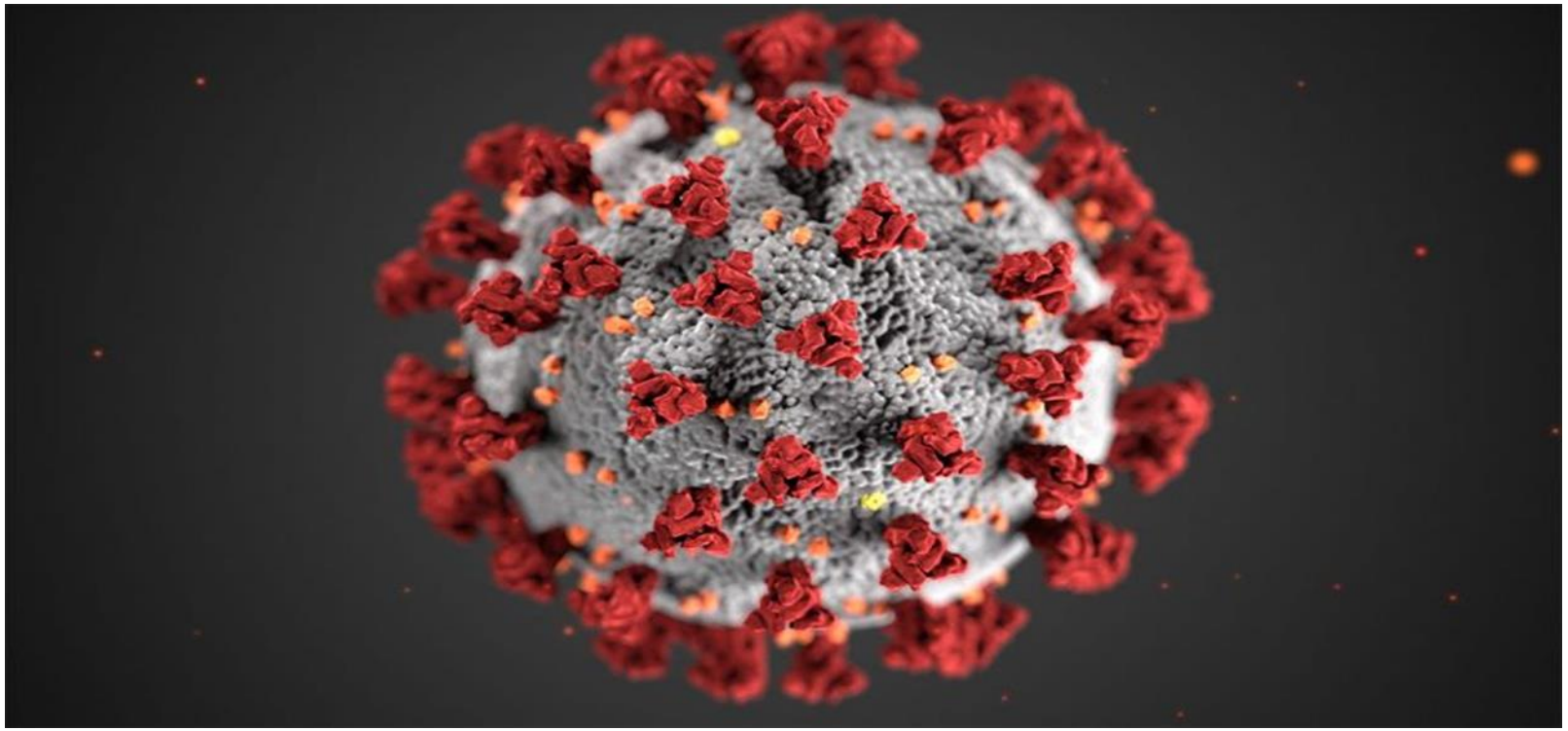
COVID-19 XBB.1.5 Spring Campaign
Immunization Orientation



Presented by
Provincial Population & Public Health
Provincial CDC Immunization Team
April 2024

Objective

- To provide clinical information related to COVID-19 disease and immunization
    - **NOTE**: always use the online resources for up-to-date information
- Operational questions will NOT be addressed during this presentation (i.e., scheduling, vaccine distribution specifics)

Additional Resources

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

- AHS COVID-19 Health Professional Immunization Information
  - 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 Biological Pages and Product Monographs
- 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

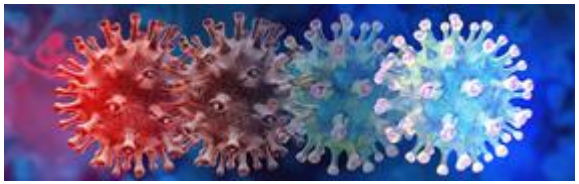
What is COVID-19?

- Coronaviruses are a large family of viruses.
  - Some coronaviruses cause respiratory illness in people, ranging from a mild common cold to severe pneumonia.
  - Other coronaviruses cause illness in animals only. Rarely animal coronaviruses can infect people, and these can spread from person to person through close contact.
- COVID-19 is the disease caused by SARS-CoV-2 virus, a new virus that was first recognized in 2019. It's referred to as a novel coronavirus strain as it was not previously identified in humans.
- Due to it being a novel virus there was no herd immunity and there were no specific treatments when it emerged.
- COVID-19 posed a serious risk to public health and the healthcare system.

What are COVID-19 Variant Strains?

- Mutations in the COVID-19 virus over time are expected and can cause variant strains of COVID-19 to emerge.
- Variant strains of COVID-19 have been identified around the world These strains are known as variants of concern if they cause more severe disease or substantially impact health systems' ability to provide care for patients with COVID-19 or other illnesses, or there is significant decrease in effectiveness of available vaccine to prevent severe disease.

World Health Organization https://www.who.int/publications/m/item/updated-working-definitions-and-primary-actions-for--sars-cov-2-variants



mRNA Vaccine Efficacy & Effectiveness

- Recombinant XBB sub-lineages continue to circulate in Canada and globally.
- COVID variants continue to be tracked in Canada and reported on a weekly basis. https://health-infobase.canada.ca/covid-19/testing-variants.html#VOC
- Individuals vaccinated with the updated XBB.1.5-containing COVID-19 vaccine are expected to benefit from a better immune response against currently circulating strains, compared to earlier formulations. Preliminary clinical data demonstrated that a dose of a monovalent XBB.1.5-containing COVID-19 vaccine generated similar immune responses against XBB sub-lineages XBB.1.5, XBB.1.16 and XBB.2.3.2.

National Advisory Committee on Immunization. (2023 September 12). Addendum to the guidance on the use of COVID-19 vaccines in the fall of 2023. https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-addendum-guidance-use-covid-19-vaccines-fall-2023/statement.pdf

How is COVID-19 Spread?

- The virus is spread mainly from person-to-person through coughing or sneezing (droplet spread).
  - The droplets are propelled less than 2 metres through the air; smaller droplets (aerosols) can be infectious over longer distances
- People may also become infected by touching an object or a surface that has the COVID-19 virus on it and then touching their mouth, eyes or nose.
- Median incubation period is estimated at 7 days from exposure to onset.
- Most people (97.5%) develop symptoms within 11.5 days.

COVID-19 Infectivity

- People infected with COVID-19 can spread the disease to others while they have symptoms and sometimes before they know they are ill. A person may be infectious for two days before showing symptoms.
- Some people can be infected but have no symptoms.
  - These individuals can spread the virus to others
- This is important information for those caring for others, such as parents and all health care workers.

COVID-19 Signs and Symptoms

- fever
- new cough or worsening chronic cough
- shortness of breath
- sore throat
- runny nose
- stuffy nose
- painful swallowing
- headache, chills
- muscle/joint aches
- fatigue or severe exhaustion
- GI symptoms
- loss of sense of smell or taste
- conjunctivitis
- sneezing

How Serious is COVID-19?

