Moderna (SpikeVax) Frozen Vaccine
Children 6 months to 5 years of Age

August 2, 2022

Indigenous Services Canada | Services aux Autochtones Canada

Canada

Reminder:
This videoconference/webinar will be recorded.

Moderna (SpikeVax) Frozen Vaccine – Children 6 months to 5 years of Age

Blue Cap

VACCINE DESCRIPTION	NEW AVI PRODUCT NAME	DIN
COVID-19 mRNA 1273 – mRNA Pediatric 6 months-5 years	SpikeVax 10 dose/vial (Blue Cap)	02527685

mRNA COVID-19 Vaccine Review

- Moderna COVID-19 vaccine uses the messenger RNA (mRNA) manufacturing platform.
- mRNA (messenger ribonucleic acid) vaccines contain the genetic instructions for making the COVID-19 spike protein. This protein is found on the surface of the virus that causes COVID-19.
- When a person is given the vaccine, their cells will read the genetic instructions like a recipe and produce the spike protein.
- After the protein piece is made, the cell breaks down the instructions and gets rid of them.
- The cell then displays the protein piece on its surface. Our immune system recognizes that the protein doesn't belong there and begins building an immune response and making antibodies.
- mRNA vaccines do not affect, interact with or alter your DNA in any way.

Moderna 6 months to 5 years of Age Formulation mRNA Vaccine Effectiveness

- There is very little specific data at this time for the 6 months to 5 years of age group but it is reasonable to assume vaccine effectiveness would be similar to the Moderna 12 years of age and older formulation.
- Vaccine Effectiveness Against Infection two weeks after 2nd dose:
  - 51% effective in trial participants 6 to 23 months old
  - 37% effective in trial participants 2 to 5 years old

Indications for Use

Use in Children 6 months to 4 years of age:

- (Children who are 6 months to under 5 years of age are eligible)

Children 5 years of age

- There is a limited supply of Modern (6 months -5 years) vaccine.
- Children who are starting their primary series at 5 years of age should be offered the **Pfizer BioNTech pediatric formulation** licensed for children 5 to 11 years of age.

Vaccine dosage is based on age at presentation. Regardless of vaccine type/dosage received for first dose.

Children 5 years of age

Moderna (6m-5yr) vaccine may be offered to 5-year-olds who:

- Begin their primary series prior to 5 years of age with Moderna (6m-5yr) vaccine and need to complete their primary series after turning five, or
- Are immunocompromised and their specialist recommends, or their parent/guardian requests Moderna (6m-5yr) vaccine instead of Pfizer BioNTech pediatric formulation, or
- If a parent/guardian refuses the Pfizer BioNTech pediatric formulation for their 5-year-old and requests Moderna (6m-5yr) vaccine.

Vaccine Administration

Dose:

- 0.25ml (25 mcg)

Route:

- IM (intramuscular)

Vaccine Schedule

Primary series 2 doses

- Dose 1: Day 0
- Dose 2: at least 8 weeks after dose 1

- Optimal spacing between dose 1 and dose 2 is at least 8 weeks.
- Evidence on COVID-19 mRNA vaccines in adolescents and adults shows that extending the interval between the first and second dose by several weeks leads to even higher immune responses and better protection against COVID-19 infection that is also expected to last longer.

Vaccine Administration and Schedule (continued)

- A shortened interval between dose 1 and dose 2 (no less than 28 days) may be considered in certain situations:
  - required for travel,
  - increased risk of infection based on local transmission and
  - the degree of individual risk of exposure.
- Minimum spacing between dose 1 and 2 is 28 days and is required for a dose to be considered valid.
- Currently, no data on a maximum interval between doses is available. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series.

Vaccine Schedule for *Immunocompromised* Individuals

It is recommended that individuals with certain immunocompromising conditions be immunized with a primary series of three doses of an mRNA COVID-19 vaccine.

Primary series 3 doses

- Dose 1: Day 0
- Dose 2: 28 days after dose 1
- Dose 3: 8 weeks after dose 2

- The interval between dose 2 and dose 3 is recommended to be 8 weeks because emerging evidence from the older general population indicates that a longer interval will likely result in a better immune response and longer duration of protection.
- A shortened interval no less than 28 days *may* be considered for those with increased risk for exposure and greater severity of immunodeficiency, based on their clinician's recommendation.

