



COVID-19 Vaccines Vaccine Administration and Immunization Clinic Planning

Recorded on December 12, 2020



Objectives

Part 1:

To increase knowledge and comfort in handling and administering COVID-19 vaccines.

Part 2:

To increase preparedness for planning and running COVID-19 vaccine immunization clinics.

Declaration of Interests - Bryna Warshawsky

- I have no conflicts of interest to declare.

Presentation Recorded on December 12th 2020

Every attempt has been made to present the most current information however information about COVID-19 vaccines is rapidly evolving and the information presented here may be out of date.

Please check the Public Health Agency of Canada website for the most up to date information.

<https://www.canada.ca/en/public-health.html>

Outline

- **PART 1: Handling and administering COVID-19 vaccines in all settings**
 - Storage and handling
 - Considerations regarding the vaccine administration
 - Infection prevention and control
 - Post-immunization period
- **PART 2: Immunization clinic planning**
 - Planning parameters
 - Staffing
 - Training
 - Site selection, set up and flow
 - Clinic processes
 - Supplies, vaccines, document and forms
 - Data management
 - Medical emergencies
 - Communication
 - Evaluation

Challenges

- New vaccines with new technologies
- More complex storage and handling requirements for early vaccine candidates
- More than one product available at the same time
- Two doses required for most products
 - Second dose needs to be with the same product as the first at a specified interval
- Limited eligibility criteria initially and then large numbers of people to immunize
- Administering in the context of circulating COVID-19
 - Resource issues
 - Infection prevention and control issues

Part 1:

Handling and administering COVID-19 vaccines in all settings

Pfizer / BioNTech – Storage and handling

- **Storage:**
 - -80°C to -60°C for up to expiry date (6 months from manufacturing)
 - +2 to 8°C for up to 5 days. Do not refreeze.
 - Protection from light during storage by keeping vaccine in its original carton
 - The diluent can be stored at room temperature
- **When product received in thermal shipper**, within 24 hours will need to be inspected, data logger stopped, and then three choices:
 - 1) **Maintain in an ultra-low freezer** at -80°C to -60°C for up to expiry date; OR
 - 2) **Replenish the dry ice in the thermal shipper** - initially and then up to five additional times, 5 days apart for up to a total of 30 days. Will need to insert a new data logger to monitor the temperature; OR
 - 3) **Put in the refrigerator** at + 2 to 8°C for up to 5 days.
- Will need training and personal protective equipment to handle dry ice
- **Transport to another site – not currently permitted**
 - Additional information is expected

Subject to change

Pfizer / BioNTech - Thawing

- **Do not touch items from the freezer with bare hands**
- **Thaw at:**
 - **Room temperature** for 30 minutes
 - Can stay at room temperature for 2 hours before mixing with diluent
 - OR
 - **Refrigerator** for about 3 hours to thaw a tray
 - Can stay at refrigerator temperature +2-8°C for 5 days
 - Should come to room temperature before mixing with diluent
- Mark all the dates and times, so you know when can use the product until:
 - Use start times
 - Can also use end times, but indicate which time is which
- The thawed suspension may contain white to off-white amorphous particulates

Pfizer / BioNTech – Dilution (using diluent provided)

1. Allow to come to room temperature before mixing with diluent
 - Can stay at room temperature for 2 hours before mixing with diluent
2. Gently invert 10 times (**do not shake**)
3. Use alcohol-based hand rub to clean hands
4. Wipe the vial stoppers for the vaccine and diluent with alcohol swabs and allow to dry
5. Using aseptic technique and a 21 gauge or thinner needle, take 1.8 ml of 0.9% sodium chloride provided by the manufacturer (diluent) and inject it into the vaccine vial
6. With the needle still in the vial, withdraw 1.8 ml of air from the vaccine vial
7. Discard the needle and syringe in the sharps container
8. Discard the remaining diluent in the sharps container (use only once)
9. Gently invert 10 times (**do not shake**)
10. Check for particulates or discolouration (expect an off-white colour)
11. Mark the vial with the date and time of dilution
12. Use within 6 hour after dilution
 - Can be stored at room temperature during this time; avoid direct sunlight
 - Discard in sharps container if not used by 6 hours after dilution (try not to waste any)

