.gov.nl.ca/covid-19/vaccine/>
6. COVID-19 Vaccine Resources for Health Care Professionals in Newfoundland and Labrador (including links to vaccine product monographs): <https://www.gov.nl.ca/covid-19/vaccine/resources-for-health-care-professionals/>
7. Newfoundland and Labrador COVID-19 Pandemic Update Data Hub: <https://covid-19-newfoundland-and-labrador-gnl.hub.arcgis.com/>
8. NACI Recommendations on the use of COVID-19 vaccines (December 23, 2020): <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html>
9. SOGC Statement on COVID-19 Vaccination in Pregnancy (December 18, 2020): <https://sogc.org/en/-/COVID-19/en/content/COVID-19/COVID-19.aspx>
10. Canadian Immunization Guide Immunization of immunocompromised persons (updated May 2018): <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-3-vaccination-specific-populations/page-8-immunization-immunocompromised-persons.html>

Appendix 1. Considerations when discussing the risks and benefits of the COVID-19 vaccines

The following considerations adapted from the SOGC may help to support health care providers in Newfoundland and Labrador in a discussion on COVID-19 vaccines with an individual in a priority group who is pregnant, breastfeeding, immunosuppressed, or has an autoimmune condition. These elements may help to weigh the risks and benefits to arrive at an informed and individualized decision during this time while NACI recommends that they should not routinely be offered the vaccine in the absence of data as individuals from these populations were not included in clinical trials.

General considerations

- Local epidemiology and risk of community acquisition of COVID-19
- Workplace situation and risk of work-related acquisition of COVID-19
- Individual risk for COVID-related morbidity including consideration of comorbidities
- Availability of data and evolving information related to the safety and efficacy of vaccine in the specific population (e.g., during pregnancy, breastfeeding, when immunosuppressed, or in those with an autoimmune condition)
- Individual beliefs and personal risk assessment of the available data

Context and epidemiology

- Individuals who are in current priority groups have been selected as a result of being either at highest risk of exposure to COVID-19, the most likely to experience severe complications due to COVID-19, or are essential to maintaining the provincial pandemic response.
- At this time, the transmission of the COVID-19 virus remains low in Newfoundland and Labrador as a result of travel restrictions and other public health measures that are in place. In recent months, with the ongoing surge of COVID-19 elsewhere, people who have tested positive for COVID-19 in the province have acquired the virus outside of the province or have been a close contact of someone who is COVID-19 positive. Information is updated daily on the provincial dashboard: <https://covid-19-newfoundland-and-labrador-gnl.hub.arcgis.com/>.
- The risk of acquiring or being exposed to COVID-19 in a health care or other institutional or congregate setting in the province is currently low as a result of limited transmission, widespread public health measures, adequate public health and testing capacity, and availability of personal protective equipment.
- Evidence from across Canada has shown that differential access to material resources, privilege and power, and the resulting health inequities, influence COVID-19 morbidity and mortality (illness and death). Further context is available in the Chief Public Health Officer's Report: <https://www.canada.ca/en/public-health/corporate/publications/chief-public-health-officer-reports-state-public-health-canada/from-risk-resilience-equity-approach-covid-19.html>.
- More information about local epidemiology and context is available through the Regional Health Authorities.

Specific evidence and rationale

- Specific considerations concerning the use of COVID-19 vaccines in individuals who are pregnant and/or breastfeeding are included in Appendix 2; for individuals who are immunosuppressed in Appendix 3; for individuals with an autoimmune condition in Appendix 4.

