Ministry of Health

COVID-19: Vaccine Storage and Handling Guidance – Pfizer-BioNTech and Moderna COVID-19 Vaccines

Version 2.0 – February 1, 2021

Highlights of changes

- Updated information on temperature excursion.
- Added sections of Receipt of Vaccine and When Product is Damaged.
- Updates to Appendix B and C.

This guidance provides basic information only. It is not intended to provide medical advice, diagnosis or treatment, or legal advice.

Please check the Ministry of Health (MOH) COVID-19 website regularly for updates to this document.

The intended audience for this guidance document includes hospitals and public health units that are:

- Storing, distributing and/or administering the Pfizer-BioNTech or the Moderna COVID-19 vaccines.
- Involved in the assessment of temperature excursions, including the vaccine return process;
- Providing education for the storage and handling of ultra-low temperature (ULT) and frozen vaccines and the use of temperature monitoring devices, such as data loggers.

Vaccines are sensitive biological substances that can lose their potency and effectiveness if they are exposed to temperatures (heat and/or cold) outside of the required temperature range for the specific product (i.e., ultra-low or frozen temperatures) or when exposed to light. See Appendix A for additional information.

Failure to adhere to vaccine handling and cold chain requirements may reduce vaccine potency (resulting in a lack of protection against COVID-19) and/or increased local reactions at the site of the vaccine administration.

The loss of vaccine effectiveness due to cold chain exposures to adverse conditions is cumulative, permanent and irreversible.

For additional information refer to:

- Vaccine Storage and Handling Protocol, 2018[1]
- Vaccine Storage and Handling Guidelines, 2012. A copy can be requested by emailing OPHS.protocols.moh@ontario.ca.

If you work at a hospital and have further questions, contact your local public health unit.

If you work with a public health unit and have further questions, contact the Ministry of Health's Emergency Operations Centre (MEOC) directly at EOCOperations.moh@ontario.ca.

Initial Set-Up of ULT and Freezer Storage Units for mRNA COVID-19 Vaccine Products

- All ULT and freezer storage units that will be storing the COVID-19 vaccine are required to be set up so that temperatures are stabilized at the recommended temperature range specified by the manufacturer prior to placing any vaccine into the unit.
- **Pfizer-BioNTech COVID-19 vaccine**: The internal temperature of the unit should be stabilized between -80°C to -60°C (-112°F to -76°F) prior to stocking vaccine. Recommended storage temperature is -70°C.
- **Moderna COVID-19 vaccine:** The internal temperature of the unit should be stabilized at -25°C to -15°C (-13°F to +5°F) prior to stocking vaccine. Recommended storage temperature is -20°C.
- Monitor temperatures for 2 to 7 consecutive days. Maximum, minimum, and current temperatures need to be recorded twice daily in a Temperature Log

[1] Please note Public Health Units must comply with Ontario Public Health Standards including the Vaccine Storage and Handling Protocol, 2018.

Book. These temperatures should be within the required storage temperature range prior to storing vaccine in the storage unit.

Inspections

Facilities storing COVID-19 vaccine in ULT or freezer storage units should ensure that annual inspections (including temperature calibration) and regular maintenance of all ULT or freezer storage units is completed by a certified company. A copy of these inspections from facilities may be requested to ensure that vaccine storage and handling conditions are being adhered to.

Monitoring Vaccine Storage Unit Temperatures at the Point of Distribution

Monitoring vaccine storage equipment and temperatures is a daily responsibility to ensure the safety of the vaccine supply. Facilities should implement routine monitoring activities to identify out-of-range temperatures quickly and take immediate action to correct them to prevent any loss of vaccines.

Each facility that receives COVID-19 vaccines should:

- Document the time and the current, maximum and minimum temperatures of all vaccine storage units in the Temperature Log Book[2] twice daily (beginning and end of each business day) and reset the digital temperature monitoring device after recording/downloading the readings.[3] As there are several different data loggers required for the monitoring of the specialized storage units, please consult the product specifications for your particular data loggers, including the requirements for downloading and replacement;
- View the temperatures every time the storage unit is accessed;
- Maintain temperature logs and data logger temperature downloads for a minimum of one year (unless internal policy requires a longer retention period). This data may be requested by the ministry;

[2] Please note that while the Temperature Log Book identifies refrigerated vaccines, it can also be used for ULT and freezer storage units.

[3] Refer to the product specification sheets for your device(s). Ensure to share these sheets with your local public health unit and consult with them with any questions.

- Inspect the storage unit during the twice-daily checks, and, if required, rotate inventory and remove any expired vaccines;
- Check unit doors throughout the day and always at the end of the day to ensure they are tightly closed to prevent temperature changes and exposure to light;
- A remote monitoring system that allows for the notification of temperature excursions and power disruptions is recommended; and
- Develop and have contingency plans in place that plan for events such as power outages and vaccine storage unit malfunctions.
    - Ensure vaccine storage units can connect to and run on emergency power.
    - Have plans for alternative storage, which could include another comparable purpose-built storage unit; portable storage unit (e.g., credo cube; portable ULT); or using an alternative storage facility.
- Contact the MEOC for any temperature excursions at EOCOperations@ontario.ca. See below section on Temperature Excursion.

Data Loggers

As there are several different data loggers required to monitor the specialized storage units, please consult the product specifications for your particular data loggers, including the requirements for downloading and replacement.

