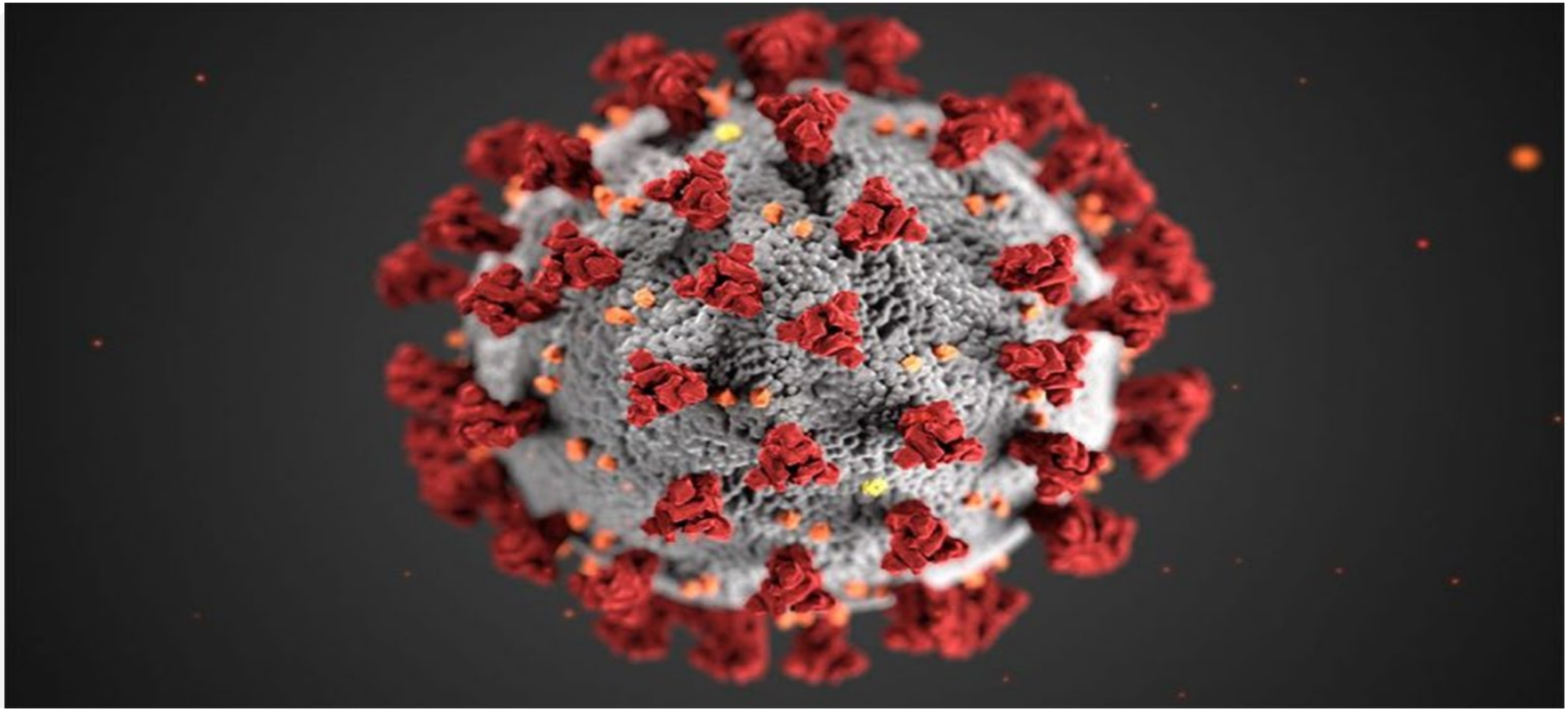
COVID-19 KP.2 Immunization Program Spring 2025



April 2025

Alberta Health Services

Objective

- To provide a clinical information update related to the spring 2025 COVID-19 KP.2 Immunization Program.

*Always use the online resources for the most up to date information.

Key Program Resources

For more detailed information it is important for staff to refer to additional program resources such as:

- COVID-19 Health Professional Immunization webpage
  - Insite for AHS employees or External site for non-AHS employees
- AHS Immunization Program Standards Manual (IPSM) Vaccine Biological pages are located at
  - Insite for AHS employees or External site for non-AHS employees
- COVID-19 Vaccine Product Monograph
- AHS Vaccine Storage and Handling Standard and e-learning module
- Alberta Health Adverse Events Following Immunization (AEFI) Policy
- Site specific reporting requirements and data collection guidelines
- Alberta Immunization Policy: Alberta Outreach Immunization Program

Anaphylaxis Management Resources

Alberta Health Services employees need to ensure they have completed the Anaphylaxis Management | Insite (albertahealthservices.ca) learning module.