Pfizer / BioNTech – Drawing up

Stable if pre-drawn for 6 hours

1. Use alcohol-based hand rub
2. Swab the vial stopper with the alcohol wipe and let dry
3. Using aseptic technique and a new needle and syringe, draw up 0.3 ml into a 1 ml Luer lock syringe (or 3 ml if 0.1 ml graduations)
4. Keep the needle in the vial if need to remove any air from the syringe
5. Repeat steps 2, 3, and 4 to get 5 doses per vial.

Pfizer / BioNTech – Administering the vaccine

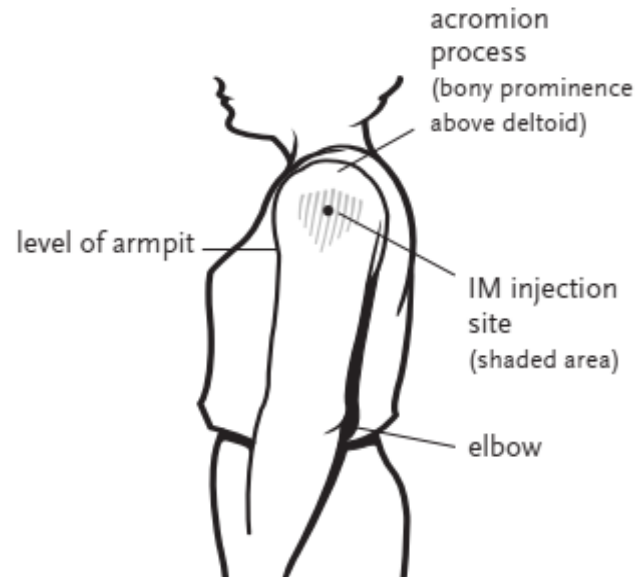
1. Use alcohol-based hand rub
2. Check syringe for particulates, discoloration (off-white color expected) and correct dose (0.3 ml); ensure it isn't cold
3. Prepare the skin with alcohol wipe from the centre moving outwards – allow to dry
4. Give 0.3 ml dose intramuscularly in the deltoid
5. Discard needle and syringe immediately (or after activating the safety engineered device) into the sharps container
 - Do not put used needle down on the workstation
6. Use alcohol-based hand rub

Return 21 to 28 days later for second dose

- Do not re-start series if delayed

Landmarking for the deltoid

Intramuscular (IM) injection site for children and adults



Give in the central and thickest portion of the deltoid muscle – above the level of the armpit and approximately 2–3 fingerbreadths (~2") below the acromion process. See the diagram. To avoid causing an injury, do not inject too high (near the acromion process) or too low.

Acquired from <https://www.immunize.org/catg.d/p2020.pdf> on December 6, 2020. We thank the Immunization Action Coalition.

Moderna – Storage and handling

- **Storage:**
 - -20°C (-25°C to -15°C) for up to 6 months*
 - +2 to 8°C for up to 30 days. Do not refreeze.
 - Do not store on dry ice
- **Transport to another site**
 - Keep frozen during transport. Do not store on dry ice
 - Monitor temperatures
 - May change in the future

*The exact expiry date of a vaccine lot should be determined by scanning the QR code on the vial/carton with a smart device or at the following website:
www.modernatx.com/covid19vaccine-eua

