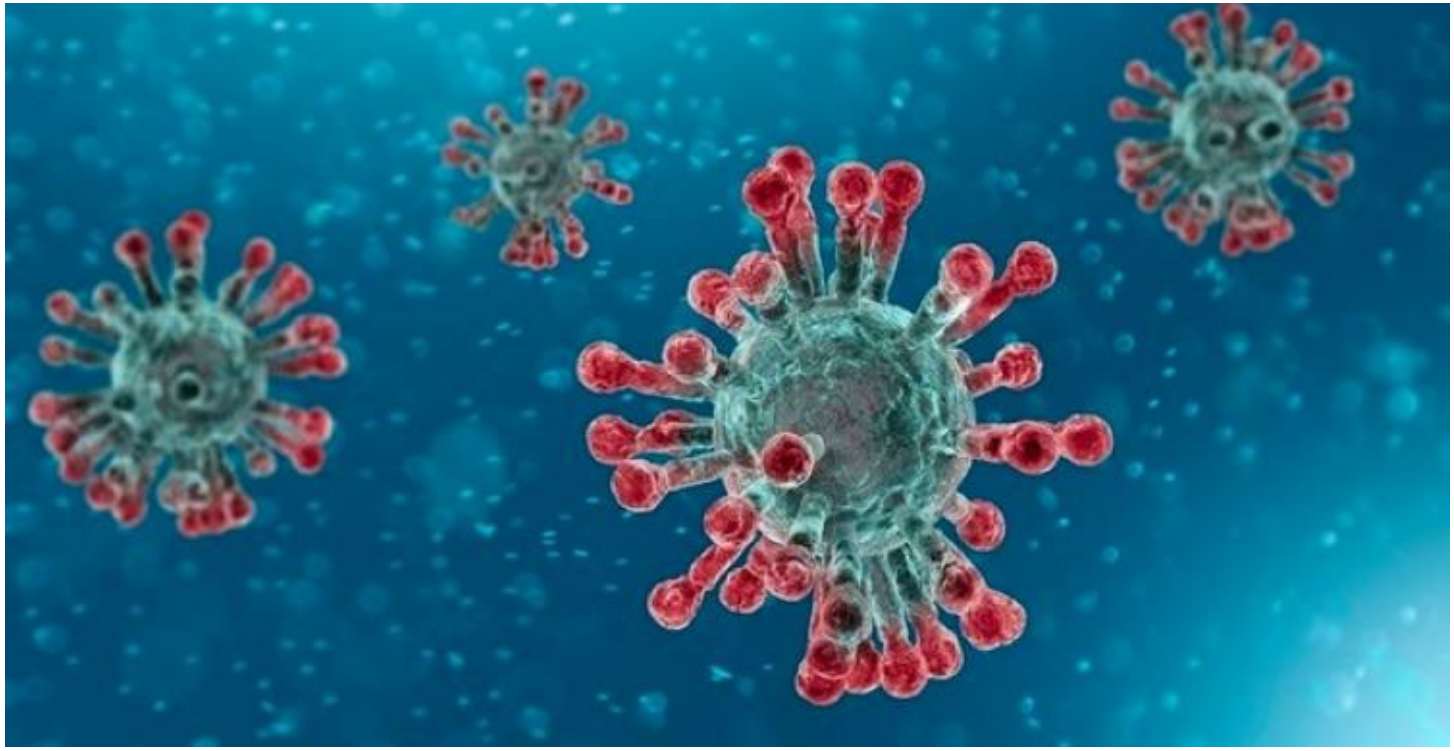
Alberta Health Services

COVID-19 Moderna (Spikevax) 6 to 11 Years Formulation Immunization Orientation



Presented by
Provincial Population & Public Health
Provincial CDC Immunization Team
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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)

Introduction

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 Product Monographs
- AHS Vaccine Storage and Handling Standard and e-learning modules*
- Alberta Health Adverse Events Following Immunization (AEFI) Policy
- Site specific reporting requirements and data collection guidelines