- Data loggers are continuous monitoring and recording devices that provide detailed information on all temperatures recorded at pre-set intervals. Data loggers provide the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range. When using data loggers, the facility should:
    - Continuously record all vaccine storage unit temperatures;
    - Check the digital temperature monitoring device at least twice daily, at the start and end of each day, to confirm that vaccine storage unit temperatures remained within the acceptable range for proper vaccine storage. Record minimum, maximum, and current temperatures in the Temperature Log Book after each check;
    - Continue twice-daily observations and recording of the external vaccine storage unit temperature display;
    - Review the print-outs/downloadable reports from the data logger when

the vaccine storage unit temperatures are outside the range of those indicated for the vaccine;

- Change batteries annually, or as required;
- It is recommended that an external alarm monitoring system is installed, which alerts staff within and outside of work hours when there is a temperature excursion. Note: an external alarm system is a requirement for public health units (see Vaccine Storage and Handling Protocol, 2018);
- Program the continuous temperature recording system for at least a 30-minute interval for recordings;
- Place the data loggers in the middle of the vaccine storage unit with vaccines surrounding it;
- Place the data logger away from doors or walls of the refrigerator;
- Download data loggers on a weekly basis, and when an alarm is triggered. Logs should be kept for a minimum of one year and be available in the event the ministry requests this data. If single-use data loggers are utilized, ensure you have an adequate supply of data loggers before downloading;
- Download the data from the data logger immediately when an out of range temperature occurs to determine the duration of the temperature excursion incident and to determine if vaccine is suitable for continued use or is no longer viable;
- For data loggers that are utilized to record the minimum, maximum, and current temperatures twice daily, data should be downloaded after the temperature recordings in order to reset the minimum, maximum and current temperature readings from the previous readings. If single-use data loggers are utilized, ensure you have adequate supply; and
- For data loggers that are utilized in conjunction with a maximum-minimum thermometer (e.g., for refrigerated vaccines), data can be downloaded on a weekly basis (if no out-of-range temperatures occur) provided that the minimum, maximum and current temperature readings are documented from the maximum-minimum thermometer.

Vaccine Transport

General

Movement of COVID-19 vaccine from the storage unit into the clinic space is permissible (e.g., to a different floor/wing; to departments such as Occupational Health). Caution should be taken to minimize shaking or agitation of the vaccine during transport due to the fragility of the products, as advised by the manufacturers.

The ministry has developed guidance regarding the onward transportation of COVID-19 vaccines. Guidance regarding the transportation of Pfizer-BioNTech can be found in Appendix B and for Moderna vaccine in Appendix C.

During Vaccine Storage Unit Malfunction/ Electricity Disruption at the Point of Storage

When a malfunction occurs, the facility should:

- Document the time and the maximum, minimum and current temperature of the vaccine storage unit in the Temperature Log Book and reset the maximum-minimum thermometer (if applicable);
- Not allow the vaccine to remain in a non-functioning unit for an extended period of time;
    - Factors including the amount of vaccine being stored in the unit, the external temperatures (e.g., summer vs. winter) and the type, model and age of the vaccine storage unit will affect the duration of time vaccines within the unit will be kept within the vaccine manufacturers specified temperature range;
- During a scheduled or a time-limited electricity disruption where the power is expected to be restored before the vaccine storage unit temperature rises above the recommended range, the facility should follow these steps:
    - Keep the storage unit door closed until the power is restored to maintain an acceptable temperature range for as long as possible; and
    - Record maximum, minimum and current temperatures:
        - Continue to monitor the temperatures inside the vaccine storage unit at 30-minute intervals if the digital temperature monitoring device

allows digital temperature monitoring without opening the storage unit doors;

- If this is not possible, keep the door closed and immediately implement plans for transfer of the vaccine into a functioning unit (i.e., ultracold/freezer portable unit or vaccine refrigerator unit);

- If it is unknown whether the problem can be corrected in time to maintain an appropriate temperature, the facility should initiate its contingency plan by:
  - Transferring vaccines to an alternative storage facility (that is connected to a generator) by:
    - Contacting the local public health unit to notify them of the need to transport vaccine to a different location. The public health unit will notify the MEOC. This alternative storage facility or storage should be identified as part of local contingency plans prior to receipt of vaccine.
    - Conducting an inventory of vaccines while packing all vaccines, using portable unit and/or insulated containers with appropriate packing materials and digital temperature monitoring devices. See below for the specifics for packing either vaccine.
  - Recording the time and insulated container temperature before transporting the vaccines to and upon arrival at the alternative storage facility; and
  - Continuing to read and record the maximum, minimum and current temperatures twice daily.

Pfizer-BioNTech Vaccine

- If placed in an ULT portable unit (-80°C to -60°C), the vaccines can go back into an ULT unit. To the extent possible, vials should be kept in the tray during transport. If this is not possible, the vials need to be securely stored (not rolling around) in the storage device.
- If placed in an insulated container for +2°C to +8°C temperature range, the vaccines should go back into a refrigerator and not be refrozen. Note: If the vaccines do not need to be discarded due to a temperature excursion, these doses need to be used within 5 days (120 hours), minus any time in the container.

Moderna Vaccine

  - If placed in a portable freezer unit (-25°C to -15°C), the vaccines can go back into a freezer unit. To the extent possible, vials should be kept in the boxes during transport. If this is not possible, any individual vials need to be securely stored (not rolling around) in the storage device.
  - If placed in an insulated container for +2°C to +8°C temperature range, the vaccines should go back into a refrigerator and not be refrozen. Note: If the vaccines do not need to be discarded due to a temperature excursion, these doses need to be used within 30 days minus any time in the container.