Appendix 2. Excerpt from the NACI recommendations on pregnancy and breastfeeding

NACI recommends that COVID-19 vaccine should not be routinely offered to individuals who are pregnant until after completion of pregnancy, until further evidence is available (Strong NACI Recommendation). However, a complete 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)

NACI recommends that COVID-19 vaccine should not be routinely offered to individuals who are breastfeeding, until further evidence is available (Strong NACI Recommendation). However, a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group who are breastfeeding if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. (Discretionary NACI Recommendation)

Summary of evidence and rationale:

- Currently, there is limited evidence of pregnancy as an independent risk factor for severe COVID-19, though evidence is evolving.
- Currently, there are no data on the safety and efficacy of COVID-19 vaccines in pregnancy or during breastfeeding. Pregnant or breastfeeding individuals were excluded from the mRNA COVID-19 vaccine clinical trials.
- Currently, there are no data to suggest outcomes of inadvertent administration of COVID-19 vaccine to pregnant individuals or their developing fetus in clinical trials. 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.
- Individuals who are pregnant, breastfeeding, or of reproductive age may be at increased risk of exposure to SARS-CoV-2 (e.g., healthcare or essential workers) and/or at increased risk of severe COVID-19 disease (e.g., due to pre-existing medical condition, body mass index of 40 or more) and may wish to be vaccinated despite the lack of evidence of COVID-19 vaccination in pregnancy or during breastfeeding in order to protect themselves. Therefore, the balance of benefits and risks must be made on a case-by-case basis.
- 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 any time after pregnancy, taking into account whether an individual is breastfeeding.
- 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 should 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, including unintended COVID-19 vaccination during pregnancy.
- 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.
- Vaccine recipients and health care providers are encouraged to report any exposure to 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.

Appendix 3. Excerpt from the NACI recommendations on immunosuppression

NACI recommends that COVID-19 vaccine should not be routinely offered to individuals who are immunosuppressed due to disease or treatment until further evidence is available (Strong NACI Recommendation). However, a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group in this population 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)

Summary of evidence and rationale:

- Currently, there is limited evidence that immunosuppression is an independent risk factor for severe COVID-19, though evidence is evolving.
- Currently, there are no data on COVID-19 vaccination in individuals who are immunosuppressed. Participants in the mRNA COVID-19 vaccine clinical trials only included individuals who were not immunosuppressed, such as those with stable infection with human immunodeficiency virus (HIV), and those not receiving immunosuppressive therapy during the trial.
- No safety signals of concern have been noted to date in non-immunosuppressed participants with an immunocompromising condition (e.g., stable HIV infection) included in the clinical trials.
- The relative degree of immunodeficiency in individuals who are immunocompromised is variable depending on the underlying condition, the progression of disease and use of medications that suppress immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.
- In general, non-replicating vaccines may be administered to immunocompromised people because the antigens in the vaccine cannot replicate. However, the magnitude and duration of vaccine-induced immunity are often reduced. It is currently unknown whether immunocompromised individuals will be able to mount an immune response to mRNA vaccines.
- People living with HIV that are considered immunocompetent may be vaccinated.
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves and update recommendations as needed.

Appendix 4. Excerpt from the NACI recommendations on autoimmune conditions

NACI recommends that COVID-19 vaccine should not be routinely offered to individuals with an autoimmune condition until further evidence is available (Strong NACI Recommendation). However, a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group in these populations 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)

Summary of evidence and rationale:

- Currently, there is limited evidence that having an autoimmune condition is an independent risk factor for severe COVID-19, though evidence is evolving.
- Currently, there are very limited data on COVID-19 vaccination in individuals who have an autoimmune condition. Although participants with autoimmune conditions who were not immunosuppressed were not excluded from trials, they constitute a very small proportion of trial participants and represent a very narrow range of autoimmune conditions.
- The spectrum of autoimmune conditions is diverse. The relative degree of autoimmunity in individuals with autoimmune conditions is variable depending on the underlying condition, the severity and progression of disease and use of medications that impact immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis.
- Other applications of mRNA technologies have been for the treatment of cancer, which required an immune response directed against an individual's cancer cells. This raised the theoretical concern that mRNA vaccines for infectious diseases would behave similarly, eliciting inflammation and possibly exacerbating existing autoimmune diseases. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk.
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves and update recommendations as needed.