Refer to COVID-19 Vaccine Orientation to review:

- What is COVID-19
- Fit to Immunize Assessment
- Infection Prevention and Control
- Commitment to Comfort Principles
- Anaphylaxis
- Vaccine Recording
- Adverse Events Following Immunization Reporting
- Vaccine Administration
- Immunocompromised and Auto-Immune Disorders
- Tuberculin Skin Testing and COVID-19 vaccines
- Vaccine Storage and Handling Principles
- General Pregnancy Information
- General Breastfeeding Information

COVID-19 Vaccines Available in Alberta

- **Recombinant Protein Subunit**
  - Novavax (Nuvaxovid)
- **Viral Vector-based**
  - AstraZeneca/COVISHIELD
  - Janssen (Johnson & Johnson)
- **mRNA**
  - Pfizer Ultra Frozen Vaccine
  - Moderna Frozen Vaccine

What are mRNA COVID-19 Vaccines?

- **Pfizer** and **Moderna** COVID-19 vaccines 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.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine Effectiveness

There is no specific data at this time for the 6-11 year old 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 Omicron:

Infection:

- 48% effective at protecting against infection at least 2 weeks after the 2nd dose
- 72% effective at protecting against infection at least 2 weeks after the 3rd dose

Hospitalization:

- 85% effective at preventing hospitalization at least 2 weeks after the 2nd dose
- 99%effective at preventing hospitalization at least 2 weeks after the 3rd dose

Moderna 6 to 11 Years of Age Formulation mRNA COVID-19 Vaccine Summary

	Moderna 6 to 11 Years of Age Formulation COVID-19 Ultra Frozen
Dosage/Route	0.25 mL / IM into the deltoid muscle (deltoid or vastus lateralis)
Packaging	Multi-dose: 5 mL vial - 20 doses per vial
Eligibility	As per indication
Indication	Albertans 6 years up to and including 11 years of age
Ingredients	• mRNA (new technology) – nucleoside-modified mRNA (modRNA) platform • formulated in lipid nanoparticles (LNPs) • no adjuvants or preservatives
Schedule	**2 doses** • Optimal spacing between dose 1 and dose 2 is at least 8 weeks • A shortened interval between dose 1 and dose 2 of 21 days as per product monograph may be considered in certain situations: required for travel or increased risk due to immunocompromising conditions. • Minimum interval: 21 days required to consider dose valid • Third dose indicated for specific eligible groups (see Scheduling Slides for more information)

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine Indications

- Vaccine formulation to administer is based on age at presentation, regardless of vaccine/formulation received for first dose.

- Children who received a first dose of the adult formulation of Pfizer or Moderna COVID-19 vaccine at age 11 years will complete their second dose with the pediatric Pfizer formulation if still 11 years of age when presenting for second dose.

- Children who received their first dose of pediatric Pfizer vaccine at 11 years of age and are now 12 years of age when presenting for second dose, will receive the adult formulation of Pfizer for their second dose.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine Schedule

Optimal spacing between dose 1 and dose 2 is at least 8 weeks.

- Currently, there is no direct evidence to establish an optimal interval between doses in 6-11 Years populations. However, evidence on COVID-19 mRNA vaccines in adolescents and adults shows that a longer interval between the first and second dose leads to even higher immune responses and better protection against COVID-19 infection that is also expected to last longer.
- Emerging Canadian safety surveillance data suggest a longer dose interval may reduce the risk of myocarditis/pericarditis following the second dose of an mRNA COVID-19 vaccine.

Notes:

- A shortened interval between dose 1 and dose 2 (no less than 21 days) as per product monograph may be considered in certain situations: Individuals with certain immunocompromising conditions who are likely to have less robust immune responses after one dose, individuals at increased risk for infection based on local transmission and the degree of individual risk of exposure, or required for travel.