- If an alternative storage facility cannot be identified within a reasonable timeframe, place the vaccine in the ULT/freezer portable unit and/or insulated containers withappropriate packaging material and digital temperature monitoring devices and record the temperature at the facility by:
  - Labelling the insulated containers; and
  - Continuing to monitor the temperatures inside the insulated container at 30-minute intervals using a temperature monitoring device that allows temperature viewing without opening the insulated container (e.g., in/out thermometer).

When the Vaccine Storage Unit Malfunction Has Been Corrected or the Electricity Supply to the Unit Has Been Restored at the Point of Distribution

- Document the following:
  - Maximum, minimum and current temperatures inside the vaccine storage units;
  - Length of time the power has been off; and
  - Time when the electricity supply is restored.
- Maintain the vaccines in the storage unit or remove the vaccines from the portable ULT unit, portable freezer unit and/or insulated container. If removed, place them into the purpose-built vaccine storage unit and resume regular vaccine storage and handling practices, as long as the vaccine storage unit and insulated container maintained the required temperature range as specified by the vaccine manufacturer(s).

  - If the Pfizer-BioNTech vaccine was stored in an ULT -80◦C portable unit (and not thawed), return to the ULT purpose-built storage unit.
  - If the Moderna vaccine was stored in a portable -20°C freezer unit (and not thawed), return to a purpose-built freezer unit.
  - If Pfizer-BioNTech or Moderna vaccines are kept in an insulated container, place them into the refrigerator and ensure doses are used within:
    - 5 days (120 hours) minus any time the vaccine was in the container for the Pfizer-BioNTech vaccine;
    - 30 days minus any time the vaccine was in the container for the Moderna vaccine.
- If the purpose-built vaccine storage unit is unable to maintain the required storage temperature range, maintain the vaccines in the assigned container and continue to monitor temperatures inside the container if the container. Place the vaccine back into the purpose-built unit once it is able to maintain the temperature range as specified by the vaccine manufacturer(s) in the product monograph.
- If the vaccine was not maintained in the correct range, temperature excursion has occurred; see the process below.

Temperature Excursion

During transit from the manufacturer:

When a temperature excursion occurs during transportation from the vaccine manufacturer, notify the MEOC immediately and contact the manufacturer:

- Pfizer: Contact Pfizer Customer Service at 1-833-829-2684 or CanadaCSVaccine@Pfizer.com;
- Moderna: Contact Innomar QA at 1-833-847-4270 or QA-GMP@innomar-strategies.com;
- The MEOC will notify the NOC;
- Report the outcome via email to the EOC using the following reporting format:
  - Subject: Delivery Temp Excursion Report
    - Date of Incident
    - Vaccine Delivery Site (VDS) Location

    - Number of doses impacted by the excursion
    - Manufacturer recommendations
    - Wastage (number of doses or indicate no wastage)
    - Impact on local vaccination efforts
- The MEOC will notify the NOC to advise of the incident, resolution and any impact on provincial vaccination efforts.

Temperature excursion reporting when vaccine has been in the custody of a provincial facility:

Facilities storing the COVID-19 vaccine should undertake the following if the vaccine storage units (purpose-built or insulated container(s)) were unable to maintain the required temperatures (temperature excursion):

- When using two or more temperature monitoring devices/systems, determine which will be designated as the primary device/system.
    - Record the maximum, minimum and current temperature and download any data from the storage unit or data logger and save as a PDF file.
    - Download the PDF file to a computer from the data logger.
    - Save this file using standardized file format naming, including the vaccine product, location and date (e.g., Templog_Pfizer_UHN_12-14-2020; Templog_Moderna_WECHU_12-25-2020).
- In the event that two or more temperature monitoring devices/systems are used, do not average or round the temperature data points. When submitting temperature data, ensure that data from the primary device/system is identified.
- Contact your local public health unit to report the excursion through your normal process. Public health units should have an established process in place to deal with temperature excursions after hours and on weekends to ensure that vaccine is not held in quarantine for an extended period of time.
- Email or fax the public health unit the following:
    - The date, time, temperatures (maximum, minimum and current temperature) and the details on the excursion (e.g., length of time).
    - Attach the PDF file.
- The public health unit will contact the vaccine manufacturer and initiate the Adverse Storage Conditions form with the facility.

  - Pfizer: Contact Pfizer Customer Service at 1-833-829-2684 or CanadaCSVaccine@Pfizer.com;
  - Moderna: Contact Innomar QA at 1-833-847-4270 or QA-GMP@innomar-strategies.com;
- The public health unit will notify the MEOC once the vaccine manufacturer has been contacted to alert the ministry of the cold chain incident.
- Once recommendations from the manufacturer have been received, the public health unit will follow-up with the facility to provide recommendations, education and necessary remediation.
- The public health unit will report the outcome via email to the MEOC using the following reporting format:
  - Subject: FPT Delivery Temp Excursion Report
    - Date of Incident
    - Vaccine Delivery Site (VDS) Location
    - Number of doses impacted
    - Manufacturer recommendations
    - Wastage (number of doses or indicate no wastage)
    - Impact on local vaccination efforts
- The MEOC will notify the NOC to advise of the incident, resolution and any impact on provincial vaccination efforts.
- The facility storing the vaccine will mark vaccines involved in a temperature excursion incident that have been determined to be usable, in accordance with manufacturers' recommendations and direction from the NOC/MEOC, in order to identify them in case of a future exposure(s).
- Dispose of any unusable/wasted vaccines, as directed by the public health unit. Public health units are to ensure that any wastage is documented in the ministry specified information system.