Vaccine Eligibility for *Immunocompromised* Individuals (continued)

Specific immunocompromising conditions that make an individual eligible for a three dose schedule (see biological page for full information):

- SOT recipients (pre-transplant and post-transplant) and HSCT recipients
- Malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or receiving active treatment.
- Chronic kidney disease on peritoneal dialysis or hemodialysis.
- Receiving chimeric antigen receptor CAR T-cell therapy.
- HIV-infection without viral suppression or AIDS.
- Individuals with moderate to severe primary immunodeficiency

Individuals on:

- Long term high-dose systemic steroid treatment (prednisone equivalent),
- alkylating agents,
- anti-B-cell therapies – (such as rituximab, ocrelizumab, and ofatumumab),
- Tumor-necrosis factor (TNF) inhibitors,
- antimetabolites (e.g., methotrexate, azathioprine, mycophenolate),
- Other agents that are significantly immunosuppressive at clinicians' discretion

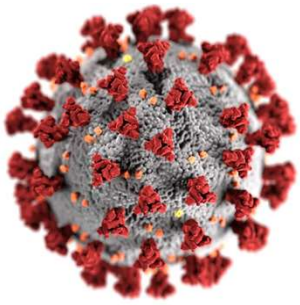
Vaccine Eligibility for *Immunocompromised* Individuals (continued)

Important points:

- Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered the 3 dose primary series.
- Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances.
- Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible to restart their COVID-19 vaccine series beginning at least 3 months post-transplant. Consultation with their HSCT physician is not necessary as long as the initial clearance letter has been received to proceed with inactivated vaccines.
- CAR T-cell therapy recipients (who are not HSCT recipients) who received COVID-19 vaccine pre- CAR T-cell therapy are eligible to restart their COVID-19 vaccine series beginning at least 3 months post CAR T-cell therapy. Consultation with their physician is not necessary as long as a clearance letter has been received to proceed with inactivated vaccines.

Interval between previous COVID-19 Infection and Immunizations

- For individuals who **have not had any previous doses**, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer considered infectious, or they may follow the suggested intervals on the following slide (with the exception of those with MIS-C who should wait at least 90 days).



Interval between previous COVID-19 Infection and Immunizations

Infection prior to initiation or completion of a primary COVID-19 immunization series	Individuals **without** certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C),	8 weeks after symptom onset or positive test (if asymptomatic).
	Individuals **with** certain immunocompromising conditions (as listed above) AND no history of MIS-C,	4 to 8 weeks after symptom onset or positive test (if asymptomatic).
	History of MIS-C (regardless of immunocompromised status),	Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.

Interval between previous COVID-19 Infection and Immunizations (continued)

Important points:

- The suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge.
- When considering whether to administer vaccine doses following the suggested intervals outlined in the table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be considered.
- These intervals are a guide and clinical discretion is advised.
- Individuals can be immunized at less than the recommended intervals from infection upon request.

Possible Reactions

- Pain, erythema, swelling at the injection site
- Injection site lymphadenopathy
- Axillary (or groin) swelling or tenderness
- Fever, chills
- Fatigue, sleepiness
- Headache
- Myalgia, arthralgia
- Irritability, crying
- Loss of appetite
- Nausea, vomiting
- Otitis media

Rare:

- Allergic reactions
- Anaphylaxis
- Febrile convulsion

Contraindications

- **Known hypersensitivity to any component of the vaccine.**
- **Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products.**
  - Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.
  - Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications
- **Anaphylactic reaction to a previous dose of Moderna (6m-5yr) vaccine**

Precautions

- Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine.
- Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.
- Administration should be postponed in individuals suffering from acute severe febrile illness.
- Immunization of children with a previous history of MIS-C should be postponed until clinical recovery has been achieved or until it has been 90 days or greater since diagnosis, whichever is longer.

Myocarditis

- The clinical trials for children 6 months to 5 years of age did not identify any cases of myocarditis following immunization with Moderna vaccine; however, rare, or very rare adverse events that occur at the frequency of less than 6 in 10,000 would not be detected with that trial size.
- Current data suggests the risk of myocarditis and/or pericarditis in children 5 to 11 years of age is lower than that of adolescents or young adults.