Stability may be extended as additional data become available

Moderna – Thaw

- **Thaw:**
 - From the **freezer to room temperature**
 - Will require 1 hour to thaw
 - Can remain at room temperature for 12 hours (but only 6 hours after vial punctured)
 - From the **freezer to the refrigerator**
 - Will require 2.5 hours to thaw
 - Can stay in the refrigerator (2-8°C) for 30 days
 - Needs to be kept at room temperature for at least 15 minutes before administering
 - Do not refreeze
- **Must be used within 6 hours of first puncturing the vial**
- Mark all the dates and times, so you know when can use the product until:
 - Use start times
 - Can also use end times, but indicate which time is which

Moderna – Drawing up

No stability data on pre-loading syringe

1. Use alcohol-based hand rub to clean hands
2. Swirl gently (**do not shake**)
3. Check for particulates or discoloration (expect a translucent to white color)
4. Swab the vial stopper with the alcohol wipe and let dry
5. Using aseptic technique and a new needle and syringe, draw up 0.5 ml
6. Repeat steps 4 and 5. Will get 10 doses per vial

Moderna – administering the vaccine

1. Use alcohol-based hand rub
2. Prepare the skin with alcohol wipe from the centre moving outwards – allow to dry
3. Give 0.5 ml dose intramuscularly in the deltoid
4. Discard needle and syringe immediately (or after activating the safety engineered device) into the sharps container
 - Do not put used needle down on the workstation
6. Use alcohol-based hand rub

Return 28 days later for second dose

- Do not re-start series if delayed

Summary of key storage and handling requirements

	Pfizer / BioNTech	Moderna
Storage	-80 to -60°C	-20°C (-25 to -15°C). Do not store on dry ice
Transportation	Information forthcoming	Frozen (subject to change)
Dilution	1.8 ml 0.9% sodium chloride provided by the National Operation Centre (NOC)	No dilution
Time in refrigerator	5 days at +2 to 8°C	30 days at +2 to 8°C
Use after first puncture	Up to 6 hours (first puncture will be for dilution)	Up to 6 hours
Maximum time at room temperature	Up to 8 hours <ul style="list-style-type: none"> • Up to 2 hours before mixing with diluent • Up to 6 hours after mixing with diluent 	Up to 12 hours (but only 6 hours after first puncture of vial)
Pre-loading in syringe	Stable for 6 hours if pre-loaded	No stability data
Dose	0.3 ml	0.5 ml
Second dose	21 to 28 days	28 days

Pre-vaccination questions

Pfizer-BioNTech (may change)

Are you feeling ill today?
Have you had a COVID-19 infection?
Are you or could you be pregnant?
Are you breastfeeding?
Are you allergic to polyethylene glycol (which is contained in the vaccine)? It can be found in some products such as cosmetics, skin care products, laxatives, cough syrups, bowel preparation products for colonoscopy, and some foods and drinks. <i>Tell the health care provider if you are allergic to anything that may contain polyethylene glycol.</i>
If this is your second dose, did you have any side effects after the first dose?
Do you have any problems with your immune system or are you taking any medications that can affect your immune system (e.g., high dose steroids, chemotherapy)? <i>Ask the health care provider if you are not sure about your medical conditions or the medications you are taking</i>
Do you have an autoimmune disease? <i>Ask the health care provider if you are not sure about your medical conditions</i>
Have you received another vaccine (not a COVID-19 vaccine) in the past 14 days? <i>You will be asked to wait for two weeks from that other vaccine to receive your COVID-19 vaccine.</i>
Do you have a bleeding disorder or are you taking any medications that could affect blood clotting? <i>Ask the health care provider if you are not sure about your medical conditions</i>
Have you ever felt faint or fainted after a past vaccination or medical procedure?

