

# COVID-19 VACCINES AND IMMUNIZATION

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PART 3 – CLINIC ORIENTATION  
JANUARY 2022

# OBJECTIVES

- COVID-19 Vaccines
  - Overview
  - mRNA vaccines and viral vector vaccines
  - Safety and efficacy
  - Recommendations for a complete series and booster doses
  - Medical directives
- COVID-19 vaccine clinic operations
  - Roles and responsibilities
  - Clinic flow
  - Routines and expectations
  - Documentation
- Immunization process
- Strategies to reduce risk of medication error

# COVID-19 VACCINES

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## Development and Approval of Vaccines

The safety and efficacy of COVID-19 vaccines are reviewed by Health Canada.

In December 2020, Health Canada authorized the first two vaccines for use in Canada for the prevention of COVID-19; Pfizer BioNTech and Moderna mRNA COVID-19 vaccines. In the fall of 2021, a pediatric formulation of the Pfizer vaccine was also authorized and is currently approved for use in those ages 5yrs-11yrs.

Approved COVID-19 vaccines completed the same [development and approval process](#) as all other vaccines approved for use in Canada. Two things happened a little differently with the COVID-19 vaccines:

- Different phases of vaccine development were occurring simultaneously, instead of waiting for one step to be done at a time (shaving off years to the usual process!).
- Health Canada fast-tracked the approval process by reviewing data as it became available throughout the development phase (instead of the usual process of reviewing all of that data once the clinical trials were completed).



# WHAT IS AN mRNA VACCINE?

- Messenger RNA are strands of genetic material that direct protein production in cells.
- Scientists have developed mRNA that directs cells to produce proteins that imitate those found in SARS-CoV-2.
- When the mRNA vaccine is injected into the body, the cells use it to make viral proteins (antigens).
- The viral proteins trigger immune cells which lead to the production of antibodies.
- In the past, mRNA technology has been focused on cancer, with tumour mRNA being used to help people's immune systems recognize and respond to the proteins produced by their specific tumours.
- mRNA vaccines are a promising alternative to conventional vaccine approaches because of high potency and the capacity for rapid and safe administration.
- mRNA vaccines to date, come with logistical challenges for delivery due to vaccine storage and handling requirements needed to keep the vaccine stable.

# MRNA VACCINES (CONT'D)

- mRNA vaccines (Pfizer Biontech and Moderna) do **not** contain:
  - Adjuvants
  - Antibiotics
  - Products of human or animal origin
  - Preservatives
  - Latex
- mRNA vaccines are considered interchangeable and can generally be safely administered to adults ages 30 yrs and over who have previously received either product as per National Advisory Committee on Immunization (NACI) guidelines, assuming there are no known contraindications for the client
- Clients ages 12-29 are recommended to receive the 12+/adult version of Pfizer vaccine
- Clients ages 5-11 years receive the pediatric formulation of the Pfizer vaccine

# VIRAL VECTOR VACCINES

- There are currently 2 viral vector vaccines approved by Health Canada and being administered in Ontario
  - Astra Zeneca
  - Janssen / Johnson&Johnson
- Viral vector vaccines use a different technology and have a slightly lower rate of protection and efficacy against the COVID-19 virus than mRNA vaccines
- Viral vector vaccines are currently not available in SMDHU community clinics, and are only available by individual request, at special public health unit led clinics

# VACCINE SAFETY: mRNA vaccines

<b>Very common adverse events</b> (occur in 10% or more of vaccinees)	<b>Pain at the injection site – more than 80% experienced this, and more frequent in those less than 56 years</b> <b>Fatigue, headache, muscle pain, chills, joint pain and fever</b> <ul style="list-style-type: none"><li>– more than ½ experienced headache and/or fatigue</li><li>– more frequent after the 2<sup>nd</sup> dose and in those less than 56 years</li></ul>
<b>Common adverse events</b> (occur in 1% to less than 10% of vaccinees)	Redness and swelling at injection site
<b>Uncommon adverse event</b> (occur in 0.1% to less than 1% of vaccinees)	Lymphadenopathy



# VACCINE SAFETY & EFFICACY

- The probability of detecting a rare or very rare (occurring in less than 0.1% of clients) adverse event in clinical trials is low given clinical trial population sizes. Therefore ongoing vaccine safety monitoring is critical, as it is with all vaccines, as the vaccine is used in larger numbers of people to be on alert for any safety signals.
- *Currently* there is no evidence available to support the efficacy of this vaccine in preventing asymptomatic infection, reducing viral shedding or in prevention of transmission of the COVID-19 virus. Therefore it is important that people continue to practice public health measures to decreased transmission even after they are vaccinated.
- Protection offered from the first dose is lower than the efficacy achieved after the second dose. In most people, a cellular immune response is achieved by one week after the second dose. As new variants emerge, protection may vary.

