Ministry of Health

General COVID-19: Vaccine Storage and Handling Guidance

Version 3.0 – September 24, 2024

Highlights of changes:

- Removal of Novavax
- Removal of appendix B: Packing an insulated container, refer to the Vaccine Storage Handling Guidelines;
- Removal of Accessing Additional Dose(s) from Vaccine Vials
- Removal of 12 transport time maximum

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.

Chapters for specific COVID-19 Vaccines can be found on the COVID-19 website

- Chapter 1: Storage and Handling of Pfizer BioNTech's COVID-19 vaccines
- Chapter 2: Storage and Handling of Moderna's COVID-19 vaccines

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

- Storing, distributing and/or administering 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 low-temperature (LT) 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.

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.

It is important to take every opportunity to vaccinate, especially for those who may be vaccine hesitant and for those who may be less likely to return for recommended doses.

Efforts should continue to be made to reduce open vial vaccine wastage. When a vial is reaching its "must use by" date try to locate other potential individuals for vaccination (e.g., waitlists) when possible.

While unused doses in open vials are expected to increase as overall vaccination rates decrease, it remains important to limit expiry of closed vials through proper inventory management and storage and handling, including fridge monitoring (e.g., temperature logs), stock rotation based on expiry and "must use by" dating, and recommended packing and transport per product specifications.

Public health units, distributors and pharmacies should also follow the:

- Vaccine Storage and Handling Protocol, 2018[1]; and
- Individual product monographs on the Government of Canada website. Health care providers should also follow the:
- Vaccine Storage Handling Guidelines;
- Individual product monographs on the Government of Canada website. In addition, health care providers who have questions should contact:
    - Your local public health unit;
    - The Vaccine Supply and Logistics (VSL) unit at vaccinesupplyandlogistics@ontario.ca, if you have already consulted with your public health unit and have further questions;
    - The Vaccine Program, Planning and Performance unit at vacpro@ontario.ca

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

Pharmacists to review the following:

- EOC Notices Executive Officer Communications - Drugs and Devices - Health Care Professionals - MOH (gov.on.ca)
- Pharmacy Playbook OPA Today: Pharmacy Playbook for COVID-19 Vaccine Administration | Ontario Pharmacists Association (opatoday.com)
- ***Note:** Some of the information in this document is **not** intended for pharmacy stores (i.e., receiving vaccines, freezer information). Pharmacists are to adhere to the EOC notices prepared by the COVID Therapeutics and Pharmacy Unit. This document is intended only to provide pharmacists with general supplementary information regarding COVID-19 vaccine storage and handling.

Table of Contents

Contents

Initial Set-Up of ULT and Freezer Storage Units for 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.
- Monitor and document minimum and maximum temperatures for 2 to 7 consecutive days to ensure storage unit stability is appropriate for vaccine storage.
- Please see the following for details:
    - Individual COVID-19 vaccine chapters.
    - Individual product monographs on the Government of Canada website.

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.

Pharmacies and health care providers require annual fridge inspections conducted by Public Health Units as per the Vaccine Storage and Handling Protocol, 2018 (ontario.ca).

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.

The Vaccine Storage Handling Guidelines, 2021 (or as current) provides details and requirements for monitoring vaccine storage units.

Each facility that receives COVID-19 vaccines should follow the section below on Temperature Excursions in the event of adverse storage conditions for COVID-19

vaccines.

Please note that while the Temperature Log Book identifies refrigerated vaccines, it can also be used for ULT and freezer storage units. Twice daily temperature monitoring is required even if continuous temperature monitoring systems are in place.

Data Loggers

As there are several different data loggers available on the market to monitor the specialized storage units, please consult the product specifications for your particular data loggers, including the requirements for downloading and replacement. For additional information on data logger requirements, please refer to the Vaccine Storage and Handling Protocol, 2018 (ontario.ca) (or as current).

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.

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 electrical 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 VSL Unit. This alternative storage facility or storage unit 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 units and/or insulated containers with appropriate packing materials and digital temperature monitoring devices.
  - 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.
- If an alternative storage facility cannot be identified within a reasonable timeframe, place the vaccine in the insulated container with appropriate 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 storage 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 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. 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 temperature range, then an excursion has occurred; see the process below.