Stabilizing Temperatures in New and Repaired Purpose-built Vaccine Storage Units

- For repaired vaccine storage units that experienced a power outage, the vaccine temperatures should be stabilized within the recommended temperature range as specified by the manufacturer prior to placing vaccine back into the unit; and

- For new purpose-built storage units, vaccine temperatures should be stabilized at the recommended temperature range specified by the manufacturer prior to placing vaccine into the unit. Monitor temperatures for 2 to 7 consecutive days. Maximum, minimum, and current temperatures need to be recorded twice daily and should be within the required storage temperaturerange prior to storing vaccine in the storage unit.

Receipt of Vaccine

This information relates to the receipt of vaccine at storage sites as well as clinic sites that will be storing COVID-19 vaccine.

When receiving the vaccine at storage sites or clinic sites that will be storing the COVID-19 vaccine, the receiving sites should:

- Designate one person as the lead for the facility who will be an authorized receiver of the vaccine delivery. This individual should ensure that standard operating policies and procedures related to vaccine storage and handling are in place and are followed;
- Designate and train alternate(s) to be responsible for the above if the lead is not available. The alternate(s) should be trained in routine and emergency policies and procedures related to vaccine storage and handling;
- Ensure that responsible staff are adequately trained and have knowledge of the requirements for vaccine storage and handling, product sensitivities, storage equipment, temperature monitoring devices, and inventory management procedures.
- Use the *Vaccine Storage and Handling Guidelines, 2012* (or as current) to educate and instruct health care providers who store publicly fundedvaccines;
- Ensure that designated and trained staff or their alternate(s):
    - Are available to receive and store vaccines when they are expected to arrive;
    - Never leave vaccines in a shipping container, unpacked or unattended;
    - Understand that vaccine deliveries require immediate attention;
- Immediately open all of the transport containers and assess the digital temperature monitoring device(s);

- Examine the shipment for evidence of damage. Quarantine the product immediately if damaged. See section below on Product Damage.
- The staff person who received the vaccine is responsible for:
    - Documenting their name, the date and time of receipt of the vaccines and sign the manifest to acknowledge the receipt of the vaccines. If the vaccines were received at a refrigerated temperature (i.e., between +2°C to +8°C), document the amount of time remaining from cumulative refrigerated storage conditions (i.e., Pfizer = 5 days/120 hours; Moderna = 30 days);
    - Unpacking the shipment and placing the vaccines immediately in the storage unit;
    - Reviewing the order against the packing slip(s) to confirm that the order is correct;
    - Receiving and recording the vaccines into inventory for use if the digital temperature monitoring device(s) indicates that the cold chain was maintained during shipping (e.g., +2°C to +8°C);
    - In the event of a temperature excursion, follow the Temperature Excursion process in this document.

Preparation for Immunization Clinics

Just in Time Vaccine Delivery

- Ensure that only the number of frozen doses of the vaccine needed for the clinic are removed from the storage unit to prevent unnecessary or accidental wastage. The vaccine should be transported frozen and thawed at the clinic location according to manufacturer specifications and stored at +2°C to +8°C prior to dilution (if required). Be sure to mark and keep track of the date and time of delivery using a system that works for your staff.
- Monitor and record temperature readings in the vaccine refrigerator or insulated container:
    - Before leaving the main storage facility with the insulated container;
    - Upon arrival at the clinic location within the building prior to starting the immunization clinic;
    - Each time the cooler is opened and at least every hour during the

immunization clinic;

- Before and after breaks, i.e., lunch breaks; and
- Upon completion of the clinic.

- Visually inspect the digital temperature monitoring device each time the insulated container is opened.
- Minimize the number of times that the insulated container is opened during the immunization clinic.
- Upon arrival at the main storage facility after the immunization clinic:
  - Place the vaccine into inventory for use if the digital temperature monitoring device(s) indicates that the temperature was maintained within the vaccine manufacturer-specified time range during the clinic and transport; and
  - Place the vaccine under quarantine in the vaccine storage unit if the digital temperature monitoring device(s) indicates an out-of-range reading and immediately assess the temperature excursion incident.
    - All cold chain incidents need to be reported to the MEOC.

Pfizer-BioNTech COVID-19 vaccine:

- Once thawed, unpunctured vials may be and stored at +2°C to +8°C for up to 120 hours (5 days) or at room temperature (up to +25°C) for no more than 2 hours. This vaccine cannot be refrozen.
- The Pfizer-BioNTech vaccine product should be used within 6 hours
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Thawed vials can be handled in room light conditions.

Moderna COVID-19 vaccine:

- Once thawed, unpunctured vials may be kept at +2°C to +8°C in a refrigerator for up to 30 days, or at +8°C to +25°C for up to 12 hours. Moderna vaccine cannot be refrozen.
- During storage, vials should be protected from light.
- The Moderna vaccine should be used within 6 hours from the time of first puncture.

- Vaccine doses wasted due to any of the following reasons are not to be returned to the local public health unit/the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS) and should be disposed of according to local, provincial and/or federal regulations. However, they should be recorded in the data solution as directed by the ministry as wastage:
    - Defective product(s);
    - Insufficient dose(s) from a single/multi-dose vial;
    - Dose(s) remaining in a multi-dose vial;
    - Suspected vaccine contamination;
    - Unused pre-drawn syringe(s);
    - Vaccine administration issue(s);
    - Vaccine stored temperature excursion(s) at clinic;
    - Refrozen vaccine(s) after being thawed;
    - Punctured/reconstituted vaccine(s) not used within 6 hours;
    - Reconstituted frozen vial(s) left at room temperature beyond 2 hours (Pfizer); and
    - Vial(s) left at room temperature beyond 12 hours (Moderna).

Note: Future updates to the data solution will include additional reasons for wastage, including those below. Record the most applicable reason.