Covenant Health employees need to ensure they have completed Covenant Health Anaphylaxis Learning Module found on CLiC.

All other providers must have Anaphylaxis Management Guidelines in place.

- Additional information available in the Canadian Immunization Guide – Vaccine Safety

COVID-19 Vaccines Available in Alberta

- mRNA
  - Moderna (Spikevax) KP.2 Frozen Vaccine (expiring June 17, 2025)
    - **Do not** use Moderna vaccine past expiry date of June 17, 2025
  - Pfizer (Comirnaty) KP.2 Ultra Frozen Vaccine

Moderna KP.2 COVID-19 Vaccine

Alberta Health Services

Moderna (Spikevax) KP.2 mRNA COVID-19 Vaccine Summary

	Moderna COVID-19 Frozen Vaccine (expiring June 17, 2025)
Dosage/Route	12 years of age and older - 0.5 mL (50 mcg) IM (deltoid or vastus lateralis) 6 months of age to 11 years of age – 0.25 mL (25 mcg) IM (deltoid or vastus lateralis)
Packaging	Multi-dose: Canadian packaging – 2.5 mL vial
Diluent	No
Indication	Albertans 6 months of age and older See biological page for specific information.
Ingredients	• mRNA (new technology) – nucleoside-modified mRNA (modRNA) platform • formulated in lipid nanoparticles (LNPs) • no adjuvants, preservatives or antibiotics
Schedule	**5 years of age and older** • Not previously immunized or previously immunized with non-KP.2 COVID-19 vaccine – one dose **6 months to 4 years of age** • Previously unimmunized – 2 doses • Previously immunized (1 or more previous doses of non-KP.2 COVID-19 vaccine) – one dose PLEASE SEE BIOLOGICAL PAGE FOR SPACING CONSIDERATIONS AND SCHEDULE FOR IMMUNOCOMPROMISED PERSONS.

Moderna KP.2 mRNA COVID-19 Vaccine Dosage and Schedule

Individuals 5 years of age and older

- 1 dose, at least 3 months from a previous non-KP.2 COVID-19 vaccine dose, regardless of the number of doses received in the past.

Dosage

- 5 to 11 years of age 0.25 mL
- 12 years of age and older 0.5 mL

Moderna KP.2 mRNA COVID-19 Vaccine Dosage and Schedule

6 months to 4 years of age

- Previously unimmunized:
  - Dose 1: day 0
  - Dose 2: at least 8 weeks after dose 1
- Previously immunized with one dose of a non-KP.2 COVID-19 vaccine series, regardless of product type:
  - 1 dose, at least 8 weeks from previous dose,
- Previously received two or more non-KP.2 COVID-19 vaccine doses, regardless of product type:
  - 1 dose, at least 3 months from previous dose

Dosage

- 6 months to 4 years of age 0.25 mL

Moderna KP.2 mRNA COVID-19 Vaccine Dosage and Schedule

Individuals 6 months to 4 years of age should complete a two-dose series of COVID-19 vaccine, regardless of the product that was administered for the first dose. The series should not be restarted.

Moderna KP.2 mRNA COVID-19 Vaccine Reactions

Common	• Pain, redness or swelling at injection site • Chills, fever • Fatigue • Headache, myalgia, arthralgia • Nausea, vomiting • Axillary swelling or tenderness • Dizziness • Hypoaesthesia or paraesthesia • In children under 5 years of age: irritability, crying, sleepiness, loss of appetite, otitis media
Rare	• Allergic reaction • Anaphylaxis • Erythema multiforme • Facial paralysis/Bell's palsy

Moderna KP.2 COVID-19 Vaccine Storage and Preparation

- Store in freezer between -50˚C to -15˚C.
- Protect from light.
- Do not refreeze after thawing.

Thawed, unpunctured vials:

- Can be stored at +2˚C to +8˚C for up to 50 days.
- Can be stored at +8˚C to +25˚C for up to 12 hours.

