Nunavut COVID-19 Vaccine Materials & Immunization Protocol

Appendix C. Orientation to Obtaining Consent for Administration of COVID-19 Vaccines

Introduction:

COVID-19 is an illness caused by a coronavirus, a type of virus. COVID-19 was first identified in late 2019 and declared a global pandemic in early 2020. In December 2020, Health Canada authorized the use of two mRNA vaccines, Moderna SPIKEVAX ® and Pfizer-BioNTech COMIRNATY ®. These vaccines cause the body to produce protection against infection from COVID-19 using messenger RNA (mRNA) to help make antibodies.

Health staff who do not usually obtain consent for vaccination may be involved in this process to increase the number of Nunavummiut who can be vaccinated at each clinic. These staff will need to be oriented to this new role so that clients are supported to make an informed decision.

The Immunization Manual (https://gov.nu.ca/health/information/manuals-guidelines) provides detailed information on obtaining consent for vaccine administration. The purpose of this document is to provide more specific information on obtaining consent for the Moderna SPIKEVAX ® and Pfizer-BioNTech COMIRNATY® vaccines as part of orientation for staff.

Informed Consent:

As indicated in the Immunization Manual:

> *"Immunization providers have an ethical and legal responsibility to ensure that individuals receiving immunizations, or their guardians, are fully informed when making a decision to receive or refuse any vaccines in Nunavut."*

The manual goes on to define the essential criteria for informed consent:

- "Consent must be given willingly and freely without coercion".
- The immunization provider must ensure the vaccine recipient is capable of consenting, or that when required, an appropriate guardian or substitute decision maker is present to give consent.
- Information regarding the risks and benefits of both receiving and not receiving the vaccination should be provided.
- The information should be given in a culturally sensitive way, preferably in the language spoken by the individual receiving the vaccine. Vaccine specific information sheets have been translated to assist in this process.
- An opportunity to ask questions should be provided.
- Minor side effects that occur frequently, any severe adverse effects (such as anaphylaxis), precautions, and contraindications should be discussed.

Age of Consent:

Both the Moderna SPIKEVAX ® COVID-19 vaccine and the Pfizer-BioNTech COMIRNATY ® vaccine is authorized for use in those 12 years of age and over. In Nunavut the age of majority, the age at which someone can consent for themselves, is 19 years. Mature minors have the necessary capacity to understand the risks and benefits of immunization. *Mature minor status is always decided on a case-by-case basis and requires a judgment call by the immunization provider. A mature minor can override the medical decisions made by his/her parents and can either give consent or refuse immunizations. (NU Immunization Manual Section 3.2.3).* Please refer to the Immunization Manual for further information regarding considerations around informed consent for mature minors.

Documentation:

The COVID-19 Vaccine Consent Form includes information identifying the client on the front and back of the form. Please ensure that this information is completed on both sides of the form when you are obtaining consent from the client or the parent/guardian. The immunizer documents administration of the vaccine on the back of the form and it is important to have the client's contact information on the same side of the sheet as their signature.

Overview of COVID-19 Infection:

COVID-19 is most commonly spread by an infected person to others through coughing, sneezing, talking, singing or breathing. Someone with COVID-19 may not have any symptoms and not know they have COVID-19, but still be able to infect others.

For most people, symptoms of COVID-19 are similar to other respiratory illnesses like the flu or common cold. A smaller number of people with COVID-19 can develop much more severe symptoms requiring hospitalization and it may result in long term side effects or even death.

Risks and Benefits of <u>Receiving</u> the Vaccine:

Benefits:

The benefit of receiving the vaccine is protection against infection by COVID-19. The Moderna SPIKEVAX ® and Pfizer-BioNTech COMIRNATY ® vaccines have been evaluated as being both safe and effective in large studies and has been authorized for use by Health Canada following careful review.

- While there is some protection 14 days after the first dose it is not known how long immunity will last after only one dose which means it is important to come back for the second dose.

Risks:

Risks of receiving the vaccine relate to both common side effects and very rare allergic reactions. As indicated in the information sheet:

> The most common reactions that people get after the Moderna and Pfizer-BioNTech vaccines are minor and include:

- Pain, redness or swelling where the needle was given as well as fatigue, headache, muscle pain, joint pain, nausea/vomiting, fever and chills.
- Swelling and tenderness in the underarm of the vaccinated side may also occur.

All of these side effects usually disappear within 1-3 days without treatment. If they do not go away, clients are advised to call the health centre.

Serious adverse events are very rare.

- Myocarditis/pericarditis, Bell's Palsy and Guillan Barre Syndrome are all serious adverse events which have been reported following administration of a COVID-19 mRNA vaccine.
- Serious allergic reactions have also been reported. Symptoms of an allergic reaction include hives (bumps on the skin that are often very itchy), swelling of the face, tongue or throat, or difficulty breathing.
- The clinic staff are prepared to manage an allergic reaction should it occur and will provide immediate medical care if someone develops any of these symptoms. More information on managing anaphylaxis and fainting is in the Practice Guidelines of the Immunization Manual (https://gov.nu.ca/health/information/manuals-guidelines)

Risks and Benefits of Not Receiving the Vaccine:

Benefits:

The benefit of refusing the Moderna or Pfizer-BioNTech Vaccine is that the client will not be at risk of having side effects from the vaccine and will not have an allergic reaction to the vaccine. The side effects and symptoms or an allergic reaction are identified above.