- Stored in ULT/freezer temperatures beyond expiry date;
- Stored in refrigerated temperatures (+2°C to +8°C) beyond 5 days (Pfizer); and
- Stored in refrigerated temperatures (+2°C to +8°C) beyond 30 days (Moderna).

When Product is Damaged

In the event of potential damage to the vaccine either during transport or while on site (e.g., damage to the shipping container, a box/tray of vaccines or vial(s), box with vaccine vials dropped) the following steps should be followed:

- Quarantine the impacted product and contact the manufacturer:
    - Pfizer: Contact Pfizer Customer Service at 1-833-829-2684 or

CanadaCSVaccine@Pfizer.com

- Moderna: Contact Innomar QA at 1-833-847-4270 or QA-GMP@innomar-strategies.com

- If the damage occurs during initial transport to the site or if product is damaged during storage or handling on site and doses are wasted based on recommendation from manufacturer, notify the MEOC and report the outcome based on recommendation from the manufacturer via email to the MEOC using the following reporting format:
  - Subject: COVID-19 Vaccine Damage Report
    - Date of Incident
    - Vaccine Delivery Site (VDS) Location
    - Number of doses impacted
    - Manufacturer Recommendations
    - Wastage (number of doses or indicate no wastage)
    - Impact on local vaccination efforts
- The MEOC will notify the NOC to advise of the incident, resolution and any impact on provincial vaccination efforts.

Appendix A: Storage Requirements for COVID-19 Vaccine Products

Storage Condition	Pfizer-BioNTech	Moderna
Frozen Vials Prior to Use	• Kept between -80°C to -60°C (-112°F to -76°F). • Protected from light, in the original packaging, until ready to use.	• Kept between -25°C to -15°C • Protected from light. • Do not store on dry ice or below -40°C.
Thawed, unpunctured vials	• Prior to dilution, the vaccine may be thawed and stored at +2°C to +8°C for up to 120 hours (5 days) or at room temperature (up to +25°C) for no more than 2 hours. • During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. • Thawed vials can be handled in room light conditions. • Do not refreeze thawed vials.	• If not punctured, the vaccine should be thawed and stored at +2°C to +8°C for up to 30 days, or at +8°C to +25°C for up to 12 hours. • During storage, vials should be protected from light. • Do not refreeze thawed vials.
Thawed, punctured vials	• After dilution, the vaccine should be stored between +2°C to +25°C and used within 6 hours from time of first puncture. • During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. • After dilution, the vaccine vials can be handled in room light conditions.	• The vaccine should be stored between +2°C to below +25°C and used within 6 hours from the time of first puncture. • During storage, vials should be protected from light.
For more information, consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database. Refer to Storage and Handling of Immunizing Agents in the Canadian Immunization Guide (CIG), Part 1 – Key Immunization Information for additional general information.		

Appendix B: Recommendations for the Onward Transport of the Pfizer COVID-19 Vaccine beyond the Initial Point of Delivery

Pfizer recommends that their vaccine be shipped in a frozen state as per the product monograph and specifications. A summary of Pfizer storage can be found at the end of this Appendix.

Where this is not feasible, in the context of the public health emergency and assessment of population risk, the Pfizer vaccine ("vaccine") may be transported beyond the initial point of delivery. For this purpose, transport refers to taking the vaccine from one site to another using a vehicle on ground, air or water. Walking the vaccine (e.g., within a facility, between adjacent buildings on a campus) is not considered transport when it is for a short period (i.e., up to 15 minutes).

This document provides a range of options related to the movement of the vaccine. The operational plan should be tailored to local circumstances, with collaboration among the hospitals and public health units. Air and water transport should be done in a frozen state.

For ground transport at +2°C to +8°C only:

- It is recommended that the vaccine is packaged for delivery in a frozen state to be transported to the clinic/facility location using an insulated cooler (e.g., Playmate), that has been preconditioned to a refrigerated temperature of +2°C to +8°C.
- In this state, the vaccine should be in transport for no more than 8 hours of cumulative time and under exceptional circumstances, no more that 12 hours (e.g., inclement weather). Opened or reconstituted vials of the vaccine, or product in syringes should not be transported. Product should be sent for 'just in time use' as part of a planned vaccination clinic versus movement for secondary storage at another facility.
- It is recommended that the vaccine is only transported at +2°C to +8°C once. Under exceptional circumstances, based on a risk assessment, the vaccine may be transported at +2°C to +8°C more than once if:
    - The cold chain has been properly monitored and documented;
    - The cumulative total travel time does not exceed 8 hours (12 hours under

exceptional circumstances) and is properly documented;

- There is documentation that captures details at the individual vial level (e.g., labels on vials);
- Vials are packed in order to minimize movement and agitation.

General Precautions for Liquid State (+2°C to +8°C) Transport of the Vaccine

- The vaccine should be handled with care and protected as much as possible from shocks, drops, vibration, etc.
- The transport container should be labelled prominently with "Fragile: Handle with Care, Do Not Drop" cautionary statements.
- The transport containers should be secured (strapped/braced) when being transported to prevent unnecessary movement.
- The vaccine should be protected from being dropped.
- Any set of cartons/vials should not be subjected to repeat instances of transport, except under exceptional circumstances as noted above. If a carton/vial has been on a transfer once, it should not be sent out again and instead be used at the site, even if the vial has not been in transit for the maximum allowable period. This is a precautionary measure since it will be difficult to keep track of the transportation time "used up" for any specific vial.
- The vaccine should be transported by hospital or public health unit staff who are trained in the transport of vaccine or other products requiring cold chain monitoring. The use of courier companies can be considered, but they should specialize in cold chain transport (e.g., bonded and contracted companies). The courier should have systems in place for tracking and monitoring vaccines and the ability to deliver the vaccines to prevent excessive movement or agitation.