Schedule for Individuals with Certain Immunocompromising Conditions

Primary series 3 doses

- Dose 1: day 0
- Dose 2: 28 days after dose 1
- Dose 3: 8 weeks after dose 2
- It is recommended that individuals with certain immunocompromising conditions be immunized with a primary series of three doses of an mRNA COVID-19 vaccine
- It is recommended that the interval between dose 1 and dose 2 be 28 days and the interval between dose 2 and dose 3 be 8 weeks
    - The interval between dose 2 and dose 3 is recommended to be 8 weeks because emerging evidence from the general population indicates that a longer interval will likely result in a better immune response and duration of protection

Schedule for Individuals with Certain Immunocompromising Conditions cont'd

- However, there is heterogeneity among those who are moderately to severely immunocompromised, and risks from COVID-19, as well as the likelihood of a reduced response to vaccines, will vary depending on the immunocompromising condition. Thus, 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.
- There are currently no data on the safety, immunogenicity, or efficacy of an additional dose of a COVID-19 vaccine in children who are immunocompromised, studies have shown that a third dose of an mRNA vaccine leads to increased immune response in some adults who are immunocompromised. An additional dose provides another opportunity for those who are immunocompromised to develop a better immune response and in turn better protection against COVID-19.

Schedule for Individuals with Certain Immunocompromising Conditions cont'd

- Specific Immunocompromising conditions that make an individual eligible for a third dose:
  - solid organ transplant recipients – pre-transplant and post-transplant
  - hematopoietic stem cell transplants recipients – pre-transplant and post-transplant while in immunosuppressed state (post-HSCT individuals are generally considered to be immunocompetent after 3 years as long as they are not on immunosuppressive drugs)
  - 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)

Schedule for Individuals with Certain Immunocompromising Conditions cont'd

- individuals on anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab)
- individuals with chronic kidney disease on peritoneal dialysis or hemodialysis
- Individuals receiving chimeric antigen receptor (CAR)-T-cell therapy

Schedule for Individuals with Certain Immunocompromising Conditions cont'd

- Individuals on:
  - long term high-dose systemic steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), or
  - alkylating agents, 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

Schedule for Individuals with Certain Immunocompromising Conditions cont'd

  - Individuals with acquired immunodeficiency syndrome (AIDS)
  - Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- 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 based on the individual's treatment.
- Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible for two doses of COVID-19 vaccine beginning 6 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.

Moderna 6-11 Years Formulation mRNA Vaccine Reactions

Common	Rare
• Pain, redness or swelling at injection site • Chills, fever • Fatigue • Headache, myalgia, arthralgia • Nausea, vomiting • Lymphadenopathy • Hypoaethesia (decreased sense of touch or sensation, numbness) • Dizziness • swelling or feeling sore in your armpit or groin	• Facial swelling/Bell's Palsy • Anaphylaxis • Myocarditis/Pericarditis

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

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine Storage

Moderna mRNA Vaccine	Storage temperatures and time limits
Primary storage: Freezer	-25°C to -15°C until expiry date
Storage: Thawed, Unpunctured	+2°C to +8°C for up to 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 -40°C
DO NOT SHAKE
PROTECT FROM LIGHT

Moderna 6 to 11 Years of Age Formulation mRNA 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 20 doses can be withdrawn from a vial of any combination of doses, once 20 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

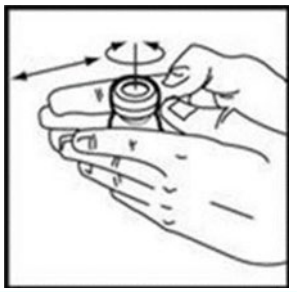
Moderna 6 to 11 Years of Age Formulation mRNA Vaccine - Preparation

- 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 1 hour from frozen state.
  - From the freezer to a vaccine fridge at +2°C to +8°C
    - thaw for 2 hours and 30 minutes from frozen state.
    - let the vial stand at room temperature for 15 minutes before administering.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine - 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**



Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Contraindications

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

- **Have had an anaphylactic reaction to a previous dose of mRNA COVID-19 vaccine*** See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.
- Less than 6 years of age or 12 years of age or older
- Have a known **type 1 hypersensitivity** to any component of the vaccine:
  - Polyethylene glycol (PEG). This potential allergen may be found in bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens solutions, products such as ultrasound gel, laxatives, cough syrup, and some food and drinks.
  - Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications

Moderna 6 to 11 Years of Age Formulation mRNA 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 – mRNA vaccines**: 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.
- Immunization of children with a previous history of Multisystem Inflammatory Syndrome (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.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Myocarditis

- The clinical trials for children 6 to 11 years of age did not identify any cases of myocarditis following immunization; however, uncommon, rare, or very rare adverse events that occurs at the frequency less often than 1 in 1,000 would not be detected with that trial size.

- More information will assist in further assessment of the risk of myocarditis/pericarditis among individuals aged 6 to 11 years of age after receiving Moderna vaccine. At this time, the risk of myocarditis/pericarditis after the second dose when using an extended interval of at least 8 weeks among children ages 6 to 11 years of age and the safety of a third dose of COVID-19 vaccine in individuals aged 6 to 11 years of age are unknown.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Myocarditis

- Available information indicates that cases of myocarditis and pericarditis:
  - occur more commonly after the second dose,
  - more often in adolescent and young adults (12 to 29 years of age),
  - more often in males, and
  - more frequently following Moderna COVID-19 vaccine than Pfizer-BioNTech COVID-19 vaccine.

- Typically onset of symptoms begins within a week after the receipt of an mRNA COVID-19 vaccine. The majority of cases are mild and individuals tend to recover quickly and investigation into long-term outcomes is ongoing.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Myocarditis

- 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 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.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Myocarditis

- In general, individuals who experienced myocarditis 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 they prefer not to wait, they should discuss decisions around the second dose with their clinician.
- 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.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Other Considerations

- Individuals with a history of confirmed COVID-19 infection who have no contraindications can be immunized with COVID-19 vaccine 8 weeks after symptom onset or positive test (if asymptomatic).
- See CMOH Order 02-2022 for definition of confirmed COVID-19 infection.
- Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
- Immunization of individuals who may be currently infected with COVID-19 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.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Other Considerations

- It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in 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.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Other Considerations

- For individuals with a history of confirmed COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.

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.
Infection after primary series	Individuals not eligible for booster doses	

Immunocompromised & Auto-Immune Disorders

- At this time, there is very limited data on the use of Moderna COVID-19 mRNA vaccine 50mcg (6 to 11 years of age) formulation in immunocompromised individuals 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 & Auto-Immune Disorders

- 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.
  - 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.

Immunocompromised & Auto-Immune Disorders

- 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.
  - 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.
  - However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.

    - Response for immunizers if individual has not consulted with their primary health care provider: "Vaccine studies are not complete on the use of this vaccine in immunocompromised individuals or those with auto-immune disorders. We recommend you speak to your physician regarding the timing of immunization based on your treatment or if you have questions about the immunization, but it is not required to receive the vaccine."

Immunocompromised & Auto-Immune Disorders

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

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Other Vaccine Products

- COVID-19 vaccines should not routinely be administered on the same day with other live or inactivated vaccines to children 6 to 11 years of age due to the need to be able to monitor for adverse events following COVID-19 immunization.

- In the absence of evidence, it is 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.

Moderna 6 to 11 Years of Age Formulation mRNA Vaccine – Other Vaccine Products

- 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.
  - Routine school immunizations can be administered regardless of spacing from COVID-19 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.

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

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

References

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11. National Advisory Committee on Immunization. (2022 January 14). Re-vaccination with COVID-19 vaccines following myocarditis and/or pericarditis. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/summary-advice-vaccination-covid-19-vaccines-following-myocarditis-with-without-pericarditis.html