Can and cannot receive the vaccine

Pfizer-BioNTech (may change)

	Column 1 CAN RECEIVE the COVID-19 Vaccine Except if also in Columns 2 or 3	Column 2 GENERALLY SHOULD NOT RECEIVE the COVID-19 Vaccine Not enough data; If high risk for COVID-19 disease and exposure, consult with health care provider	Column 3 CANNOT RECEIVE the COVID-19 Vaccine
Age	16 years of age and over	12 to 15 years of age	11 years of age and younger
Feeling unwell with symptoms that could be COVID-19			You should not be vaccinated if you have any symptoms that could be due to COVID-19 so that you do not spread infection to others.
Have or had a COVID-19 infection	You can be vaccinated if you are no longer infectious and are feeling better from a COVID-19 infection		You cannot be vaccinated while infectious so that you do not spread infection to others, or if you still feel unwell from a recent COVID-19 infection
Pregnancy		Currently pregnant or planning to become pregnant before receiving both doses of COVID-19 vaccine	
Breastfeeding		Currently breastfeeding	

Can and cannot receive the vaccine

Pfizer/BioNTech (may change)

	Column 1 CAN RECEIVE the COVID-19 Vaccine Except if also in Columns 2 and 3	Column 2 GENERALLY SHOULD NOT RECEIVE the COVID-19 Vaccine Not enough data; If high risk for COVID-19 disease and exposure, consult with health care provider	Column 3 CANNOT RECEIVE the COVID-19 Vaccine
Allergy to polyethylene glycol Found in some products such as cosmetics, skin care products, laxatives, cough syrups, bowel preparation products for colonoscopy, and some foods and drinks.			If you are allergic to polyethylene glycol, you should not be vaccinated until it is determined to be safe by an allergist or other health care provider
You had a severe reaction to a previous dose of COVID-19 vaccine, including an allergic reaction			If you had a serious or allergic reaction to your last COVID-19 vaccine, you should not be vaccinated until it is determined to be safe by an allergist or other health care provider
Medical conditions Talk with the health care provider if you are unsure about your medical conditions		Problems with your immune system from disease or treatment Autoimmune conditions	
You received another vaccine recently (not a COVID-19 vaccines)			If you received another vaccine (not a COVID-19 vaccine) in the past 14 days, it is best to wait 2 weeks from that last vaccine to receive your COVID-19 vaccine

Considerations regarding vaccine administration

- Counseling about:
 - The **benefits** of receiving the vaccine, including the efficacy of the vaccine and unknowns about duration of protection
 - What is known about vaccine **safety** and how **vaccine safety is being monitored**, including:
 - Duration of safety data
 - What side effects to expect and watch for after immunization
 - The importance of **returning for the second dose**, and where and when to go to receive the same product
 - Bringing immunization record
 - The importance of **continuing to follow public health advice** regarding mask use, physical distancing and limiting / avoiding contact with others outside of their household.
- Take the time to understand and address client's questions respecting language issues, cultural sensitivity, hearing or visual barriers, cognitive issues

Considerations regarding vaccine administration

- Informed consent addressing
 - Capacity to consent
 - Language barriers
 - Visual or hearing impairments
- Cultural sensitivity with regard to the needs of the client, including the need for privacy during vaccination
- Pain management
- Watching for people who have a history of fainting or appear faint and vaccinating lying down
- Advising clients about reporting adverse events following immunization and ensuring reporting to local public health
- National Advisory Committee on Immunization (NACI) recommends:
 - to delay other vaccines for 28 days after the last COVID-19 vaccine dose, except if needed for post-exposure prophylaxis, and
 - avoid COVID-19 vaccines if had another vaccine in the preceding 14 days
- Ensure anaphylaxis kit complete and medications not expired; Review anaphylaxis management protocols and training
- Management of needle stick injuries

Considerations regarding avoiding wastage

- Very important to avoid wastage
- Consider storage and transportation options for the vaccine when determining how much to thaw
- Consider anticipated client volume when considering how much vaccine to dilute
- Have plan to reach eligible people to provide any thawed vaccine or vaccine from a punctured vial that needs to be used as soon as possible
 - If cannot reach eligible people, immunize others, preferably in other higher risk groups as possible
 - Document how decisions were made if using vaccine in groups not currently eligible

Infection prevention and control (1)