Temperature Excursion

Regardless of what point in the vaccine cold chain (e.g., transport, storage, clinic site etc.) a temperature excursion occurs, steps should be taken to ensure the appropriate management of the affected vaccine.

Note: vaccine viability and final disposition are determined in consultation with the manufacturer's identified primary contact.

General principles: Incident based temperature excursion management processes

Temperature Excursion Management - Process Steps	
Step 1	**Quarantine the vaccine in appropriate temperature-controlled conditions, & document the excursion in COVax$_{ON}$**
Step 2	Health Care Providers and Pharmacies are to report to their local PHU and include: • The date, time, temperatures (maximum, minimum and current temperature) and the details on the excursion (e.g., length of time); and • Attach the temperature log sheets The PHU will consult the appropriate vaccine manufacturer (MFG)/ primary contact
Step 3	**Follow the manufacturer/PHU direction regarding vaccine viability and disposition.** **The facility storing the vaccine will mark vaccines involved in a temperature excursion incident that have been determined to be usable, in order to identify them in case of a future exposure(s).**
Step 4	PHU's will report the excursion to the VSL Unit at: vaccinesupplyandlogistics@ontario.ca (see Appendix A). The site at which the excursion occurred will document the outcome in COVax$_{ON}$ (e.g., report wastage), & appropriately dispose of waste (see Appendix B)

During transit from the manufacturer:

When a temperature excursion occurs during transportation of the vaccine to your site from the manufacturer or the federal government directly, quarantine the product, notify the VSL Unit and National Operations Centre (NOC) email account (see Appendix A for contact information). If outside hours of operation, email for the primary contact should be used and copy the NOC and VSL per Appendix A. For locations receiving vaccines

directly from the manufacturer (e.g., hospitals), the local public health unit and VSL should be notified of the temperature excursion.

Upon completion of the vaccine stability assessment, the PHU will report the outcome via email to the VSL Unit using the following the reporting format in Appendix A. The VSL unit will notify the NOC to advise of the incident, resolution, and any impact on provincial vaccination efforts as applicable.

Temperature excursion reporting when vaccine has been in the custody of a distributor or public health unit:

Facilities storing the COVID-19 vaccine should undertake the following if the vaccine storage units (e.g., purpose-built, 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.
- Follow the Temperature Excursion Management – Process Steps as outlined above.

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
- Prior to storing vaccine in new purpose-built storage units, the temperatures should be stabilized within the recommended range as per the manufacturer. Monitor and document minimum and maximum temperatures for 2 to 7 consecutive days to ensure storage unit stability is appropriate for vaccine storage.

Receipt of Vaccine

Note: Health care provider sites will receive vaccine in a thawed or thawing state, pharmacies and health care providers are to only store vaccine in refrigerated temperatures (e.g., +2°C to +8°C).

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 Handling Guidelines, 2021 (or as current) to educate and instruct health care providers who store publicly funded vaccines.
- 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.
    - Are trained on emergency policies and procedures related to vaccine storage and handling.
- Immediately open all of the transport containers and assess the digital temperature monitoring device(s).
    - Products should be quarantined until all necessary steps have been completed to confirm successful transport (e.g., temperature during transport, condition of product received).
- 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 signing the manifest to acknowledge the receipt of the vaccines;
    - Unpacking the shipment and placing the vaccines immediately in the appropriate 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., +2oC to +8oC);
    - In the event of a temperature excursion, follow the Temperature Excursion process in this document.
- Check vaccine expiry dates regularly and after every vaccine order.
    - Move vaccines with shorter expiry dates to the front of the refrigerator so that they can be used first;
    - Check expiry dates before vaccines are used;
    - Remove expired vaccines and dispose of them appropriately (see Appendix B). Record as wastage in COVax$_{ON}$ (see Vaccine Wastage and Returns section below).

Preparation for Immunization Clinics

Just in Time Vaccine Delivery

- Ensure that only the number of doses of the vaccine needed for the clinic are removed from the storage unit to prevent unnecessary or accidental wastage.
- PHUs and distributors should transport Pfizer-BioNTech and Moderna vaccines in frozen state. The vaccines should be 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 local public health unit.