The Following Recommendations are to be Considered for the Onward Distribution of the Pfizer Vaccine:

- Insulated containers should be packed according to the guidance provided in ministry guidance on vaccine storage and handling for refrigerated vaccines. See Appendix D.

- Transport in the largest configuration wherever possible (e.g., box), avoiding individual vial distribution, while considering the minimum number of doses needed at the onwards location to avoid wastage.
- Prevent movement in the cooler by surrounding with dunnage (padding material) inside the container to minimize product movement during transport.
- If transport is conducted at vial level, the vial should be placed in insulation and bubble wrap or similar padding to protect the product (e.g., wrap the vial in bubble wrap and place it into a medication/pill bottle).
- Do not pack vaccine that is at +2°C and +8°C with frozen vaccine vials.
- Do not allow thawed vaccines to come into contact with any frozen packs added to maintain temperature.
- Follow the configuration in Appendix D: Instructions on How to Pre-Condition and Pack an Insulated Container.
- Keep the vaccine vials upright.
- Protect the vaccine vials from light.
- Label the cooler as "Fragile: Handle with Care, Do Not Drop" and indicate that the contents are temperature sensitive.
- The pack out should be secured in the vehicle so that it does not move around. As much care as possible should be taken to minimize extra movement in the thawed state. The vaccine should be protected from being dropped. Never place the cooler in the trunk of a vehicle.
- The total transportation time should be no greater than 8 hours.
- The time in transit at +2°C to +8°C should be considered part of the 5 days (120 hours) allowed for storage at refrigerated temperatures, even if the vaccine was placed into the cooler frozen.
- The time the vaccine was removed from frozen storage, and the beyond use date and time should be recorded at the time the vaccine is removed from frozen storage and be a total of no more than 120 hours.
- Do not transport the vaccine at room temperature.
- The temperature (+2°C to +8°C) should be maintained and recorded for the duration of the transport, ensuring that the transportation locations, dates and times, including the duration of time in transit are recorded.
    - A data logger or minimum-maximum thermometer should be used to

monitor temperatures.

- Download the data logger/record minimum-maximum temperatures as soon as possible to ensure no "unwitnessed" excursions occurred while in transit.

- Upon receipt, the vaccine should be inspected, inventoried and immediately placed into vaccine fridge, noting on the storage unit temperature log the date and time of the vaccine delivery.
- The vaccine can be stored at +2°C to +8°C for a total of 120 hours, this includes the time in transit.
- Do not refreeze the vaccine.
- If the vaccine is to be used for a vaccination clinic immediately then the vaccine should be prepared and used as per the manufacturer's specifications.

Scenarios

The following scenarios may assist planning for the onward transport of the vaccine.

Scenario 1: Ground Transport between Locations

Transport from a hospital to another hospital.

- Transport of the vaccine for storage at another facility should be done in the frozen state.

Scenario 2: Ground Transport between Locations or Facilities

Transport from a hospital to a congregate living setting.

- Transport in a Playmate cooler may be carried out using a car, van or truck on paved, smooth gravel, or smooth dirt roads, following the general precautions described above. Avoid sudden movements/breaking as much as possible.
- Such transport may be conducted for up 8 hours.

Scenario 3: Medium and Long Duration Ground PLUS Air Transport

It is recommended that any transport that involves air, be done in a frozen state at this time.

Scenario 4: Short Duration Movement within a Facility or Campus

Movement of the vaccine that is stored at a long-term care home but needs to be walked over to an attached retirement home (e.g., on the same campus/property).

- Movement in a Playmate cooler using a well-functioning wheeled cart on a relatively smooth pathway. Transport may also be conducted as a hand-carry (walked only, no running).
- Following general precautions described above, such movement may be conducted for a short period (i.e., up to 15 minutes).

Vaccine Storage

The vaccine should be stored as per the product monograph and the National Advisory Committee of Immunization's (NACI) statement on Recommendations on the use of COVID-19 vaccines.

Storage Condition	Pfizer-BioNTech Vaccine
Frozen Vials	• Kept frozen between -80°C to -60°C • Protected from light • Shelf life is 6 months
Thawed, unpunctured vials	• Thawed and stored at +2°C to +8°C for up to 5 days (120 hours), or at +8°C to +25°C for up to 2 hours • During storage, vials should be protected from light • Do not refreeze thawed vials
Thawed, punctured vials	• Stored between +2°C to below +25°C and used within 6 hours from the time of first puncture • During storage, vials should be protected from light

Appendix C: Recommendations for the Onward Transport of the Moderna COVID-19 Vaccine beyond the Initial Point of Delivery

Moderna recommends that their vaccine be shipped in a frozen state as per the product monograph and specifications. A summary of Moderna vaccine storage can be found at the end of this Appendix.

Where this is not feasible, in the context of the public health emergency and assessment of population risk, the Moderna vaccine ("vaccine") may be transported beyond the initial point of delivery. For this purpose, transport refers to taking the vaccine from one site to another using a vehicle on ground, air or water. Walking the vaccine (e.g., within a facility, between adjacent buildings on a campus) is not considered transport when it is for a short period (i.e., up to 15 minutes).

This document provides a range of options related to the movement of the vaccine. The operational plan should be tailored to local circumstances, with collaboration among the hospitals and public health units. Air and water transport should be done in a frozen state.