Do not want transmission of COVID-19 while receiving the vaccine

- Large well ventilated spaces for clinics with one way flow
- Minimize crowding and time in the clinic, optimally through an appointment system
- Maintain physical distancing (client remain 2 metres apart from others outside of their household)
- Physical barriers in registration area and other areas as possible
- Screening - passive and active on entry into the clinic
 - Clients, staff and volunteers should be advised not to attend if unwell
 - No need for temperature checks
- Clients wear a mask (medical or non-medical); have extra masks available
 - If not able to wear a mask:
 - Expedite through the clinic
 - Consider having attend at the beginning or end of clinic

Infection prevention and control (2)

- Personal protective equipment for staff
 - medical mask at all times, except when eating
 - eye protection (e.g., face shield) unless behind a barrier
 - only change mask if damp, damaged or need to remove to eat
 - do not use gloves (except if skin not intact)
- Alcohol-based hand rub for clients, staff and volunteers
 - immunizers use before and after each client
- Position client so shoulder (but not face) faces immunizer
- Limit client's contact with immunization table
- Cleaning and disinfection of surfaces if client touches table; client to use alcohol-based hand rub on their hands

Infection prevention and control (3)

- Staff and volunteer breaks are outside (in vehicle alone) or in very large indoor space
 - Maintain at least 2 metre separation if need to remove mask for eating
 - Keep breaks short and spread out staff breaks to avoid crowding
 - If providing food for staff and volunteers, it should be prepackaged and staff and volunteers should not congregate around it
- No food or beverages for clients except for those who feel faint or have fainted

Immunization for staff members and volunteers

- COVID-19 immunization
 - Recommended to receive vaccine before start working at clinics or at first clinic they work at
 - Could run a staff and volunteer clinic as a first clinic to provide vaccine to staff and volunteers and to test processes
- Hepatitis B vaccination and titres (if possible to obtain titres) for those handling sharps
- Influenza vaccination if the clinics are occurring during influenza season
- Up-to-date tetanus (if possible)

Post-immunization waiting period

- Can wait in the clinic with seats as far apart as possible (at least 2 metres apart) and masks on
- Can wait outside / in vehicle, if:
 - Accompanied by a responsible adult
 - Feels well
 - No history of fainting after vaccines or medical procedures or concerns about possible vaccine allergy
 - Remains on the grounds of the clinic or in the parking lot
 - Can reach staff directly or by telephone
 - Does not drive or use other forms of transportation for 15-30 minutes after vaccination, as advised by the health care provider
 - If need assistance, can honk their horn, call the clinic on their phone or their accompanying person can get a staff member / volunteer who is in the parking lot or in the clinic

Key messages

	Pfizer / BioNTech	Moderna
Storage	-80 to -60°C	-20°C (-25 to -15°C) Not on dry ice
Dilution	1.8 ml 0.9% sodium chloride provided	No dilution
Dose	0.3 ml	0.5 ml
Return	21 to 28 days	28 days

- Open and transparent communication of benefits and risks
- Infection prevention and control extremely important
 - Quick flow through clinics, no waiting, appointments
 - Personal protective equipment for staff
 - Mask for clients
 - Physical distancing
- Clients should continue to follow advice of local public health officials regarding masking, physical distancing, limiting / avoiding contact with others outside of their household.

Additional resources

Planning Guidance for Administration of COVID-19 Vaccine

Planning Guidance for Immunization Clinics for COVID-19 Vaccines

Guidance for influenza vaccine delivery in the presence of COVID-19

<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-influenza-vaccine-delivery-covid-19.html>

Canadian Immunization Guide – Part 1- Key Immunization Information

<https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information.html>

National Advisory Committee on Immunization Statements

<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html>

Public Health Agency of Canada

<https://www.canada.ca/en/public-health.html>

Additional Resources

- Sample Vaccine Information Sheet
- Sample Consent Form
- Sample After Care Sheet
- Sample Medical Directive