Vaccine Wastage and Returns

- 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 (see Appendix B). However, they should be recorded in COVax$_{ON}$ as wastage. Follow the COVax$_{ON}$ Inventory Job Aid for direction on inventory reconciliations. Below are the options available in COVax$_{ON}$:

Closed Vial Wastage	
Damaged Doses	• DE – Defective Product – Manufacturer • WR – SVM – Suspected Vaccine Contamination - Manufacturer • DP – OS – Damaged Product • DP – TAO – Damaged product during transport within PHU or between AOs
Expired Doses	• WR – BE – Vaccine vial stored in ult/freezer/fridge temperatures beyond expiry date • WR – RB – Fridge Stable (2 – 8 degrees C) Vaccine Vial Refrigerated beyond use time
Temperature Excursions	• TE – Human Error – Electricity disruption • TE – Human error – Improper storage • TE – Temperature monitoring failure • TE – Cold storage equipment malfunction • TE – Power outage • TE – CCTM – Cold chain failure during transport from manufacturer • TE – CCTDC – Cold chain failure during transportation from distribution center • TE – RF – Vaccine vial refrozen after being thawed • WR – TT – Vaccine transported in thawed state beyond manufacturer recommendations

Open Vial Wastage
• WR - VA - Vaccine Administration Issue • WR - VAS - Vaccine Ancillary Supply Issue Causing Vaccine Wastage • WR - ID - Insufficient Dose(s) From a Single/Multi-Dose Vial • WR - Dose(s) Remaining in a Multi-dose vial • WR - UN - Unused Pre-drawn Syringe • WR - RP – Vaccine vial punctured and not used before beyond use time • WR - SV - Suspected Vaccine Contamination – Human error • TE – F - Fridge Stable (2 - 8 degrees C) vaccine vial frozen • WR - RA – Vaccine vial left in room temperature conditions beyond use time

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 PHU for further direction
    - PHUs and distributors are to contact the manufacturer/primary contact. If outside hours of operation, the PHU should email per below and copy the NOC.
- 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 VSL Unit and report the outcome based on recommendation from the manufacturer via email to the VSL Unit using the following the reporting format in Appendix A. The VSL unit will notify the NOC as required to advise of the incident, resolution, and any impact on provincial vaccination efforts.

Onward Transport of COVID-19 Vaccines beyond the Initial Point of Delivery

For this document, 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 transport and movement of the vaccine. The operational plan should be tailored to local circumstances, with collaboration among the hospitals and public health units.

If possible, air and water transport should be done in a frozen state.

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

- If applicable, 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.
- Product should be sent for 'just in time use' as part of a planned vaccination clinic versus movement for secondary storage at another facility.
- Once diluted (if applicable), transportation is recommended in syringe to prevent agitation of the product in an opened vial. This should only be completed when necessary for vaccination and not part of routine practices.
- 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 and per normal process ensure the following:
    - The cold chain has been properly monitored and 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.
- Packaging of vaccine into storage containers should be done in a 2°C to 8°C environment whenever possible. Otherwise, time at room temperature should be tracked and minimized to stay within the 2-hour allowance for room temperature.

General Precautions for Frozen and Liquid State 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.
- Vials should be stored in an upright position (i.e., standing up) during transport.

- 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 subject to repeated 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 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 Unopened Vials of COVID-19 Vaccine:

- Transport containers should be packed as per the recommendations/specifications for the container (e.g., credo cubes, Stirling coolers).
- Follow the configuration in Vaccine Storage and Handling Guidelines (ontario.ca) Instructions on How to Pre-Condition and Pack an Insulated Container.
- 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 it 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).
- 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 temperature should be maintained and recorded for the duration of the transport per temperature range), 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 the date and time of the vaccine delivery on the storage unit temperature log.
- 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.
- Do not transport the vaccine at room temperature.
- **Do not refreeze previously frozen vaccine.**

In exceptional circumstances, when transporting a syringe containing a **COVID-19 vaccine**, the following parameters should be considered and adhered to:

- A single dose of vaccine should be transported in a syringe.
- Special attention should be paid to handling and packaging of the syringe to prevent contamination.
- The syringe should be protected from light.
- There should be a tamper evident seal on the pre-drawn syringe or container during transport between locations.
- The pre-drawn syringes and the container should be labeled, identifying information to prevent errors during storage, dispensing, transport, and use. Container and pre-drawn labeling components should include:
    - Name and dosage of vaccine
    - Facility name and phone number
    - Quantity of syringes
    - The exact post-puncture date and time (i.e., 12 hours from when the

vaccine vial was first punctured)
    - Lot number
    - Initials of preparer
- The syringe should be packed appropriately in a conditioned cooler (transport container) at +2°C to +8°C and the temperature monitored during transport.
    - Note: The vaccine in the syringe can be at ambient temperature, maximum of +25°C. The vaccine should not be at a temperature below +2°C.
- A barrier of bubble wrap or corrugated cardboard (at least 1 inch) may be utilized as a barrier between ice packs and the container with pre-drawn syringes. This is to prevent direct contact between pre-drawn syringes and the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.
- The syringe should be packed to cushion it and to protect it from agitation
- A designated staff member or specialized courier in cold chain transport (e.g., bonded and contracted companies) should be used to transport the syringe. The cooler/transport container should be:
    - Handled with care and protected from shocks, drops and vibration.
    - Labeled prominently with “Fragile: Handle with care, Do Not Drop” cautionary statements.
    - Secured (strapped/braced) during transport.
- An appropriate chain of custody should be in place for the syringe during all phases of transport.
- If the information regarding the beyond use date and total transport time, or the tamper evident seal, or ability to track the syringe in any way is in question, the vaccine should not be administered and documented as wasted.
- Upon receipt of the syringe, it should be visually inspected to confirm that the full dose remains, there is no damage and that there are no particulates or discolouration.
- If the syringe(s) will not be administered by staff from the originating site, the originating site should confirm with the receiving site all details of the transport, as per above, plus confirmation that administration will be completed at the receiving site by onsite personnel.

Appendix A: Contact Information and Reporting Format for Temperature Excursions or Damaged Products

Organization	Primary Contact	Secondary Contact	Hours of Operation
Pfizer Customer Service	CanadaCSVaccine@pfizer.com	1-800-463-6001	09:00 – 17:00 AEST (M-F)
Innomar QA	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Moderna	excursions@modernatx.com **or** Storage & temperature excursion for Moderna COVID-19 vaccine (modernamedinfo.com)	1-866-663-3762	08:00 – 20:00 EST (M-F)
National Operations Center (NOC) Mailbox	vaccinenoc-cnovaccin@phac-aspc.gc.ca	1-343-572-6999	08:30-16:30 EST (M-F)
MOH, VSL Unit	vaccinesupplyandlogistics@ontario.ca	N/A	09:00 – 17:00 EST (M-F)

Reporting Format

If the vaccine undergoes a temperature excursion or is damaged, the PHU should email the VSL Unit using the following the reporting format:

Date of Incident :	
Vaccine Delivery Site (VDS) Location:	
Vaccine Name:	
Lot Number:	
Expiry Date or Manufacture Date:	
Doses Impacted:	
Manufacturer Recommendations:	
Wastage (number of doses or indicate no wastage):	
Impact on local vaccination efforts:	

Subject line Examples:

Incident	Subject Line
Temperature excursion from manufacturer	Delivery Temp Excursion Report from [PHU – location of incident]
Temperature excursion when in the custody of a vaccine service provider (e.g., hospital, PHU, Pharmacy)	FPT Delivery Temp Excursion Report from [PHU – location of incident]
Product is damaged	COVID-19 Vaccine Damage Report from [PHU – location of incident]

If the request is urgent, include ‘URGENT’ in the email subject line.

The VSL Unit will notify the NOC as required to advise of the incident, resolution and any impact on provincial vaccination efforts.

Appendix B: Vaccine Vial and Packaging Disposal

Vials, either empty or with vaccine remaining, should be disposed of per regulation and guidelines by the Ministry of the Environment and Climate Change:

- Environmental Protection Act, R.S.O. 1990, c. E.19, Regulation 347
- C-4: The Management Of Biomedical Waste In Ontario
- Registration Guidance Manual for Generators of Liquid Industrial and Hazardous Waste

Further details can be found in the Vaccine Storage Handling Guidelines, 2021.