- COVID-19 disease can lead to severe outcomes. Individuals who are infected may need to be hospitalized, admitted to the ICU or may die from the disease.

- Some individuals are at higher risk of developing complications from COVID-19 disease, including:
    - Seniors
    - Adults with existing chronic health conditions

Treatment of COVID-19

Treatment will vary depending on severity of disease.

Some Albertans will be able to stay home and manage symptoms with comfort measures such as:

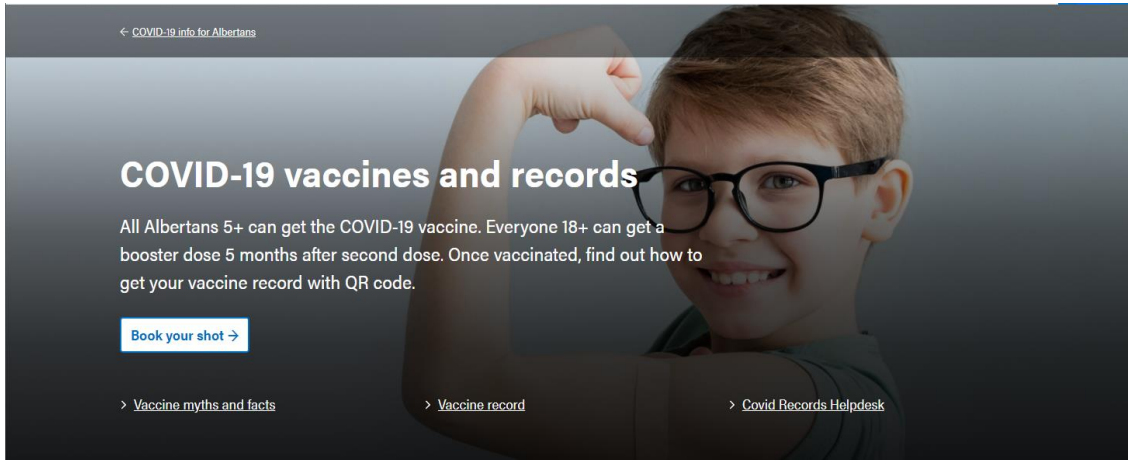
- rest
- analgesics
- fluids
- time
- antiviral medication
- monoclonal antibodies

Other Albertans will require care in an acute care facility, perhaps in an ICU.

Universal COVID-19 Immunization Program

Alberta Health (AH) has made COVID-19 vaccine available to:

- All Albertans (6 months of age and older) at no charge.
- More information on the COVID-19 vaccine program can be found on the Alberta Health website.



COVID-19 Vaccines Available in Alberta

- **mRNA**
  - Moderna (Spikevax) XBB.1.5 Frozen Vaccine
  - Pfizer (Comirnaty) XBB.1.5 Ultra Frozen Vaccine

- **Recombinant Protein, Adjuvanted**
  - Novavax (Nuvaxovid) XBB.1.5

What are mRNA COVID-19 Vaccines?

- **Moderna and Pfizer** COVID-19 vaccine use 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.

What are Recombinant Protein COVID-19 Vaccines?

- **Novavax Nuvaxovid** consists of a purified full-length SARS-CoV-2 recombinant spike (S) protein nanoparticle administered as a co-formulation with the adjuvant Matrix-M.
- Matrix-M is a novel saponin-based adjuvant that facilitates activation of the cells of the innate immune system, which enhances the magnitude of the S protein-specific immune response.
- Matrix-M has been used in Novavax Nuvaxovid clinical trials and in pre-licensure studies targeting other pathogens but has not previously been used in any licensed vaccine.

National Advisory Council on Immunization, Recommendations on the use of Novavax Nuvaxovid COVID-19 vaccine, 17 February 2022

Vaccine Storage and Handling Principles

Protection of COVID-19 vaccine potency and stability is important

- Vaccines not kept in proper conditions may become ineffective
- The public trusts that the vaccine they receive will be effective
- COVID-19 vaccines are sensitive products and variances from the recommended handling may cause wastage due to:
  - Cold chain excursions
  - Rough handling causing vaccine to be jostled
  - Use of vaccine beyond time limits / expiry

Vaccine Storage and Handling Principles

Every immunizer **must**:

- Understand cold chain excursions and their implications
- Identify the key staff members at the clinic responsible for vaccine management
- Understand the specific vaccine storage and handling recommendations for each product
- Understand how to monitor and interpret min/max thermometer readings
- Understand the actions required when a cold chain excursion is identified (quarantine product and notify clinic lead)

Review AHS Vaccine Storage and Handling webpage (see next slide)

Vaccine Storage and Handling Principles

Vaccine Storage and Handling

Vaccines are sensitive biological products that may become less effective or destroyed when exposed to temperatures outside the recommended range or inappropriately exposed to light.

- Alberta Health Vaccine Cold Chain Policy
- Alberta Health Vaccine Storage and Handling for COVID-19 Vaccine

These policies as well as the Alberta Health Services (AHS) Vaccine Storage and Handling Standard set out requirements and provide direction to AHS Public Health, AHS non-Public Health and community providers to ensure:

- Vaccine efficacy and safety is protected, ensuring a safe and potent vaccine is administered
- Vaccine providers are knowledgeable regarding vaccine storage, handling and timely reporting of cold chain excursions

Alert

This is a reminder to all vaccine providers involved in the provincially funded immunization program. All vaccine storage and handling requirements outlined in the Alberta Health Vaccine Cold Chain Policy must be met in order to receive provincially funded vaccine. If you have questions about equipment required for vaccine storage and handling please follow up with your Zone Contact.

The following resources have been developed to outline the requirements for storage and handling of provincially funded vaccine within Alberta.

Vaccine Storage & Handling Documents | Education and Training Resources | Cold Chain Excursion Reporting | Zone Contacts

- Vaccine Storage and Handling Standard
  - Summary of Cold Chain Management Requirements
  - Temperature Monitoring Log
  - Vaccine Packing Checklist
  - Routine Cleaning of Vaccine Storage Equipment
  - Vaccine Refrigerator Maintenance and Cleaning Log
  - Vaccine Storage and Handling Audit for Sites Storing Provincially Funded Vaccine
  - Audit Tool Process – Instructions for Use
  - Cold Chain Management Form
  - Vaccine Transport and Handling - Courier Services

Moderna mRNA COVID-19 Vaccine Summary

	Moderna COVID-19 Frozen
Dosage/Route	12 years of age and older - 0.5 mL / IM (deltoid or vastus lateralis) 6 months of age to 11 years of age – 0.25 mL/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 and antibiotics
Schedule	**5 years of age and older** • Not previously immunized or previously immunized– one dose **6 months to 4 years of age** • Not previously immunized – 2 doses • Previously immunized (1 or more previous doses) – one dose PLEASE SEE BIOLOGICAL PAGE FOR SPACING CONSIDERATIONS AND SCHEDULE FOR IMMUNOCOMPROMISED PERSONS.