Thawed, punctured vials:

- Can be stored at +2°C to +8°C for 24 hours.
  - Discard after 24 hours.
- Can be stored at room temperature up to +25°C for 12 hours.
  - Discard after 12 hours.

Moderna Storage and Preparation

Multidose vials are supplied as a frozen dispersion, does not contain preservative. Thaw vaccine before use:

- Vaccine can be thawed in two ways:
  - From the freezer to room temperature (between +15˚C to +25˚C), thaw for 45 minutes from frozen state.
  - From the freezer to a vaccine fridge (+2˚C to +8˚C), thaw for 6 hours from the frozen state.
- After thawing, let vial stand at room temperature for 15 minutes before administering.
- Must not be reconstituted, mixed with other medicinal product, or diluted.
- No dilution is required.
- Swirl gently after thawing and before each withdrawal.
- Do not shake vial.

Pfizer KP.2 COVID-19 Vaccine

Alberta Health Services

Pfizer (Comirnaty) KP.2 mRNA COVID-19 Vaccine Summary

	Pfizer COVID-19 Ultra Frozen
Dosage/Route	12 years of age and older - 0.3 mL (30 mcg) / IM (deltoid or vastus lateralis)
Packaging	Multi-dose: Canadian packaging – 1.8 mL vial
Diluent	No
Indication	Albertans 12 years of age and older See biological page for specific information
Ingredients	• mRNA (new technology) – nucleoside-modified mRNA (modRNA) platform • formulated in lipid nanoparticles (LNPs) • no adjuvants, preservatives and antibiotics
Schedule	**12 years of age and older** • 1 dose, at least three months from previous non-KP.2 COVID-19 vaccine dose, regardless of the number of doses received in the past PLEASE SEE BIOLOGICAL PAGE FOR SPACING CONSIDERATIONS AND SCHEDULE FOR IMMUNOCOMPROMISED PERSONS.

Pfizer KP.2 mRNA COVID-19 Vaccine Dosage and Schedule

Individuals 12 years of age and older

- 1 dose, at least three months from previous non-KP.2 COVID-19 vaccine dose, regardless of the number of doses received in the past.

Dosage

- 12 years of age and older 0.3 mL

Pfizer KP.2 mRNA COVID-19 Vaccine Reactions

Common	• Pain, redness or swelling at injection site • Chills, fever • Fatigue • Headache, myalgia, arthralgia • Nausea, vomiting, diarrhea
Uncommon	• Lymphadenopathy • Malaise, lethargy, dizziness • Hypoesthesia, paresthesia, asthenia • Decreased appetite • Hyperhidrosis, night sweats
Rare	• Allergic reaction • Anaphylaxis • Facial swelling/Bell's Palsy* • Myocarditis/Pericarditis* • Erythema multiforme* *There were no cases of facial swelling/Bell's Palsy, myocarditis/pericarditis and erythema multiforme following Pfizer Moderna XBB.1.5 immunization during the study period; however, these reactions were reported post-market following Moderna (Original).

Pfizer KP.2 mRNA COVID-19 Vaccine Storage and Preparation

- Store in ultra low temperature freezer between -90˚C to -60˚C
- Protect from light until thawed
- Do not refreeze after thawing
- Thawed, unpunctured vials:
  - Can be stored at +2˚C to +8˚C for up to 10 weeks
  - Can be stored at +8˚C to +25˚C for up to 12 hours
    - Discard after 12 hours
- Thawed, punctured vials:
  - Can be stored at +2°C to +25°C for 12 hours.
    - Discard after 12 hours.

Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vials and cartons.

Pfizer KP.2 COVID-19 Vaccine Storage and Preparation

- Multidose vials are supplied as a frozen dispersion, does not contain preservative. Thaw vaccine before use.
- Vaccine can be thawed in two ways:
  - From the freezer to room temperature (between +15˚C to +25˚C), thaw for 30 minutes from frozen state.
  - From the freezer to a vaccine fridge (+2˚C to +8˚C), thaw for 6 hours from the frozen state.
- Must not be reconstituted, mixed with other medicinal product, or diluted.
- No dilution is required.
- Before use, mix the thawed vaccine by inverting the vial gently 10 times.
- Do not shake vial.