# COMPLETE SERIES AND BOOSTER DOSES

- It is recommended that clients receive at minimum a 2-dose series of an mRNA vaccine, or 2 doses of Astra Zeneca (or one dose AZ + one dose mRNA) or one dose of Janssen vaccine in order to be considered “fully vaccinated” in Canada
- Booster doses to protect against waning immunity are now also highly recommended and being prioritized for many populations including:
  - Those 18 years of age or older.
  - Residents of long-term care homes, retirement homes and First Nation elder lodges, and seniors living in other congregate settings.
  - Health care workers and designated essential caregivers in congregate settings (including long-term care home and retirement home staff and designated caregivers).
  - Pregnant women
  - Educators and childcare workers
  - Individuals who received two doses of the AstraZeneca vaccine or one dose of the Janssen vaccine.
  - First Nation, Inuit and Métis adults and their non-Indigenous household members who are 16 years of age or older.
- Moderately / severely immunocompromised clients are advised to have a 3 dose primary series and are now eligible for a 4<sup>th</sup> dose booster 84 days following completion of their series



# REVIEW OF MEDICAL DIRECTIVES AND RESOURCES VACCINE ADMINISTRATION

- **Please review the following:** You will be required to attest that you have reviewed these directives and resources prior to your first shift in the clinic
- **Pfizer BioNTech COVID-19**
  - Simcoe Muskoka District Health Unit - [Pfizer-BioNTECH COVID-19 Immunization Directive](#)
  - [Pfizer-BioNtech COVID-19 Vaccine Product Monograph](#)
- **Pediatric Pfizer BioNTech COVID-19 - Pediatric**
  - Simcoe Muskoka District Health Unit - [Pediatric Pfizer-BioNTech COVID-19 Immunization Directive](#)
  - Pfizer –Pediatric BioNtech Product Monograph <https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf>
  - [Pediatric Directive Training Powerpoint](#)
- **Moderna COVID-19**
  - Simcoe Muskoka District Health Unit - [Moderna COVID-19 Immunization Directive](#)
  - [Moderna COVID-19 Vaccine Product Monograph](#)
- [NACI Recommendations on the use of COVID-19 vaccine\(s\)](#)

# CLINIC OPERATIONS

# ROLES & RESPONSIBILITIES AT THE CLINIC

- **Security guard** screens all visitors on entry to the building, sits at the entrance.
- **Clinic support** check clients in for appointments and manage clinic inventory
- **Immunizers** responsible for assessment, health teaching, implementation (Immunizes clients as per medical directive and guidance documents), assists with aftercare as needed
- **After Care Staff** remind clients to check if they have received confirmation email re: dose administered, observe for client well being after immunization, move clients to first aid room if needed
- **Vaccine Prep** reconstitute and pre-load syringes for immunizers, maintain count of vaccines drawn throughout the day
- **Clinic Coordinators** lead the clinic operation, provide direction on how the clinic will be set up and will run, assist immunizers, answer questions, consult re: concerns, balance vaccine inventory
- **Clinic Manager** 1 per clinic site to address issues/concerns, consults with AMOH/MOH as needed – may be on site or offer remote support
- **Volunteers** multiple roles, help with line management, direct clients to immunizers, and support clinic flow and help monitor aftercare



# CLINIC FLOW

- Client presents to the clinic as a booked appointment or as a walk-in client
- Screened for COVID-19 symptoms and exposures
- Eligibility for dose verified and signed in
- Attends immunization station for further assessment, health teaching, immunization
- Waits in aftercare area post-immunization and is monitored
- Leaves clinic once well and has waited for designated time

# CLINIC ROUTINES & EXPECTATIONS

- Shift starts 30 mins prior to clinic opening to the public - allows time for set-up, cleaning and daily huddle
- All staff attend the huddle: Coordinators will review any clinic updates, key messages for any specific needs that day or going forward, provide break times for all staff, etc
- Immunizers are responsible for cleaning and setting up their stations: Re-stock and wipe down your station as needed throughout shift and at end of clinic.
- Throughout the day note any supplies that are low in the clinic to the Coordinator or Clinic Support staff so they can be ordered and replaced
- Sharps containers must be closed and properly stored at end of each shift
- Team work is key! All hands on deck, if a colleagues requires assistance with a client, please support them when possible. If you identify a H&S concern, bring to coordinators attention ASAP or if it is immediate deal with it right away ie wet floor – wipe up to prevent fall.