Moderna mRNA Vaccine Dosage and Schedule

Individuals 5 years of age and older

- 1 dose

Dosage

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

Moderna mRNA 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-XBB.1.5 COVID-19 vaccine series:
  - 1 dose, at least 8 weeks from previous dose, regardless of product type.
- Previously received two or more non-XBB.1.5 COVID-19 vaccine doses:
  - 1 dose, at least 3 months from previous dose

Dosage

- 6 months to 4 years of age 0.25 mL

Moderna mRNA Vaccine Dosage and Schedule

Note:

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

Pfizer 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) 5 years of age to 11 years of age – 0.3 mL (10 mcg) /IM (deltoid or vastus lateralis)
Packaging	Multi-dose: Canadian packaging – 1.8 mL vial
Diluent	No
Indication	Albertans 5 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	**5 years of age and older** • 1 dose, at least three months from previous 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 mRNA Vaccine Dosage and Schedule

Individuals 5 years of age and older

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

Dosage

- 5 to 11 years of age 0.3 mL
- 12 years of age and older 0.3 mL

Novavax Vaccine Summary

	Novavax COVID-19 Vaccine
Dosage/Route	0.5 mL / IM (deltoid or vastus lateralis)
Packaging	Multi-dose vial – 5 doses per vial
Diluent	No
Indication	• Individuals 12 years of age and older
Composition	• NUVAXOVID is composed of purified full-length SARS-CoV-2 recombinant spike (S) protein nanoparticle • Adjuvanted with saponin-based Matrix-M
Schedule	**12 years of age and older** • previously unimmunized – 1 dose • previously immunized with non-XBB.1.5 COVID-19 VACCINE – 1 dose at least 3 months from previous non-XBB.1.5 regardless of number of doses in the past PLEASE SEE BIOLOGICAL PAGE FOR SPACING CONSIDERATIONS AND SCHEDULE FOR IMMUNOCOMPROMISED PERSONS.

Novavax Vaccine Dosage and Schedule

Immunocompetent Individuals 12 years of age and older:

- Previously unimmunized:
  - One dose
- Previously received at least 1 dose of non-XBB.1.5 COVID-19 vaccine, regardless of product type:
  - 1 dose, at least 3 months from previous non-XBB.1.5 COVID-19 vaccine dose, regardless of the number of doses received in the past.

Notes: As of April 15, 2024, unimmunized individuals only require a single dose of Novavax XBB.1.5 COVID-19 vaccine to have a complete COVID-19 vaccine series.

- This takes into account high levels of seroprevalence in the population due to COVID-19 infection.

Persons who received a dose of mRNA XBB.1.5 before April 15, 2024, are not eligible for a dose of Novavax.

Additional XBB.1.5 COVID-19 Vaccine Dose

Starting April 15, 2024, the following individuals who are at increased risk of severe illness from COVID-19 may receive an additional dose of XBB.1.5 COVID-19 vaccine:

- Individuals 65 years of age and older
- Adults 18 years of age and older who reside in seniors congregate care living settings.
- Individuals who have certain moderate to severe immunocompromising conditions.
  - Please assess for eligibility and dosing as per vaccine indication
- First Nations, Métis, and Inuit individuals, including First Nations on and off reserve.
  - Please assess for eligibility and dosing as per vaccine indication

➢ One dose, at least 6 months from previous XBB.1.5 COVID-19 vaccine dose. However, a shorter interval of 3 months may be used in senior congregate care settings.

Schedule for Individuals with Certain Immunocompromising Conditions

Moderna

Individuals 6 months to 4 years of age

- Previously unimmunized/received fewer than 3 doses of non-XBB COVID-19 vaccine:
  - 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.

- Previously received 3 or more doses of non-XBB.1.5 COVID-19 vaccine:
  - 1 dose, at least 3 months from previous dose

Use appropriate dose of vaccine for age.

Schedule for Individuals with Certain Immunocompromising Conditions

Moderna and Pfizer

Individuals 5 years of age and older

- Previously unimmunized:
  - Dose 1: day 0
  - Dose 2: at least 8 weeks after dose 1; however, a minimum interval of 4 weeks may be considered.
- Unimmunized post-HSCT and/or CAR T-cell therapy recipients:
  - Dose 1: day 0
  - Dose 2: 28 days after dose 1
  - Dose 3: 8 weeks after dose 2; however, a minimum interval of 4 weeks may be considered.

Use appropriate dose of vaccine for age.

Schedule for Individuals with Certain Immunocompromising Conditions

Moderna and Pfizer

Individuals 5 years of age and older

- Previously received 1 or 2 doses of non-XBB.1.5 COVID-19 vaccine:

If an individual has received one or two non-XBB.1.5 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.

- Previously received 3 or more doses of non-XBB.1.5 COVID-19 vaccine:
  - 1 dose, at least 3 months from previous dose

Use appropriate dose of vaccine for age.

Schedule for Individuals with Certain Immunocompromising Conditions

Notes:

- Based on data from studies of original mRNA COVID-19 vaccines, Moderna Spikevax original (100 mcg) induces somewhat higher antibody levels compared to Pfizer-BioNTech Comirnaty original (30 mcg) and protection (against infection and severe disease) may be more durable. It is reasonable to expect a similar result from Moderna Spikevax XBB.1.5.
- For individuals 12 to 29 years of age who are completing a three-dose series, there is no longer a product preference between Moderna Spikevax and Pfizer BioNTech Comirnaty with the use of XBB.1.5- containing COVID-19 vaccines.

Schedule for Individuals with Certain Immunocompromising Conditions

- 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 and potentially due to a lower dosage of the available Moderna Spikevax vaccine (50 mcg in the XBB.1.5 formulation compared to 100 mcg in the original monovalent formulation).
- 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.

- It is recommended that individuals with certain immunocompromising conditions be immunized with a mRNA COVID-19 vaccine series. This is to provide stronger protection for those who may have a suboptimal immune response to vaccines.

Schedule for Individuals with Certain Immunocompromising Conditions

Novavax

Individuals 12 years of age and older

It is recommended that all immunocompromised individuals receive mRNA XBB.1.5 COVID-19 vaccine as there is less data available about the Novavax XBB.1.5 COVID-19 vaccine compared to mRNA COVID-19 vaccines in this population. However, Novavax XBB.1.5 COVID-19 vaccine can be offered to individuals if requested.

- Previously Unimmunized:
  - Dose 1: day 0
  - Dose 2: at least 8 weeks after dose 1; however, a minimum interval of 4 weeks may be considered.
- Unimmunized post-HSCT and/or CAR T-cell therapy recipients:
  - Dose 1: day 0
  - Dose 2: 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

Novavax

- Previously received 1 or 2 doses of COVID-19 vaccine:

If an individual has received one or two non-XBB.1.5 COVID-19 vaccine doses, the previous dose(s) should be counted, and the series should not be restarted.

  - Dose 1: day 0
  - Dose 2: 28 days after dose 1
  - Dose 3: 8 weeks after dose 2; however, a minimum interval of 4 weeks may be considered.

- Previously received 3 or more doses of non-XBB.1.5 COVID-19 vaccine:
  - 1 dose, at least 3 months from previous dose.

Schedule for Individuals with Certain Immunocompromising Conditions

Note:

- There are no data available on the interchangeability of Novavax Nuvaxovid XBB.1.5 with other COVID-19 vaccines to complete a series.
  - Evidence from original COVID-19 vaccines indicates that a mixed schedule that included original Novavax Nuvaxovid demonstrated acceptable safety profiles. It is not unreasonable to expect a similar safety profile for a mixed schedule which includes Novavax Nuvaxovid XBB.1.5 COVID-19 vaccine.
  - Based on evidence from original COVID-19 vaccines, a mixed schedule including Novavax Nuvaxovid may not be as immunogenic as continuing with an mRNA vaccine.
- With non-XBB COVID-19 vaccine formulations, the immune response was somewhat better with longer intervals between vaccine doses. It is reasonable to assume that this would also apply to Novavax XBB.1.5 COVID-19 vaccine.

Additional XBB.1.5 COVID-19 Vaccine Dose

Starting April 15, 2024, moderately to severely immunocompromised individuals who are at an increased risk of severe illness from COVID-19 may receive an additional dose of XBB.1.5 COVID-19 vaccine

- Please assess for eligibility and dosing as per vaccine indication

- One dose, at least 6 months from previous XBB.1.5 COVID-19 vaccine dose. However, a shorter interval of 3 months may be used in senior congregate care settings.