Additional KP.2 COVID-19 Vaccine Dose

Biannual Dose Implementation Date: April 28,2025

Additional KP.2 COVID-19 Vaccine Dose for Moderna and Pfizer

The following individuals who are at an increased risk of severe illness from COVID-19 may receive an additional (biannual) dose of KP.2 COVID-19 vaccine at least 3 months from previous KP.2 COVID-19 vaccine:

- Individuals 65 years of age and older
- Adults 18 years of age and older who **reside** in continuing care homes and senior supportive living accommodations
- Individuals 6 months of age and older who have certain moderate to severe immunocompromising conditions
- First Nations, Metis, and Inuit individuals who are 6 months of age and older, no matter where they live

Immunocompromising Conditions

Alberta Health Services

Immunocompromising Conditions

Specific immunocompromising conditions that make an individual eligible for a three dose COVID-19 vaccine series:

- Solid organ transplant (SOT) recipients – pre-transplant and post-transplant.
- Hematopoietic stem cell transplant (HSCT) recipients – pre-transplant and post-transplant while in an immunosuppressed state and individuals receiving Chimeric Antigen Receptor (CAR) T-Cell therapy. See:
  - Standard for Immunization of Transplant Candidates and Recipients
  - Immunization for Adult HSCT Transplant Recipients
  - Immunization for Child HSCT Transplant Recipients
- Individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention).

Immunocompromising Conditions

Immunocompromised Individuals cont'd

- Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis.
- Individuals on:
  - long term high-dose systemic steroid treatment (prednisone equivalent of equal to or greater than 2 mg/kg/day or 20 mg/day if weight greater than 10 kg, for 14 days or greater), or
  - alkylating agents, or
  - anti-B-cell therapies-including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), or
  - antimetabolites (e.g. methotrexate, azathioprine, mycophenolate), or
  - tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or
  - other agents that are significantly immunosuppressive at clinicians' discretion.

Immunocompromising Conditions

Immunocompromised Individuals cont'd

- HIV-infected individuals without viral suppression or those with acquired immunodeficiency syndrome (AIDS).
- Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).

Schedule for Individuals with Certain Immunocompromising Conditions

Moderna – 6 months of age and older

Pfizer – 12 years of age and older

Unimmunized/previously received fewer than 3 doses of COVID-19 vaccine

- Immunocompromised individuals should follow the schedule below and receive the appropriate number of doses of Moderna or Pfizer KP.2 COVID-19 vaccine to complete a three-dose COVID-19 vaccine series. Regardless of whether they have received one or two non-KP.2 COVID-19 vaccine doses, the previous dose(s) should be counted, and the series should not be restarted.
  - Dose 1: day 0
  - Dose 2: at least 28 days after dose 1
  - Dose 3: 8 weeks after dose 2; however, a minimum interval of 4 weeks may be considered.

Schedule for Individuals with Certain Immunocompromising Conditions

Previously received 3 or more doses of a non KP.2 COVID-19 vaccine

- 1 dose, at least 3 months from previous COVID-19 vaccine dose, regardless of the number of doses received in the past.

Provide appropriate dose for age.

COVID-19 Vaccine – Contraindications and Precautions

Contraindications

COVID-19 vaccine should **not** be administered to individuals who:

- **Have had an anaphylactic reaction to a previous dose of same COVID-19 vaccine**
- Are less than licensed age for the product being used
- Have a known **severe hypersensitivity** to any component of the vaccine

Precautions

- 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.

NOTE: 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.

Myocarditis and/or Pericarditis

- Very rare cases of myocarditis and/or pericarditis following immunization with Moderna Spikevax or Pfizer Comirnaty or Novavax vaccines have been reported during post authorization use.
  - Compared to the original monovalent primary series, the risk of myocarditis and/or pericarditis is now expected to be lower due to the use of a 1-dose schedule in most individuals.

  - Post-market safety surveillance data on previous formulations of mRNA COVID-19 vaccine indicate that the risk of myocarditis following a booster dose is lower compared to that following the second dose in the primary series, and current data do not show a product-specific difference in the risks of myocarditis and/or pericarditis after a booster dose of an mRNA COVID-19 vaccine.

- Anyone receiving a COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.

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 vaccines.
  - If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.

- Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of a COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.

Myocarditis and/or Pericarditis

In most circumstances, further doses of COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an COVID-19 vaccine.