Myocarditis (continued)

Available information on myocarditis and/or pericarditis following mRNA vaccines (from individuals twelve years of age and older) indicates that cases of myocarditis and pericarditis:

- Occur more commonly after the second dose;
- More often in adolescents and young adults (12 to 29 years of age); more often in males;
- More frequently following Moderna COVID-19 vaccines than Pfizer-BioNTech COVID-19 vaccine;
- Typically have onset of symptoms within a week after the receipt of an mRNA COVID-19 vaccine;
- Majority of cases were mild, individuals recovered quickly and the investigation into long-term outcomes is ongoing.

Myocarditis (continued)

- It is unknown if individuals with a history of previous myocarditis and/or pericarditis are at higher risk of vaccine associated myocarditis and/or pericarditis.
  - Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines if they are no longer followed clinically for cardiac issues.
  - If there are questions or concerns about prior history of myocarditis or pericarditis and immunization, it is recommended that the child's clinician be consulted. However, consultation with a clinician is not required to receive COVID-19 vaccines.
- In general, individuals who experienced confirmed myocarditis (with or without pericarditis) within 6 weeks after receiving a first dose of mRNA COVID-19 vaccine, are advised to defer receiving a second dose until more data is available as per NACI's recommendation. If there is a preference not to wait, decisions around the second dose should be discussed with the child's clinician.

Myocarditis (continued)

- Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of an mRNA COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can receive the next dose of vaccine when they are symptom free and at least 90 days have passed since previous immunization.
- Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine.

Immunocompromised and Auto-Immune Disorders

- At this time, there is no data on the use of Moderna (6m-5yr) vaccine in immunocompromised children aged 6 months to 5 years and those with auto-immune disorders.
- Individuals who are immunocompromised and those with auto-immune disorders who are receiving immunosuppressive therapy may have a diminished immune response.
- COVID-19 vaccine may be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune disorder if an informed consent is given by the parents/guardians after a discussion on benefits and potential risks.

Immunocompromised and Auto-Immune Disorders (continued)

- It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions, especially regarding the timing of immunization based on the individual's treatment.

Exceptions:

- SOT clients require consultation with their primary health care provider or medical specialist prior to receiving COVID-19 vaccine.
- HSCT clients do not require consultation if the initial clearance letter has been received to proceed with inactivated vaccines.

Other Considerations

- Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
- Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
  - However, individuals with COVID-19-like symptoms should not go to an immunization/venue in order to minimize the risk of COVID-19 transmission.
  - Individuals within facilities who are isolated due to COVID-19-like symptoms can be provided COVID-19 vaccine if they are well enough to be immunized.
- It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in immunocompromised individuals. It is still unknown what antibody level correlates with protection against COVID-19, and serology testing in many labs may also not detect antibodies developed as a response to vaccine. Serology testing should not be used as evidence to inform whether vaccine doses have been effective.

Composition

- **Lipid nanoparticles (these help the mRNA enter the cell):**
  - PEG2000-DMG LSM-102, 1,2-dimyristoyl-rac-glycero-3-methoxy-polyethyleneglycol,
  - 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]),
  - Cholesterol
  - Lipid SM-102
- **pH stabilizers (help maintain the pH of the vaccine):**
  - Acetic acid
  - Sodium acetate trihydrate
  - Trometamol
  - Trometamol hydrochloride
- **Other**
  - Sucrose (protects the nanoparticles when frozen)

Administration with other products

- SpikeVax (6m-5yr) vaccine **should not routinely be administered on the same day with other live or inactivated vaccines** to children 6 months to 5 years of age due to the need to monitor for adverse events following COVID-19 immunization.
- **Recommended, but not required** to wait for a period of at least 14 days before and after the administration of COVID-19 vaccine and the administration of another vaccine, if it does not create a barrier to receipt of vaccines. This is to allow for accurate attribution of adverse events following immunization and inform risk estimates of any adverse event that may be associated with the COVID-19 vaccine.

Administration with other products (continued)

- Clients should not be turned away if presenting for administration of more than one vaccine on the same day or if they are within the 14-day period between the COVID-19 vaccine and another vaccine. If the parents/guardians want to proceed after the importance of having a 14-day spacing has been emphasized, COVID-19 immunization can occur on the same day or within 14 days of administration of another vaccine.
- Based on evidence including real world experience from the use of COVID-19 vaccine in adolescents and adults, administering the pediatric COVID-19 vaccine on the same day or within 14 days of any other live or inactivated vaccine is not expected to have an impact on the safety or effectiveness of the vaccine.
- If a COVID-19 vaccine is administered on the same day as another vaccine or within 14 days of another vaccine, neither dose should be repeated.