For ground transport at +2°C to +8°C only:

- It is recommended that the vaccine is packaged for delivery in a frozen state to be transported to the clinic/facility location using an insulated cooler (e.g., Playmate), that has been preconditioned to a refrigerated temperature of +2°C to +8°C.
- In this state, the vaccine should be in transport for no more then 8 hours of cumulative time and under exceptional circumstances, no more that 12 hours (e.g., inclement weather). Opened vials of the vaccine, or product in syringes should not be transported. Product should be sent for 'just in time use' as part of a planned vaccination clinic versus movement for secondary storage at another facility.
- It is recommended that the vaccine is only transported once at +2°C to +8°C. Under exceptional circumstances, based on a risk assessment, the vaccine may be transported at +2°C to +8°C more than once if:
    - The cold chain has been properly monitored and documented;
    - The cumulative total travel time does not exceed 8 hours (up to 12 hours

under exceptional circumstances) and is properly documented;

- There is documentation that captures details at the individual vial level (e.g., labels on vials);
- Vials are packed in order to minimize movement and agitation.

General Precautions for Liquid State (+2°C to +8°C) Transport of the Vaccine

- The vaccine should be handled with care and protected as much as possible from shocks, drops, vibration, etc.
- The transport container should be labelled prominently with "Fragile: Handle with Care, Do Not Drop" cautionary statements.
- The transport containers should be secured (strapped/braced) when being transported to prevent unnecessary movement.
- The vaccine should be protected from being dropped.
- Any set of cartons/vials should not be subjected to repeat instances of transport except under exceptional circumstances as noted above. If a carton/vial has been on a transfer once, it should not be sent out again and instead be used at the site, even if the vial has not been in transit for the maximum allowable period. This is a precautionary measure since it will be difficult to keep track of the transportation time "used up" for any specific vial.
- The vaccine should be transported by hospital or public health unit staff who are trained in the transport of vaccine or other products requiring cold chain monitoring. The use of courier companies can be considered, but they should specialize in cold chain transport (e.g., bonded and contracted companies). The courier should have systems in place for tracking and monitoring vaccines and the ability to deliver the vaccines to prevent excessive movement or agitation.

The Following Recommendations are to be Considered for the Onward Distribution of the Moderna Vaccine:

- Insulated containers should be packed according to the guidance provided in ministry guidance on vaccine storage and handling for refrigerated vaccines. See Appendix D.

- Transport in the largest configuration wherever possible (e.g., box), avoiding individual vial distribution, while considering the minimum number of doses needed at the onwards location to avoid wastage.
- Prevent movement in the cooler by surrounding with dunnage (padding material) inside the container to minimize product movement during transport.
- If transport is conducted at vial level, the vial should be placed in insulation and bubble wrap or similar padding to protect the product (e.g., wrap the vial in bubble wrap and place into a medication/pill bottle).
- Do not pack vaccine that is at +2°C and +8°C with frozen vaccine vials.
- Do not allow thawed vaccine to come into contact with any frozen packs added to maintain temperature.
- Follow the configuration in Appendix D: Instructions on How to Pre-Condition and Pack an Insulated Container.
- Keep the vaccine vials upright.
- Protect the vials from light.
- Label the cooler as "Fragile: Handle with Care, Do Not Drop" and indicate that the contents are temperature sensitive.
- The pack out should be secured in the vehicle so that it does not move around. As much care as possible should be taken to minimize extra movement in the thawed state. The vaccine should be protected from being dropped. Never place the cooler in the trunk of a vehicle.
- The total transportation time should be no greater than 8 hours.
- The time in transit at +2°C to +8°C should be considered part of the 30 days allowed for storage at refrigerated temperatures, even if the vaccine was placed into the cooler frozen.
- Do not transport the vaccine at room temperature.
- The temperature (+2°C to +8°C) should be maintained and recorded for the duration of the transport, ensuring that the transportation locations, dates and times, including the duration of time in transit are recorded.
    - A data logger or minimum-maximum thermometer should be used to monitor temperatures.
    - Download the data logger/record minimum-maximum temperatures as soon as possible to ensure no "unwitnessed" excursions occurred while in

transit.

- Upon receipt, the vaccine should be inspected, inventoried and immediately placed into a vaccine fridge, noting on the storage unit temperature log the date and time of the vaccine delivery.
- The vaccine can be stored in the fridge for up to 30 days.
- Do not refreeze the vaccine.

Scenarios

The following scenarios may assist with planning for the onward transport of the vaccine.

Scenario 1: Short Duration Movement within a Facility or Campus

Movement of the vaccine that is stored at a long-term care home but needs to be walked over to an attached retirement home (e.g., on the same campus/property).

- Movement in a Playmate cooler using a well-functioning wheeled cart on a relatively smooth pathway. Transport may also be conducted as a hand-carry (walked only, no running).
- Following general precautions described above, such movement may be conducted for a short period (i.e., up to 15 minutes).

Scenario 2: Ground Transport between Locations or Facilities

Transport from one public health unit to a congregate living setting.

- Transport in a Playmate cooler may be carried out using a car, van or truck on paved, smooth gravel, or smooth dirt roads, following the general precautions described above. Avoid sudden movements/braking as much as possible.
- Such transport may be conducted for up 8 hours.

Scenario 3: Medium and Long Duration Ground PLUS Air Transport

It is recommended that any transport that involves air, be done in a frozen state at this time.

Vaccine Storage

The vaccine should be stored as per the product monograph and the National Advisory Committee of Immunization's (NACI) statement on Recommendations on the use of COVID-19 vaccines.