- However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician.
  - If another dose of vaccine is offered, it should be a Pfizer-BioNTech KP.2 COVID-19 vaccine, if 12 years of age and over. This is due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech original (30 mcg) vaccine compared to the Moderna Spikevax original (100 mcg) vaccine among individuals 12 years of age and older.

- Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of COVID-19 vaccine.

Pregnancy

- COVID-19 vaccine should be offered to pregnant individuals regardless of trimester of pregnancy because of the increased risk that infection poses in pregnancy.
- The safety and efficacy of Moderna Spikevax and Pfizer Comirnaty KP.2 in pregnant women has not yet been established.
- However, data available on the original mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance. COVID-19 vaccines can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.
  - It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns.
  - However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.

Pregnancy

COVID-19 mRNA Vaccine use in Pregnancy and Newborn and Early Infant Outcomes

Study done in Ontario, Canada, using multiple linked health administration databases, singleton births with estimated dates of delivery from May 1, 2021, to September 2, 2022, in which the mother received at least one mRNA COVID vaccine while pregnant.

- 142 006 infants included in the study, 85 670 were exposed to 1 or more COVID-19 vaccine doses in utero
- Infants of vaccinated mothers had lower risks of severe neonatal morbidity, neonatal death and NICU admission compared with no maternal COVID-19 vaccination before delivery
- No association between maternal vaccination in pregnancy and neonatal readmission or 6-month hospital admission
- Maternal mRNA COVID-19 vaccination during pregnancy was not associated with increased adverse newborn and early infant outcomes and may be protective against adverse newborn outcomes.

Jorgensen SCJ, Drover SSM, Fell DB, et al. Newborn and Early Infant Outcomes Following Maternal COVID-19 Vaccination During Pregnancy. *JAMA Pediatr.* Published online October 23, 2023. doi:10.1001/jamapediatrics.2023.4499

Breastfeeding

- It is unknown whether COVID-19 vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded.

- Recent reports have shown that breastfeeding people who have received mRNA COVID-19 vaccines have antibodies in their breastmilk, which could help protect their babies. More data are needed to determine the level of protection these antibodies might provide to the baby.

- COVID-19 vaccine is recommended for individuals who are breastfeeding
  - It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns.
  - However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.

Co-administration with other vaccines

- For co-administration with other vaccines, refer to the “Administration With Other Products” section in the relevant COVID-19 vaccine biological page.

Other Program Resources

Alberta Health Services

Commitment to Comfort

Needle Fears

- This can affect people to a degree that they avoid immunization

Commitment to Comfort | Alberta Health Services outlines five principles to improve the immunization experience, health outcomes, satisfaction and encourage repeat attendance to healthcare encounters.

- Make a comfort plan
- Use positive language
- Use comfort positions
- Shift attention
- Use numbing cream

Adverse Events following Immunization (AEFI)

- An adverse event following immunization (AEFI) is defined as a serious or unexpected event temporally associated with immunization.
- Alberta Health developed an Active Surveillance and Reporting of AEFI Policy for COVID-19 vaccine, found in the IPSM and on the Alberta Health website. The policy includes a list of reportable AEFI and Adverse Events of Special Interest (AESI). AESI are additional reportable events specific to COVID-19 vaccine.
- Severe reactions, i.e., anaphylaxis, death and other high-profile / serious events (VITT), should be reported within 24 hours and all other reactions within 3 days to the AEFI Team.
- “Reportable AEFIs” are reported to Alberta Health, and in turn to the National Surveillance Program.

AEFI Reporting

- **AHS Public Health** - AEFI reporting will continue to follow the procedure outlined in the AEFI Standard in the Immunization Program Standards Manual (IPSM).

- **Non-AHS Public Health Practitioners** report AEFI through the AEFI report form found at: www.ahs.ca

- Consult with AHS Adverse Event Following Immunization (AEFI) Team at AEFI@ahs.ca or 1-855-444-2324 as soon as possible for any case where there is uncertainty as to whether a symptom following immunization is related to the immunization.

Infection Prevention and Control (IPC)

IPC's mandate is to reduce the incidence of healthcare associated infections in patients, residents, and clients by:

- process and outcome surveillance
- outbreak identification and management
- consultation and education
- policy and procedure development
- research

For more information go to the AHS IPC website at:

https://www.albertahealthservices.ca/info/page6410.aspx

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QUESTIONS?

Thank You

Email **CDCIMM@ahs.ca** or call

1-855-444-2324