# CLINIC ROUTINES & EXPECTATIONS

- Vaccine inventory is monitored by the clinic coordinators – there are 3 to 4 kinds / doses of vaccine pre-drawn up in the clinic - coordinators will advise what vaccine you can have at your station and how to make additional requests throughout the day as needed
- Vaccine usage may be tracked by all immunizers at their stations and is reported to coordinators to help balance clinic inventory prior to end of each shift
- Currently in our community clinics we administer:
  - Pfizer BioNTECH 0.3mL (ages 12+ and specifically 12-29 years)
  - Pfizer Pediatric 0.2mL (ages 5-11 yrs)
  - Moderna 0.25 – booster dose for those ages 30-69
  - Moderna 0.5 – booster dose for those ages 70+ and some other priority populations



# DOCUMENTATION – COVAX

- You will receive an activation email from Salesforce to support your login to CovaxON our documentation and client management system for COVID-19 immunization – it is important to respond and activate your login within 24 hours of receipt of the email
- You will need to add the Salesforce Authenticator app to your phone – [COVaxon - How to Set Up the Salesforce Authenticator App.pdf](#)
- Demonstration of how to use the system will be provided during the virtual session you have been asked to attend
- You will have an opportunity to shadow a clinic nurse (observe) during your first shift to consolidate your learning re: immunization assessment, technique, and documentation

# AFTER CARE

- Ensure all vaccine recipients are observed following immunization. This is the most common time for a severe allergic response to take place.
  - Dose 1 or 2 – 15 mins
  - Booster dose – 5 mins so long as no adverse reactions to dose 1 or 2 and no hx significant allergies / anaphylaxis
  - Clients who have significant allergies / hx anaphylaxis are to be monitored in aftercare for 30 minutes
- All clients should receive an aftercare sheet from their immunizer that outlines what to expect, common side effects and when to seek medical attention
- NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.
  - Analgesics and antipyretics were used in clinical trials of COVID-19 vaccine for the management of pain and/or fever after vaccination. There is currently no evidence on the benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.

# EMERGENCY RESPONSE: ANAPHYLAXIS

- In the event of a serious allergic response that leads to an anaphylactic reaction, the immunizer, coordinator and other clinic staff will work together to respond immediately to support the client, engage EMS, administer epinephrine, monitor vital signs, and reduce the risk of progression of the response
- Anaphylaxis is a life-threatening condition

**Please review the following: you will be required to attest that you have reviewed this directive prior to your first shift at the clinic**

- [Anaphylaxis Management and Administration of Epinephrine Directive](#)

# Additional Vaccine Information for Review

- [Pfizer-BioNTech COVID-19 Vaccine Information Sheet](#)

# IMMUNIZATIONS



# SETTING UP FOR IMMUNIZATION

- Clean and disinfect all station surfaces prior to setting up.
- Consider ease of use / ergonomics, safety and client confidentiality when setting up
- No food or drink is allowed in the clinical area – water bottles and food can be left in the staff break area
- Gather supplies as needed (see next slide)
- Ensure point of care sharps container is placed for safe access and not on floor
- Make sure you have easy access to a garbage container or bag

# SETTING UP FOR IMMUNIZATION : YOUR WORKSTATION

- iPad/Laptop
- Medical directives and quick-reference guides for practice
- Alcohol based hand rub
- Alcohol wipes to clean injection site
- Gloves (for use only as needed)
- Basket for pre-drawn syringes and paper drapes to cover them to protect from prolonged exposure to light
- Band-Aids
- Sharps container
- After Care / record sheets and pen
- Emesis bag
- Brown paper bag for garbage

# OBTAINING CONSENT

According to the Health Care Consent Act & CNO standards nurses are accountable for obtaining consent for all interventions they provide.

**A person is capable of giving consent if he or she:**

- Understands the information
- Appreciates the consequences of a decision or lack of decision

**There is no minimum age for consent**

[COVID-19 Vaccine Screening and Consent form](#)



# CONSENT TO TREATMENT

- The consent must relate to the treatment
- The client must have the capacity to consent
- The consent must be given voluntarily
- The consent must not be obtained through misrepresentation or fraud
- The consent must be informed

## WHAT IS INFORMED CONSENT?

The client must be provided with information about the treatment, that a reasonable person in the same situation would require to make a decision to consent or refuse.