Schedule for Individuals with Certain Immunocompromising Conditions

Immunocompromising Conditions

- Specific immunocompromising conditions that make an individual eligible for a third dose:
  - 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).
  - Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis

Schedule for Individuals with Certain Immunocompromising Conditions

Immunocompromised Individuals cont'd

- 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
  - Individuals on 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.
- 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

Note:

- Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered the appropriate number of COVID-19 vaccine doses that an individual is eligible for.
- Immunization of 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.

Interval between infection and immunization

Interval between previous COVID-19 infection and COVID-19 immunization:

- 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 or not to administer vaccine doses following the suggested intervals outlined in the tables found in the biological pages, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and risk of 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.
- 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 infectious, or they may follow the intervals found in the tables in the biological pages (except for those with multisystem inflammatory syndrome in children [MIS-C] who should wait at least 90 days).

Moderna mRNA COVID-19 Vaccine Reactions

Common	Rare
• Pain, redness or swelling at injection site • Chills, fever • Fatigue • Headache, myalgia, arthralgia • Nausea, vomiting • Axillary swelling or tenderness • Erythema • Dizziness	• 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 Moderna XBB.1.5 immunization during the study period; however these were reported post-market following Moderna (Original).

As with any immunization, unexpected or unusual side effects can occur.
Refer to product monograph for more detailed information.

Pfizer mRNA COVID-19 Vaccine Reactions

Common	Rare
• Pain, redness or swelling at injection site • Chills, fever • Fatigue • Headache, myalgia, arthralgia • Nausea, vomiting, diarrhea • Erythema • Hypoesthesia, paresthesia	• 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 XBB.1.5 immunization during the study period; however these were reported post-market following Pfizer (Original).

As with any immunization, unexpected or unusual side effects can occur.
Refer to product monograph for more detailed information.

Novavax Vaccine Reactions

Common	Rare
• Pain in your arm, hand, leg or foot • Redness, swelling or feeling sore at injection site • Fever • Fatigue • Malaise • Headache, arthralgia, myalgia • Nausea, vomiting	• Allergic reaction • Anaphylaxis
As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.	

Moderna XBB.1.5 Vaccine Storage

Moderna mRNA Vaccine	Storage temperatures and time limits
Primary storage: Freezer	-25°C to -15°C until expiration date
Storage: Thawed, Unpunctured	+2°C to +8°C for 30 days **OR** +8°C to +25°C for 24 hours
Usage Limit: Thawed, Punctured	+2°C to +25°C for 24 hours
DO NOT REFREEZE OR STORE ON DRY ICE OR BELOW -50°C **DO NOT SHAKE** **PROTECT FROM LIGHT**	

Moderna XBB.1.5 Vaccine Management

- All multi-dose vials to be thawed in the fridge must be marked with the **date and time** of removal from freezer.
  - Moderna COVID-19 vaccine must be used within 30 days of removal from freezer and stored in fridge at +2°C to +8°C
- All multi-dose vials must be marked with the **date and time** when thawed and stored at room temperature.
  - Moderna COVID-19 vaccine must be used within 24 hours if stored at room temperature
- All multi-dose vials must be marked with the **date and time** when **punctured**.
  - Moderna COVID-19 vaccine must be used within 24 hours if first dose is withdrawn
  - A maximum of 10 doses can be withdrawn from a vial of any combination of doses; once 10 doses have been withdrawn the vial must be discarded
- Communicate use of near expiry vials to other staff members, so the vaccine can be used before it expires; this becomes more important at the end of a clinic.
- Vaccine should be withdrawn from the vial by the immunizer administering the vaccine.

Moderna XBB.1.5 Vaccine – Preparation

- The Moderna COVID-19 Vaccine is primarily stored in a freezer (-25°C to -15°C) and vaccine must be thawed prior to administration.

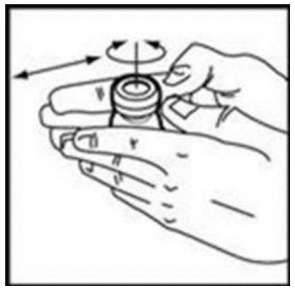
- **Vaccine can be thawed in 2 ways**:
  - From the freezer to room temperature (+15°C to +25°C)
    - thaw for 45 minutes from frozen state.

  - From the freezer to a vaccine fridge at +2°C to +8°C
    - thaw for 2 hours from frozen state.

- Let the vial stand at room temperature for 15 minutes before administering.

Moderna XBB.1.5 – Preparation

- **No dilution** is required.
- The Moderna COVID-19 Vaccine multiple dose vial contains a frozen suspension that does not contain preservative and must be thawed prior to administration. Strict adherence to aseptic techniques must be followed.
  - thaw as indicated in the Storage section on biological page
- **Swirl** vial gently after thawing and **swirl gently** between each withdrawal.
- **Do Not Shake**



Pfizer XBB.1.5 Vaccine Storage

Pfizer mRNA Vaccine	Storage temperatures and time limits
Primary storage: Ultra Freezer	-90°C to -60°C until expiration date
Storage: Thawed, Unpunctured	+2°C to +8°C for 10 weeks **OR** +8°C to +25°C for 12 hours
Usage Limit: Thawed, Punctured	+2°C to +25°C for 12 hours

DO NOT REFREEZE
DO NOT SHAKE
THAWED VIALS CAN BE HANDLED IN ROOM LIGHT CONDITIONS

Pfizer XBB.1.5 Vaccine Management

- All multi-dose vials to be thawed in the fridge must be marked with the **date and time** of removal from ultra freezer.
  - Pfizer COVID-19 vaccine must be used within 10 weeks of removal from freezer and stored in fridge at +2°C to +8°C
- All multi-dose vials must be marked with the **date and time** when thawed and stored at room temperature.

  - Pfizer COVID-19 vaccine must be used within 12 hours if stored at room temperature
- All multi-dose vials must be marked with the **date and time** when **punctured**.
  - Pfizer COVID-19 vaccine must be used within 12 hours if first dose is withdrawn
  - Use low dead volume syringes to ensure 6 doses can be extracted. If standard syringes are used there may not be sufficient volume to extract the 6th dose.
- Communicate use of near expiry vials to other staff members, so the vaccine can be used before it expires; this becomes more important at the end of a clinic.
- Vaccine should be withdrawn from the vial by the immunizer administering the vaccine.

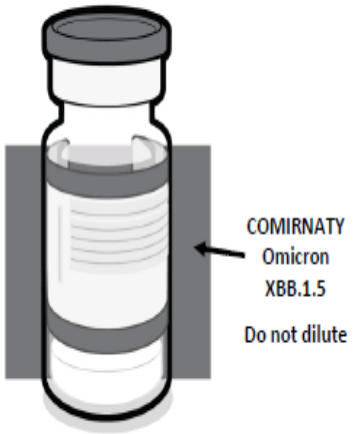
Pfizer XBB.1.5 – Preparation

- The Pfizer COVID-19 Vaccine is primarily stored in a freezer (-90°C to -60°C) and vaccine must be thawed prior to administration.
- **Vaccine can be thawed in 2 ways**:
  - From the freezer to room temperature (+15°C to +25°C)
    - thaw for 30 minutes from frozen state.
  - From the freezer to a vaccine fridge at +2°C to +8°C
    - thaw for 6 hours from frozen state.