Administration with other products (continued)

Currently there is no data on the impact of the COVID-19 mRNA vaccines on tuberculin skin testing or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.

- If tuberculin skin testing or an IGRA test is required for baseline screening, it should be administered and read before administration of any COVID-19 vaccine immunization or delayed for at least 28 days after a dose of COVID-19 vaccine.
- Immunization with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing (including read) have been completed.
- If tuberculin skin testing is required for other reasons (e.g., contact tracing, immigrants, query LTBI), testing should not be delayed, as these are theoretical considerations. However, re-testing (at least 28 days after a dose of COVID-19 vaccine) of individuals with negative results for whom there is high suspicion of TB infection may be prudent in order to avoid missing cases due to potentially false-negative results.

Administration with other products (continued)

Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19 just because they received these pharmacological interventions. This applies to people who received these before receiving any COVID-19 vaccine dose or between doses.

- A study among nursing home residents and staff demonstrated that recipients of a SARS-CoV-2 monoclonal antibody (bamlanivimab), mounted a robust immune response to mRNA immunization, regardless of age, risk category or vaccine type.
- Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown.
- There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients.
- Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who got the monoclonal antibodies or convalescent plasma for their infection.

Administration with other products (continued)

- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis.

- mRNA COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product not specific to COVID-19 treatment has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.

Appearance

Frozen and thawed vaccine:

- white to off-white

Storage

- Can be stored in a freezer between -25°C and -15 °C.
- Protect from light

Vaccine can be thawed in two ways:

1. From the freezer to room temperature (between +15°C to +25°C), thaw for 45 minutes from frozen state.
2. From the freezer to a vaccine fridge +2°C to +8°C; thaw for 2 hours from frozen state. Let the vial stand at room temperature for 15 minutes before administering.

- Do not refreeze after thawing.
- Thawed vials and filled syringes can be stored in room light conditions.

Storage (continued)

For **complete information on storage and handling of the vaccine, see the *Alberta Vaccine Storage and Handling for COVID-19 Vaccine.***

Thawed, unpunctured:

- Thawed, unpunctured vials can be stored at +2°C to + 8°C up to 30 days,
- Thawed, unpunctured vials may be stored at +8°C to +25°C for up to 24 hours.

Thawed, punctured vials:

- Thawed, punctured vials (first dose is withdrawn) can be stored at +2°C to +25°C for 24 hours
- Discard after 24 hours.
- Vials can be punctured a maximum of 10 times and any remaining vaccine after 10 punctures is to be discarded (can't take 11 doses from a vial).

Transportation

- **Unpunctured vials** can be transported a maximum of three separate occasions in a thawing/thawed state; e.g. vaccine depot to public health office (1), public health office to outreach site (2), and outreach site to public health office (3).
- The total transportation time for the maximum allowance of three separate shipments should be no longer than 10 hours.
- The transported vaccine must be labelled “transported thawing/thawed” and
- the total time in transportation must be tracked.
- This time can be extended to 12 hours in extenuating circumstances e.g. vehicle breakdown, poor road conditions. This would not be routine practice.
- Cartons or individual vials protected from movement and kept upright.
- **Thawed and Punctured Vials: cannot transport**

Preparation/Reconstitution

The Moderna COVID-19 Vaccine multiple dose vial contains a frozen suspension that does not contain preservative and must be thawed prior to administration.

- No reconstitution is required.
- The product should be thawed in ways indicated in the “Storage and Handling” section.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake**.

License

Licensed for:

- 6 months to 5 years of age

Off-License use:

- Third dose as part of primary series for individuals 6 months to 5 years of age with certain immunocompromising conditions