Risks:

The risk of refusing the vaccine is that the client may be infected by COVID-19. This means the client could develop severe symptoms requiring hospitalization and potentially long-term effects from COVID-19.

A client who refuses the vaccine, and is infected by COVID-19, could also infect members of their household and community, making it more difficult to prevent the spread of the outbreak.

Rationale for Health Questions on Consent Form:

There are several questions on the Consent Form where the client is asked to respond 'yes' or 'no' for the person receiving the vaccine. This section will provide the rationale on why these questions are asked:

Do you feel sick with a fever today? (If yes please provide details below)

> Consideration should be given to postponing vaccination in persons with severe febrile illness. Persons with moderate or severe acute illness should be vaccinated as soon as the acute illness

has improved. Please note, it would be rare for someone who is this sick to be at the vaccination clinic.

Have you had COVID-19? (If yes please indicate when symptoms started below)
You can still receive the vaccine if you've had or think you've had COVID-19 before.

If someone has had COVID-19 it is important to ask when their symptoms started to make sure they are not still infectious. They are no longer infectious 10 days after their symptoms start at which time they can be vaccinated. Vaccination provides additional protection even if someone has had COVID-19.

Are you, or could you be pregnant? *(You will still be offered the vaccine.)*

If someone is, or could be pregnant, they need to know that pregnant people were not included in the initial studies on the Moderna and Pfizer-BioNTech vaccines but there is now international real world data to show that COVID-19 vaccines are safe and effective in pregnancy. These clients should be offered the opportunity to discuss vaccination with a nurse or doctor.

If this is your second or third dose, did you have any side effects after a previous dose? (*If yes, please provide details below*.)

If the client had an anaphylactic reaction to the first dose of the Moderna SPIKEVAX ® or Pfizer-BioNTech COMIRNATY ® vaccine they will need to discuss it with the nurse or doctor at the clinic and they should not be offered any additional doses without further consultation from the Office of the Chief Public Health Officer.

Do you have any problems with your immune system or are you taking any medications that can affect your immune system (e.g., high dose steroids, chemotherapy)? (*If yes, please provide details below.*)

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. Nunavut currently recommends a 3rd dose be given to individuals with moderate to severe immunosuppression. Please refer to the relevant COVID-19 immunization protocol for inclusion criteria and further guidance.

Have you received a TB test (TST or IGRA) in the past 4 weeks? (*If yes, when was the TB test: Day / Month / Year).*

A TST or IGRA should not be administered within 28 days of an mRNA COVID-19 vaccine.

There is a theoretical risk that the Moderna COVID-19 vaccine may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks afterwards. Vaccination may take place at any time after all steps of tuberculin skin testing (including reading) have been completed.

However, in cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. In this situation, re-testing, at least 4 weeks post immunization, of individuals with negative results for whom there is high suspicion of TB infection may be prudent to avoid missing cases due to potentially false-negative results.

Please refer to additional guidance provided by the Nunavut Tuberculosis Program.

Do you have a bleeding disorder or are you taking any medications that could affect blood clotting? (*If yes, please provide details below*.)

> As with other intramuscular injections, Moderna and Pfizer-BioNTech COVID-19 Vaccines should be given with caution in individuals with bleeding disorders, such as haemophilia, or individuals currently on anticoagulant therapy, to avoid the risk of haematoma or bad bruise following the injection, and when the potential benefit clearly outweighs the risk of administration. The immunizer will apply pressure to the site for an extra minute to minimize the risk of a bruise.

Have you have had a serious reaction to a vaccine in the past? (If yes, please provide details below.)

> If someone has had a serious reaction to any vaccine in the past the immunizer needs to be aware of the earlier reaction so they can be prepared, for example, by vaccinating someone lying down if they have fainted before. If someone has previously had an allergic reaction to a vaccine, the immunizer needs to be aware so they can immunize the person at the Health Centre rather than an off-site clinic.

Are you allergic to polyethylene glycol (PEG) or tromethamine which are ingredients in the vaccine?

> Two vaccine components have been identified as potentially resulting in a rare allergic reaction Polyethylene glycol (PEG) can rarely cause allergic reactions and is found in products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, cosmetics, skin creams, medical products used on the skin and during operations, toothpaste, contact lenses and contact lens solution.

Have you ever had a severe allergic reaction for which you were prescribed an EpiPen? *(If yes please provide details below.)*

> The very limited number of people worldwide who have had a severe allergic reaction to either the Pfizer or the Moderna vaccines had a history of severe allergic reactions for which they had been prescribed an EpiPen. These people will still be offered the vaccine but clients who say yes to this question can be watched for a longer period of time – 30 minutes post vaccination rather than the usual 15.