Pfizer 12 years and older XBB.1.5– Preparation

COMIRNATY Omicron XBB.1.5 For 12 Years of Age and Older: DO NOT DILUTE
(Single Dose & Multiple Dose Vials with Gray Cap and Gray Label Border)

VIAL AND DOSE VERIFICATION

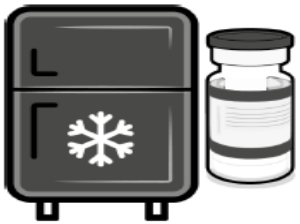


Gray plastic cap and label with gray border

- Verify that:
  - the vial has a gray cap and a label with a gray border;
  - the product name on the vial states that the vaccine is COMIRNATY Omicron XBB.1.5; AND
  - the vial is a single dose vial (containing 1 dose) or a multiple dose vial (containing 6 doses) by checking the label and follow the applicable handling instructions below.
- Do not use COMIRNATY Omicron XBB.1.5 with orange plastic cap and an orange label border, blue plastic cap and a blue label border, or maroon plastic cap and a maroon label border to prepare doses for individuals aged 12 years and older.

COMIRNATY Omicron XBB.1.5 For 12 Years of Age and Older: DO NOT DILUTE
(Single Dose & Multiple Dose Vials with Gray Cap and Gray Label Border)

THAWING PRIOR TO USE



Can be stored in the refrigerator (2°C to 8°C) for up to 10 weeks prior to use

- Thaw single dose or multiple dose vial(s) of COMIRNATY Omicron XBB.1.5 before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)].
    - Single dose vials: A 10 vial pack of single dose vials may take 2 hours to thaw.
    - Multiple dose vials: A 10 vial pack of multiple dose vials may take 6 hours to thaw.
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Thawed vials can be stored in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 10 weeks prior to use within the expiry date.
- Thawed vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use.

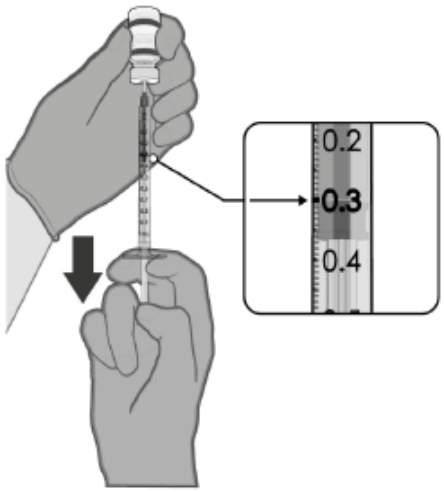
Gently × 10

- Before use, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
- Do not use if liquid is discoloured or if particles are observed after mixing.

Pfizer 12 years and older XBB.1.5– Preparation

COMIRNATY Omicron XBB.1.5 For 12 Years of Age and Older: DO NOT DILUTE
(Single Dose & Multiple Dose Vials with Gray Cap and Gray Label Border)

PREPARATION OF INDIVIDUAL 0.3 mL DOSES



Withdraw 0.3 mL dose of vaccine

Single dose vials

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw a single 0.3 mL dose of COMIRNATY Omicron XBB.1.5.
- Discard vial and any excess volume.

Multiple dose vials

- Multiple dose vials contain 6 doses of 0.3 mL each.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of COMIRNATY Omicron XBB.1.5 (for 12 years of age and older) preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Administer immediately and no later than 12 hours after first puncture.
- Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to adhere to minimizing volume loss during dose extraction.

COMIRNATY Omicron XBB.1.5 For 12 Years of Age and Older: DO NOT DILUTE
(Single Dose & Multiple Dose Vials with Gray Cap and Gray Label Border)

Record the discard time on the vial label.
Use within 12 hours after first puncture.

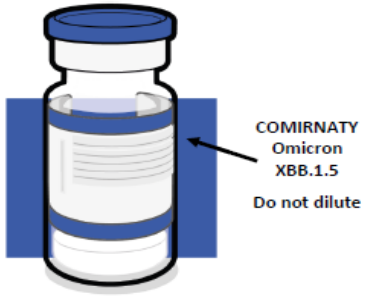
Multiple Dose Vial Only:

- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after first puncture. Record the discard time on the vial label.

Pfizer 5 to 11 years XBB.1.5– Preparation

COMIRNATY Omicron XBB.1.5 For Age 5 Years to <12 Years: DO NOT DILUTE
(Single Dose & Multiple Dose Vials with Blue Cap and Blue Label Border)

VIAL AND DOSE VERIFICATION



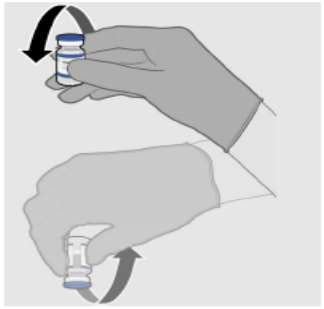
Blue plastic cap and label with blue border

- Verify that:
  - the vial has a blue cap and a label with a blue border;
  - the product name on the vial states that the vaccine is **COMIRNATY Omicron XBB.1.5**; **AND**
  - the vial is a single dose vial (containing 1 dose) or a multiple dose vial (containing 6 doses) by checking the label and follow the applicable handling instructions below.
- Do not use COMIRNATY Omicron XBB.1.5 with gray plastic cap and a gray label border or maroon plastic cap and a maroon label border to prepare doses for individuals aged 5 years to <12 years.

THAWING PRIOR TO USE

Can be stored in the refrigerator (2°C to 8°C) for up to 10 weeks prior to use within the expiry date.

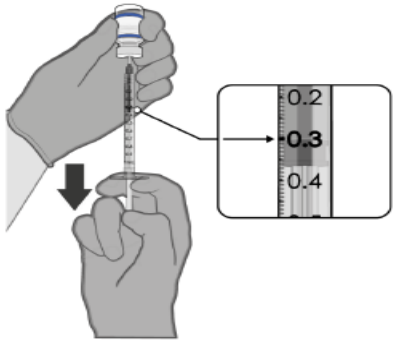
- Thaw single dose or multiple dose vial(s) of COMIRNATY Omicron XBB.1.5 before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)].
    - Single dose vials: A 10 vial pack of single dose vials may take 2 hours to thaw.
    - Multiple dose vials: A 10 vial pack of multiple dose vials may take 6 hours to thaw.
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Thawed vials can be stored in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 10 weeks prior to use within the expiry date.
- Thawed vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use.



Gently × 10

- Before use, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
- Do not use if liquid is discoloured or if particles are observed after mixing.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES



Withdraw 0.3 mL dose of vaccine

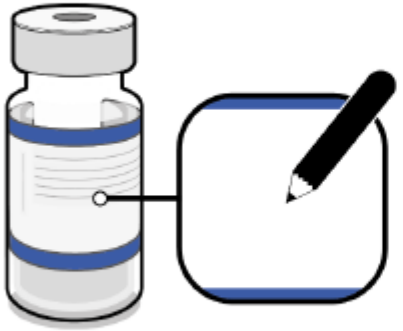
Single dose vials

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw a single 0.3 mL dose of COMIRNATY Omicron XBB.1.5.
- Discard vial and any excess volume.