### **This information must include:**

- The nature of the treatment
- Expected benefits
- Risks and side effects
- Alternative courses of action
- Likely consequences of not having the treatment

**You must answer requests for additional information**



# FOSTER CARE – CONSENT – FAMILY CONNEXIONS

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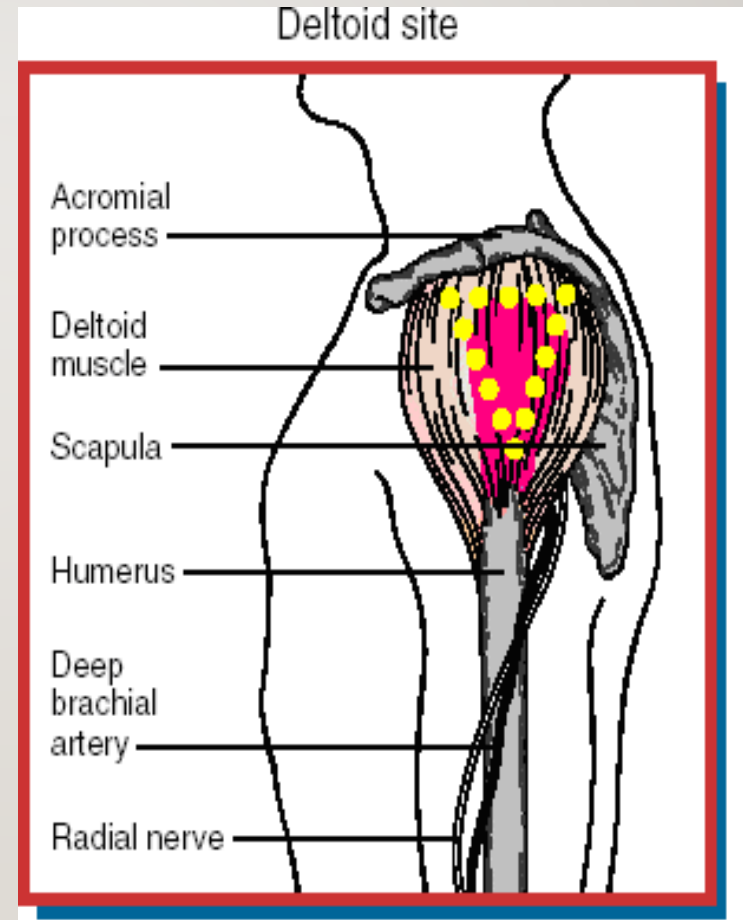
- There are a few steps to what is required including;
- Establishing/obtaining the child's consent-they will need to be informed with age appropriate tools/approaches
- Identifying and deciding on issues that may arise if the parents of children in temporary care are opposed to the decision to vaccinate the child.
- Distributing letters to caregivers/foster parents to bring to the clinics to verify guardianship and preparing foster parents with information they need related to the child health history or issues
- For Nov 8<sup>th</sup>, you could advise your staff of the process above that we are working through.
- The consent questions have been provided to Family connexions so Foster parent/Guardian can be prepared to answer all consent questions.

# ASSESSMENT AND PLANNING

- Assessment must confirm it is safe to proceed with immunization – follow questions in Covax
- Identify any risk factors for your client
- Familiarize yourself with the contraindications in the medical directives
- If uncertain, STOP and ask before proceeding

# IM LANDMARKING - DELTOID

- This diagram shows correct land marking for the deltoid site.
- Deltoid is the preferred site for all COVID-19 vaccines
- Injection should be given 3 finger widths below the acromial process



# INTRAMUSCULAR INJECTIONS

- Select the appropriate injection site
- Gently massage the site
- Cleanse the skin
- Use at least a 1” needle for I.M. injections
- Quickly and firmly insert the needle deep into the muscle at a 90° angle supporting the syringe and **rapidly** inject the vaccine into the muscle

## When Using Retractable Safety Needles

- Place the fleshy part of your thumb in the centre of the plunger
- You have to apply enough pressure to activate the device but the pressure should be on the flange and your fingers; not on the client
- Do not hesitate when you are coming to the end of the injection



# REDUCE THE PAIN

- Self-Distraction
- Positive Language
- Physical Comfort
- Deep Breathing
- Inject Vaccine Rapidly without aspiration

# STRATEGIES TO AVOID MEDICATION ERRORS

- Take your time
- Focus – Limit Distractions
- Follow the 8 Rights every time
  - the right client;
  - the right medication;
  - the right reason;
  - the right dose;
  - the right frequency;
  - the right route;
  - the right site;
  - the right time.
- Med Errors must be documented and reported to Manager as soon as possible, Manager will complete consultation as needed
- and determine appropriate follow up with client
- [LG0103 – Reporting of Medication Error & Near Miss Policy](#)
  - [LG0103\\_FI\\_Medication Error Form](#)

# Policy review

Please review all policies linked at this site:

[Policies for COVID-19 Clinic Orientation](#)