Landmarking Children < 12 months old

Children < 12 months old

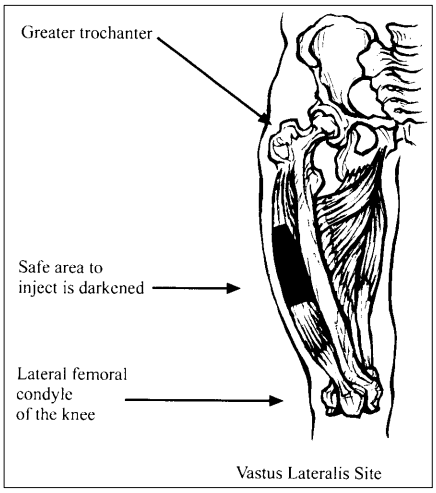
Supplies

- 1 mL syringe
- 25G - 7/8" to 1" needle

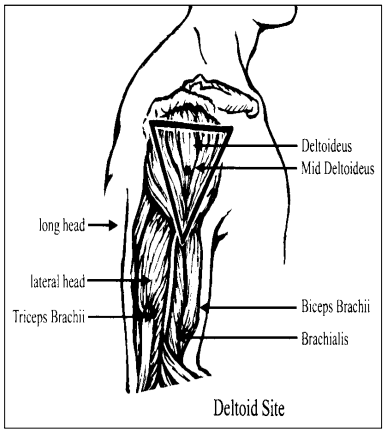
Location

- insert at 90-degree angle into vastus lateralis - middle third of anterior thigh and slightly lateral to the midline

Note: This site can be used for children older than 12 months of age with inadequate deltoid muscle mass.



Landmarking for Children



Children ≥ than 12 months old

Supplies

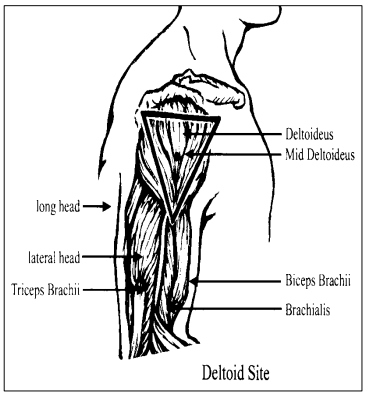
- 3 mL syringe
- 25G - 5/8 to 1" needle

Location

- Insert at 90-degree angle mid portion of deltoid

Importance of Landmarking

- Shoulder injury related to vaccine administration (SIRVA) can occur when an intramuscular deltoid injection is administered into the shoulder joint.
- Improper landmarking can cause damage to the musculoskeletal structures, including the bursae, tendons, and ligaments.
- Ensure the correct needle length is used for the correct depth.
- Ensure the injection avoids the top 1/3 of the deltoid.



For more information, visit: https://www.cfp.ca/content/cfp/65/1/40.full.pdf

Who Can Immunize?

- Follow *FNIHB-Alberta Region's Guidelines for the Administration of COVID-19 Vaccinations Based on Professional Designation*
- Contact your regulatory body if you unsure
- Contact the FNIHB Nursing Education Team if more information about training is needed

Who Can Immunize? (continued)

Registered Nurses

- RNs (CHNs and HCNs) and NPs who DO hold a current FNIHB Immunization Provider Certificate:
  - Can provide routine COVID-19 immunizations for all age groups if they have the knowledge, skills, and competence to administer the vaccine and complete the mandatory requirements on the COVID-19 Vaccine Education Checklist
- RNs (CHNs and HCNs) and NPs who DO NOT hold a current FNIHB Immunization Provider Certificate:
  - Can provide COVID-19 immunizations for eligible clients older than 5 years of age if they have the knowledge, skills, and competence to administer the vaccine and complete the mandatory requirements on the COVID-19 Vaccine Education Checklist

Who Can Immunize? (continued)

Licensed Practical Nurses

- LPNs can provide COVID-19 immunizations for clients older than 5 years of age if they have the knowledge, skills, and competence to administer the vaccine and complete the mandatory requirements on the *COVID-19 Vaccine Education Checklist*.

NOTE: LPNs are not able to administer this vaccine due to the age of the children.

Who Can Immunize? (continued)

Paramedics

- Administering vaccines falls within Authorized Restricted Activities for PCP and ACP.
- Paramedics can provide COVID-19 immunizations for eligible clients older than 5 years of age if they have the knowledge, skills, and competence to administer the vaccine and complete the mandatory requirements on the COVID-19 Vaccine Education Checklist.

NOTE: Paramedics are not able to administer this vaccine due to the age of the children.

COVID-19 Vaccines

There are many different COVID-19 vaccines, different ages, different doses – need to be diligent to avoid errors

Vaccine	Age	Colour Cap
Moderna (Spikevax)	6 months – 5 years	Blue
Moderna (Spikevax)	6 years – 11 years 12 years and older	Red
Pfizer (Comirnaty)	5 – 11 years	Orange
Pfizer (Comirnaty)	12 years and older	Purple

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Questions?

VCHELP@FNTN.CA

References and Resources

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