Multiple dose vials

- Multiple dose vials contain 6 doses of 0.3 mL each.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of COMIRNATY Omicron XBB.1.5 (for 5 years to <12 years) preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Administer immediately and no later than 12 hours after first puncture.
- Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is

Pfizer 5 to 11 years XBB.1.5 – Preparation

COMIRNATY Omicron XBB.1.5 For Age 5 Years to <12 Years: DO NOT DILUTE (Single Dose & Multiple Dose Vials with Blue Cap and Blue Label Border)	
	important to adhere to minimizing volume loss during dose extraction.
 **Record the discard time on the vial label.** **Use within 12 hours after first puncture.**	Multiple Dose Vial Only: • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 12 hours after first puncture. Record the discard time on the vial label.

mRNA COVID-19 Vaccine Transport

- First choice is to transport vaccine in **frozen state**
- In exceptional scenarios, can be transported in a thawing/thawed state at +2°C to +8°C in appropriate validated containers
  - For **Moderna** vaccine, the total transportation should be no longer than 10 hours. The time can be extended to 12 hours in extenuating circumstances but would not be routine practice.
  - The transported vaccine must be labelled “transported thawing/thawed” and the total time in transportation must be tracked.
- Temperature must be maintained and recorded during transport
- Full cartons or individual vials can be transported, and care should be taken to minimize extra movement in the thawed state
  - Prevent contact with ice packs in packing containers
  - Prevent movement in packing containers; keep vials upright in packing containers
  - Packing containers should be secured in a vehicle so vaccine does not move around

mRNA COVID-19 Vaccine Transport

- **Moderna vaccine:** time in transit in the thawed state should be considered part of the 30 days allowed for storage at +2°C to +8°C
- **Pfizer vaccine:** time in transit in the thawed state should be considered part of the 10 weeks allowed for storage at +2°C to +8°C
- Do not refreeze thawed product
- Do not transport vaccine at room temperature
- Do not transport vials that have been punctured, except
  - Transportation of **Moderna Spikevax XBB.1.5** punctured vials is permitted. However, transport with caution as there is a risk of microbial contamination during transport of punctured vials. Ensure post-puncture thawed vaccine is discarded after 24 hours.
- Record transportation locations, dates and times, including the duration of time in transit

Novavax Vaccine Storage

Nuvaxovid Vaccine	Storage temperatures and time limits
Pre-puncture storage:	Store at +2°C to +8°C for 12 months, not exceeding the original expiry date
Post-puncture storage:	+2°C to +8°C for 12 hours **OR** +2°C to +25°C for 6 hours Discard if not used within this time.
Check puncture date/time and storage time limits prior to administration **DO NOT FREEZE** **PROTECT FROM LIGHT**	

Novavax COVID-19 Vaccine Transport

- Maintain cold chain at +2°C to +8°C
- There are no concerns from a stability perspective in transporting Novavax vaccine.
- Vaccine may be transported post-puncture with infection control considerations including hand hygiene, cleaning vial with alcohol wipe pre-puncture and post-puncture before returning to vaccine bag.

COVID-19 Vaccine – 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 **type 1 hypersensitivity** to any component of the vaccine:

  For **Moderna and Pfizer** vaccine:

  - Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.
  - 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.

  For **Novavax** vaccine:

  - Polysorbate 80 – medical preparations (e.g., vitamin oils, tablets, anticancer agents) and cosmetics.

COVID-19 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.
- The safety and effectiveness of Pfizer-BioNTech Omicron XBB.1.5 for individuals 6 months of age and older are inferred from studies which evaluated the primary series and booster vaccination with Pfizer-BioNTech and supported by studies which evaluated a booster dose of Pfizer-BioNTech Original & Omicron BA.4/BA.5 in individuals 6 months of age and older.

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.

COVID-19 Vaccine – Precautions cont'd

- 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.
- 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.
- 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 a COVID-19 vaccine.
- 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.

COVID-19 Vaccine – Precautions cont'd

- 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.
- 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.
  - 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. An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy.
- The safety and efficacy of Moderna Spikevax, Pfizer Comirnaty and Novavax XBB.1.5 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.

Pregnancy

- Evidence to date shows that COVID-19 immunization during pregnancy is safe and does not increase risk for miscarriage, stillbirth, low birth weight, preterm birth, NICU admission, or other adverse pregnancy/birth outcomes.
- It is recommended that individuals consult their primary health care provider or obstetrician for any vaccine related questions or concerns.
- However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine.
- Those requesting Novavax must acknowledge the absence of evidence on the use of a Novavax COVID-19 vaccine in this population and the preference for an mRNA vaccine due to published effectiveness and safety data.

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.
  - Ensure appropriate documentation.

COVID-19 Vaccine & Other Vaccine Products

- COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines), tuberculin skin tests or IGRA (QFT) tests to individuals 6 months of age and older.
  - 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.
  - In the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test.
  - However, repeat tuberculin skin testing or IGRA (at least 4 weeks post COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered to avoid missing persons with TB infection.

COVID-19 Vaccine & Other Vaccine Products

- 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.

COVID-19 Vaccine & Other Vaccine Products

- Individuals who are to receive Evusheld (tixagevimab and cilgavimab) as pre-exposure prophylaxis should wait at least 2 weeks following COVID-19 immunization to minimize interference.

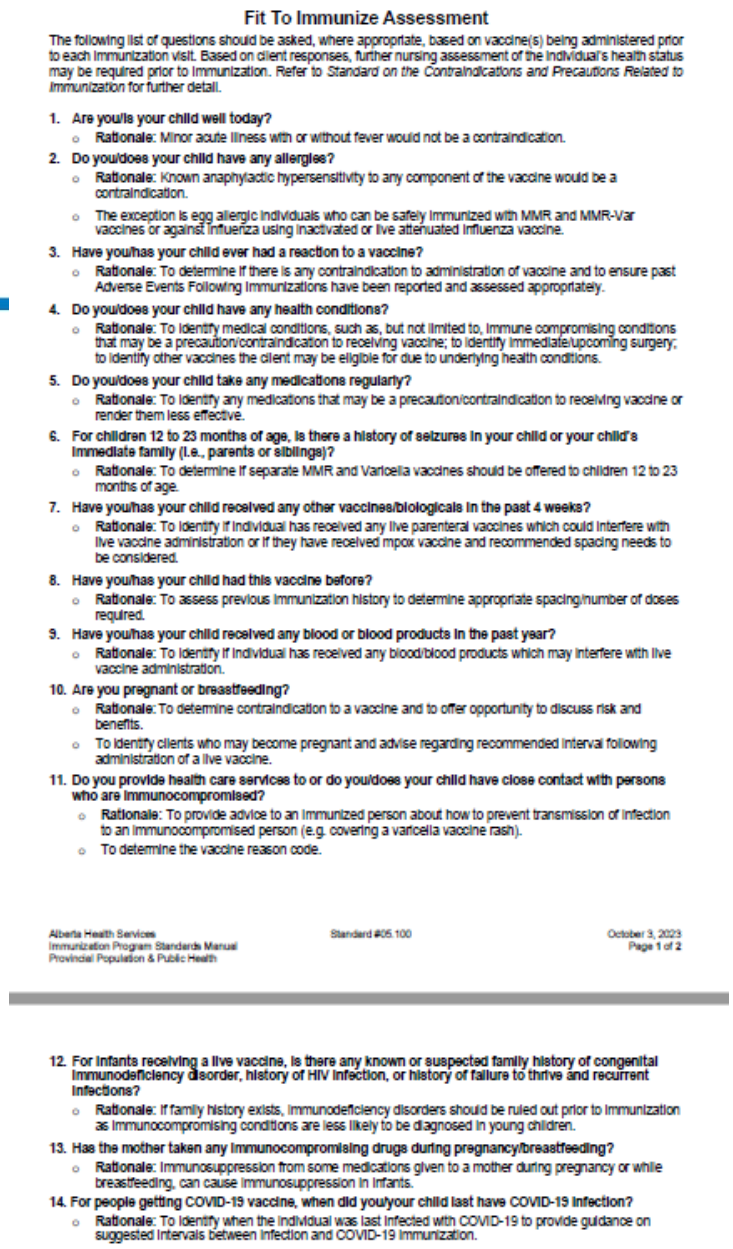
Note:

- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis 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 has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.