Storage Condition	Moderna
Frozen Vials	• Kept frozen between -25°C to -15°C • Protected from light • Do not store on dry ice or below -40°C • Shelf life is 6 months + 30 days further at refrigerated state
Thawed, unpunctured vials	• Thawed and stored at +2°C to +8°C for up to 30 days, or at +8°C to +25°C for up to 12 hours • During storage, vials should be protected from light • Do not refreeze thawed vials
Thawed, punctured vials	• Stored between +2°C to below +25°C and used within 6 hours from the time of first puncture • During storage, vials should be protected from light

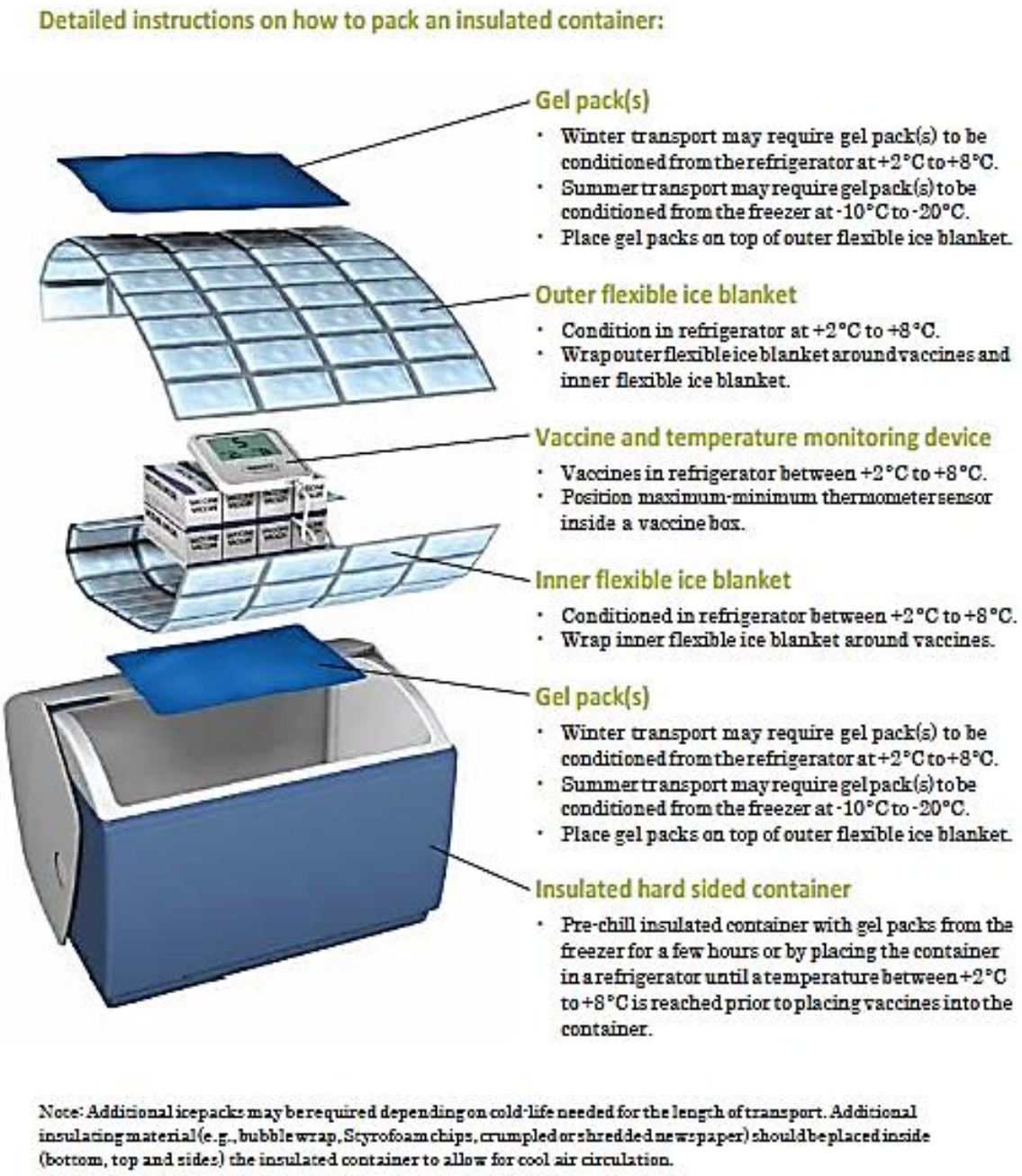
Appendix D: Instructions on How to Pre-Condition and Pack an Insulated Container

Pre-conditioning

Steps to prepare an insulated container and related materials prior to the transportation or storage of vaccines can be found in the *Vaccine Storage and Handling Guidelines*, 2012. Freezing episodes happen very easily in all coolers, usually in the first 2 hours after packing:

- Pre-chill the insulated container prior to use by placing preconditioned icepacks inside the insulated container for at least 1 hour. After the hour, remove all icepacks. Placing the cooler in the refrigerator overnight can facilitate the pre-conditioning process.
- Pre-condition icepacks. Vaccines are vulnerable to freezing when transported in an insulated container if icepacks have not been correctly conditioned. Icepacks come out of the freezer at a temperature of approximately -20°C. Keeping the icepacks at room temperature for a period for time allows the ice at the core of the icepack to rise to 0°C. This process is called "conditioning". An icepack is adequately conditioned as soon as beads of water cover its surface. The conditioning process usually takes approximately 20 to 30 minutes.
- Prepare your temperature monitoring device.
- Ensure all other items necessary to pack the insulated container are ready and easily accessible, including pre-conditioned ice blankets at +2°C to +8°C.

Packing an Insulated Container



From the ministry's *Vaccine Storage and Handling Guidelines, 2012*. A copy can be requested by emailing OPHS.protocols.moh@ontario.ca.