Fit to Immunize Assessment

The immunizer will:

- Assess the need for immunization.
- Confirm the client has not received a dose of COVID-19 vaccine previously, or if they have, determine which vaccine was given.
- If client is presenting for second dose ensure proper vaccine product is used and meets recommended spacing between doses.
- Complete a “Fit To Immunize” assessment for COVID-19 vaccine:
  - health status today
  - history of allergies
  - previous reactions (check if previously reported adverse event)
  - chronic health condition/medications
  - autoimmune condition/immunocompromised
  - pregnancy/breastfeeding



Fit To Immunize Assessment

The following list of questions should be asked, where appropriate, based on vaccine(s) being administered prior to each immunization visit. Based on client responses, further nursing assessment of the individual's health status may be required prior to immunization. *Refer to Standard on the Contraindications and Precautions Related to Immunization for further detail.*

1. **Are you/is your child well today?**
   - **Rationale:** Minor acute illness with or without fever would not be a contraindication.
2. **Do you/does your child have any allergies?**
   - **Rationale:** Known anaphylactic hypersensitivity to any component of the vaccine would be a contraindication.
   - The exception is egg allergic individuals who can be safely immunized with MMR and MMR-Var vaccines or against influenza using inactivated or live attenuated influenza vaccine.
3. **Have you/has your child ever had a reaction to a vaccine?**
   - **Rationale:** To determine if there is any contraindication to administration of vaccine and to ensure past Adverse Events Following Immunizations have been reported and assessed appropriately.
4. **Do you/does your child have any health conditions?**
   - **Rationale:** To identify medical conditions, such as, but not limited to, immune compromising conditions that may be a precaution/contraindication to receiving vaccine; to identify immediate/upcoming surgery; to identify other vaccines the client may be eligible for due to underlying health conditions.
5. **Do you/does your child take any medications regularly?**
   - **Rationale:** To identify any medications that may be a precaution/contraindication to receiving vaccine or render them less effective.
6. **For children 12 to 23 months of age, is there a history of seizures in your child or your child's immediate family (i.e., parents or siblings)?**
   - **Rationale:** To determine if separate MMR and Varicella vaccines should be offered to children 12 to 23 months of age.
7. **Have you/has your child received any other vaccines/biologicals in the past 4 weeks?**
   - **Rationale:** To identify if individual has received any live parenteral vaccines which could interfere with live vaccine administration or if they have received mpox vaccine and recommended spacing needs to be considered.
8. **Have you/has your child had this vaccine before?**
   - **Rationale:** To assess previous immunization history to determine appropriate spacing/number of doses required.
9. **Have you/has your child received any blood or blood products in the past year?**
   - **Rationale:** To identify if individual has received any blood/blood products which may interfere with live vaccine administration.
10. **Are you pregnant or breastfeeding?**
    - **Rationale:** To determine contraindication to a vaccine and to offer opportunity to discuss risk and benefits.
    - To identify clients who may become pregnant and advise regarding recommended interval following administration of a live vaccine.
11. **Do you provide health care services to or do you/does your child have close contact with persons who are immunocompromised?**
    - **Rationale:** To provide advice to an immunized person about how to prevent transmission of infection to an immunocompromised person (e.g. covering a varicella vaccine rash).
    - To determine the vaccine reason code.

Alberta Health Services
Immunization Program Standards Manual
Provincial Population & Public Health

Standard #05.100

October 3, 2023
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12. **For infants receiving a live vaccine, is there any known or suspected family history of congenital immunodeficiency disorder, history of HIV infection, or history of failure to thrive and recurrent infections?**
    - **Rationale:** If family history exists, immunodeficiency disorders should be ruled out prior to immunization as immunocompromising conditions are less likely to be diagnosed in young children.
13. **Has the mother taken any immunocompromising drugs during pregnancy/breastfeeding?**
    - **Rationale:** Immunosuppression from some medications given to a mother during pregnancy or while breastfeeding, can cause immunosuppression in infants.
14. **For people getting COVID-19 vaccine, when did you/your child last have COVID-19 infection?**
    - **Rationale:** To identify when the individual was last infected with COVID-19 to provide guidance on suggested intervals between infection and COVID-19 immunization.

Informed Consent

- Clients must give informed consent before immunization
- Prior to immunizing the immunizer must:
  - Determine that the client is eligible (based on current phase and/or eligibility requirements)
  - Review the disease being prevented
  - Review vaccine
  - Discuss:
    - risks and benefits of getting the vaccine and not getting the vaccine
    - side effects and after care
    - how the vaccine is given
  - Provide the opportunity to ask questions
  - Affirm verbal consent

COVID-19 Vaccine Administration

7 Rights of Immunization, ensure that you have:

- ✓ Right product (vaccine)
- ✓ Right client
- ✓ Right dose
- ✓ Right time (date/time, interval between doses, usage expiry of vial)
- ✓ Right route, needle length, site/land marking and technique
- ✓ Right reason (meets eligibility criteria)
- ✓ Right documentation (including reason code)

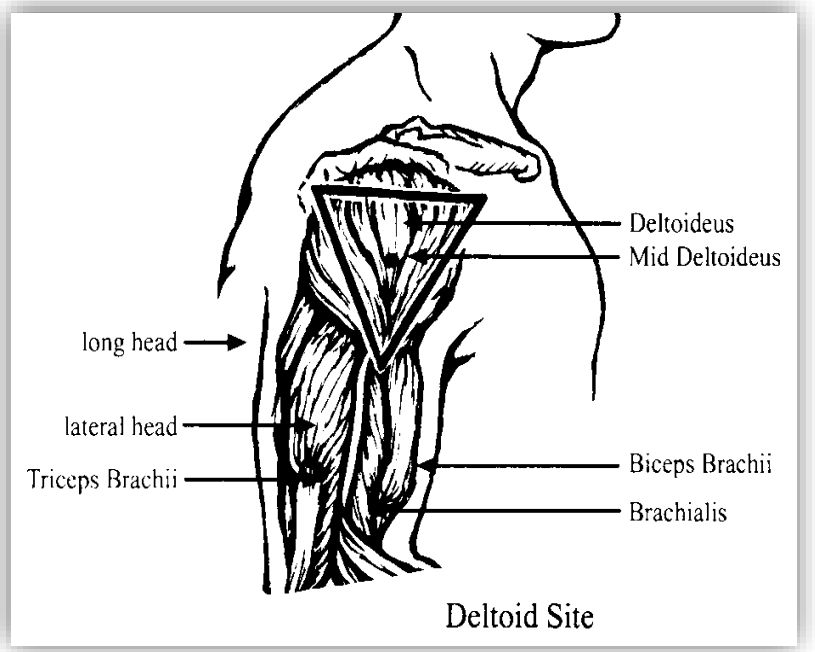
COVID-19 Vaccine Administration

- Expose and position the client's limb for injection.
- Cleanse the injection site with a single-use antiseptic swab.
- Allow the site to dry.
- Secure the injection site using the appropriate stabilization technique.
- Insert the needle at a 90º angle.
- Administer the vaccine with controlled pressure.
- Activate the safety engineered device.
- Discard the needle and syringe, and empty vaccine vials into an appropriate sharps container.
- Use a cotton ball and apply pressure to the injection site.
- Reinforce the 15 min wait period with the client or parent/guardian.

Intramuscular Injections

Recommended Immunization Site:

- Mid portion of **deltoid**
- 1 mL or 3 mL syringe
- 25G - 1” to 1½” needle depending on muscle mass and adipose tissue
- Insert at 90 degree angle



Limb Integrity

- Do not administer an immunizing agent in a limb that is likely to be affected by a lymphatic system problem.

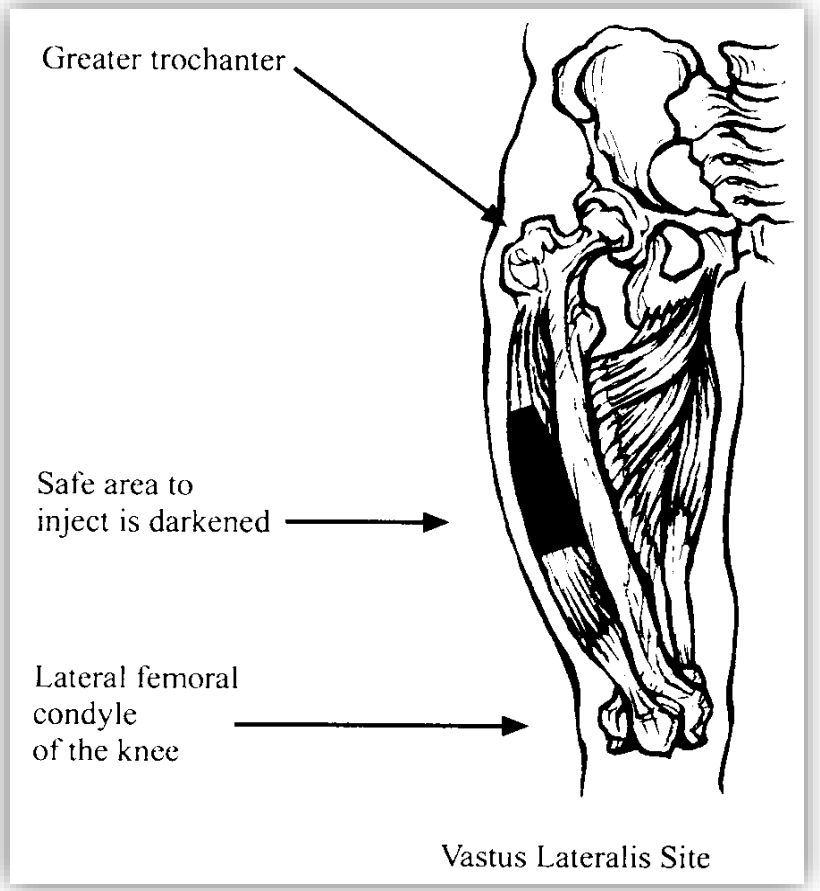
- Individuals who present with A-V fistula (vascular shunt for hemodialysis) and those who have had mastectomies with lymph node curettage, lymphedema, axilla lymphadenectomies, limb paralysis and upper limb amputations may have short term or long term circulatory (e.g., lymphatic systems) implications that may impair vaccine absorption and antibody production.

- **Vastus lateralis** is an alternative site.

Intramuscular Injections

Alternate site when deltoid is not suitable

- **Vastus lateralis** – middle third of anterior thigh and slightly lateral to the midline.
- 1 mL or 3 mL syringe
- 25G 1” to 1½” needle depending on muscle mass and adipose tissue.
- Insert at 90 degree angle.



Infection Prevention & Control (IPC)

- Infection Prevention and Control is dedicated to **preventing infections** acquired within healthcare facilities. **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
  - guideline, policy, and procedure development
  - research

- For more information go to the AHS Infection Prevention & Control
  - Personal Protective Equipment – Infection Prevention & Control
  - Hand Hygiene – Infection Prevention & Control

Commitment to Comfort

Needle Fears

- Up to 25% of adults have needle fears
- Up to 10% of those are significant enough to avoid immunizations
  - This translates to **350,000** Albertans

Solution: The AHS Commitment to Comfort (CTC)

- There is strong evidence that these principles improve immunization experience, health outcomes, satisfaction, and repeat attendance to healthcare encounters

Commitment to Comfort – 5 Core Principles

Make a Comfort Plan

- Establish client preference and offer choice

Use Positive Language

- *Always say:* "you did well", and leave them with a positive memory "by doing this today, you are saving lives"
- *Avoid:* pain descriptors; focus on what the client can do – to make the immunization feel better (see shift attention)

Use Comfort Positions

- When safe, sit client in an upright comfortable position
- Brief muscle tense and release or lie down if client feels faint

Shift Attention

- Shift client attention to a more pleasant activity or thought (e.g., smartphone game, music, small talk)

Use Numbing Cream

- Needs to be obtained and applied by the person being immunized prior to their appointment
- Numbing cream will not be offered at the immunization sites
- Client needs to talk with a pharmacist to select and obtain a product that is right for them

Anaphylaxis

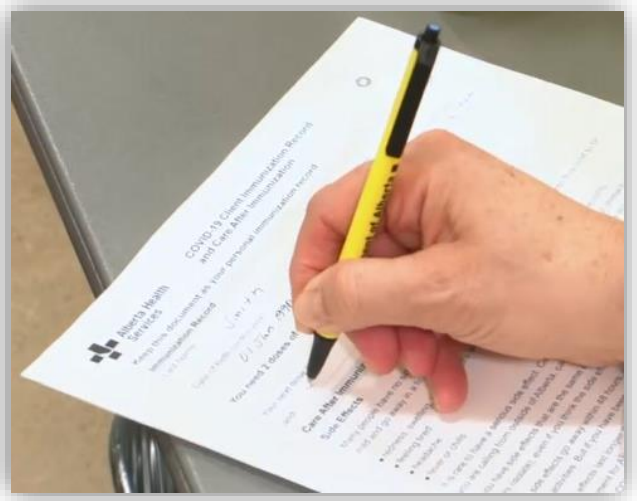
All clients are encouraged to wait for 15 minutes after immunization

- For clients with any known anaphylactic allergies, extend this recommended wait period to **30 minutes**.
- Have clients remain within the clinic area and return immediately for assessment if they feel unwell.
  - Alberta Health Services employees need to ensure they have completed the AHS Anaphylaxis Management >> Learning Module
  - Covenant Health employees need to ensure they have completed Covenant Health Anaphylaxis Learning Module found on CLiC.
  - Community providers should follow the anaphylaxis policies within their facilities.

COVID-19 Vaccine Recording

Information required to be recorded on all clients includes:

- Client demographic information
  - full name, personal health number, date of birth, gender, address including postal code
- Reason code for immunization
- Dose number
- Vaccine name & lot number
- Dosage administered
- Site of injection
- Route of administration
- Date of immunization
- Immunizer's first initial and last name, designation & signature



COVID-19 Vaccine Recording

- All Zone Public Health will be doing direct data entry into the Meditech system where possible. When Meditech is unavailable, a downtime work sheet will be available for documentation and should be entered into Meditech as soon as possible.
- The COVID-19 Client Immunization Record and Care After Immunization document is available for immunizers to provide to clients after immunization.
- Community Providers may use the COVID-19 Immunization Record or their own client record.
- Please follow your zone/site process for client specific reporting of administration of COVID-19 vaccine to Alberta Health.

Return Visit – Next Dose

- Note the date to return on the client's *COVID-19 Immunization Record* for next dose, if applicable and provide the form to the client.
  - Check site process regarding how to book for next dose.
- Refer to current COVID-19 vaccine biological pages for spacing recommendations.

Reason Codes

When completing documentation include the immunization “reason code”:

✓Start at the top of the priority list

✓Choose the first code that applies

Care After Immunization

- To be provided to every client receiving vaccine.
- Outlines expected side effects and aftercare for same.
- Please ensure you are providing the appropriate care after immunization record.
- Will also serve as client's record of immunization.

Adverse Events Following Immunization Reporting

- 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.

Adverse Events Following Immunization 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 → Search "AEFI" in the search box

- 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.

Questions?

- Clinical immunization questions should first be directed to your site lead. You may be asked to contact CDCIMM@ahs.ca

- Process and operational questions should be directed to your Site Lead

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