

Ministry of Health

COVID-19: Vaccine Storage and Handling Guidance

Version 7.4 – March 24, 2022

Highlights of changes:

- Addition of Novavax Nuvaxovid COVID-19 vaccine

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 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.

As part of the current efforts to reach increased vaccination coverage targets in the province to protect individuals and the population, 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.

Therefore, opening a vial to vaccinate one or a small number of individuals may be necessary to support vaccination efforts and reaching provincial targets. This is especially important where a vial is reaching its “must use by” date. Efforts should continue to be made in these instances to locate other potential individuals for vaccination (e.g., waitlists) wherever 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 should also follow the:

- [Vaccine Storage and Handling Protocol](#), 2018¹;
- 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](#);
- Ministry of Health's Emergency Operations Centre (MEOC) at EOCOperations.moh@ontario.ca, if you have already consulted with your public health unit and have further questions.

For details and guidance on withdrawing additional doses of vaccines from single vials and pooling product across vaccine vials refer to Appendix H.

- Pfizer-BioNTech has two (2) formulations of the COMIRNATY® vaccine authorized for use in Canada.

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

- Pediatric Pfizer-BioNTech COVID-19 Vaccine for children 5 to < 12 years of age ("Pediatric Pfizer-BioNTech vaccine"). This vaccine has an orange cap and label and;
- Pfizer-BioNTech COVID-19 Vaccine ("Pfizer-BioNTech vaccine") for use in those aged 12 years of age and older, which has a purple cap and label².
- AstraZeneca's VAXZEVRIA™ COVID-19 Vaccine will be referred to AstraZeneca.
- Moderna's SPIKEVAX™ COVID-19 Vaccine will be referred to as Moderna.
- Janssen COVID-19 Vaccine manufactured by Janssen will be referred to as Janssen.
- Novavax Nuvaxovid COVID-19 vaccine will be referred to as Novavax.

² There may be residual vials still available with a purple cap but without the purple label.

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Refrigerator Stable COVID-19 Vaccine Storage and Transport

For the authorized COVID-19 vaccines from AstraZeneca and Novavax, storage and handling guidance and recommendations should follow existing practices for refrigerator stable vaccines at +2°C to +8°C.

Please see the following for details:

- [Appendix A: Storage Requirements for COVID-19 Vaccine Products](#);
- Individual product monographs on the [Government of Canada website](#);
- [Vaccine Storage and Handling Protocol](#), 2018³;
- [Vaccine Storage Handling Guidelines](#).

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 vaccine:** The internal temperature of the unit should be stabilized between -90°C to -60°C (-130°F to -76°F) prior to stocking vaccine. Recommended storage temperature is -70°C.
- **Pediatric Pfizer-BioNTech vaccine:** The internal temperature of the unit should be stabilized between -90°C to -60°C (-130°F to -76°F) prior to stocking vaccine.
- **Moderna and Janssen vaccines:** 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. Prior to storing vaccine in the storage unit, the temperatures should be within the required storage temperature. Monitor and document minimum and maximum temperatures for

³ Please note Public Health Units must comply with Ontario Public Health Standards including the Vaccine Storage and Handling Protocol, 2018.

2 to 7 consecutive days to ensure storage unit stability is appropriate for vaccine storage.

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](#)⁴ twice daily (beginning and end of each business day) and reset the digital temperature monitoring device after recording/downloading the readings.⁵ As there are several different data loggers required for the monitoring of the specialized storage units, 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. Report any out-of-range temperatures immediately.

⁴ Please note that while the Temperature Log Book identifies refrigerated vaccines, it can also be used for ULT and freezer storage units.

⁵ 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.

- 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.
- 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.
- 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 Logistics and Inventory Management (L&IM) Team for any temperature excursions at Covid.Logistics@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 vaccines can be found in [Appendix B](#), and for Moderna vaccine in [Appendix C](#), and AstraZeneca in [Appendix D](#), Janssen in [Appendix E](#), [and Novavax in Appendix F](#).

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 Logistics & Inventory Management (L&IM) Team. 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 (-90°C to -60°C) or in a freezer temperature portable unit (-25°C to -15°C), the vaccines can go back into an ULT unit. For vaccines stored at freezer temperatures of -25°C to -15°C, the vaccine may be returned to a ULT storage unit only once. Any hours used for transport at this temperature range are cumulative and should be tracked to ensure the 2-week limit for storage at -25°C to -15°C is followed. 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 31 days, minus any time in the container.

Pediatric Pfizer-BioNTech Vaccine

- If placed in an ULT portable unit (-90°C to -60°C), the vaccines can go back into a purpose built ULT storage unit. The Pediatric Pfizer-BioNTech COVID-19 vaccine cannot be stored at -25°C to -15°C.
- Vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons.
- The vaccine may be thawed and stored in refrigerated temperatures (+2°C to +8°C) for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer.
- 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 portable storage device

Moderna Vaccine

- If placed in a portable freezer unit (-25oC to -15oC), 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 +2oC to +8oC 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 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).

Janssen Vaccine

- Based on information provided from the manufacturer, vaccine can be shipped and stored in a frozen state. For further details visit: https://www.janssenmedicalinformation.ca/covid-19_vaccine_resources
- To review the Janssen COVID-19 product monograph visit: <https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf>
- 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 portable storage device.
- The vaccine can be stored and transported at +2°C to +8°C for a single period of up to 6 months, not exceeding the original expiry date.
 - Upon moving the product to a refrigerator at +2°C to +8°C the updated expiry date must be written on the carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable.
- If an alternative storage facility cannot be identified within a reasonable timeframe, place the vaccine in the portable freezer unit and/or insulated containers 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).

AstraZeneca and Novavax Vaccines

- AstraZeneca can be stored and transported at +2°C to +8°C up to expiry.
- The Novavax vaccine can be stored and transported at +2°C to +8°C for up to 9 months.
- 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).

Pfizer-BioNTech Vaccine

- If the Pfizer-BioNTech vaccine was stored in an ULT -90°C portable unit, or in a unit at -25°C to -15°C (and not thawed), return to the ULT purpose-built storage unit.
 - The Pfizer-BioNTech vaccine can stored in a freezer at -25°C to -15°C for up to two weeks.
 - Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -90°C to -60°C.
 - The total time vials are stored or transported at -25°C to -15°C should be tracked and not exceed a cumulative total of 2 weeks.

Pediatric Pfizer-BioNTech Vaccine

- If the Pediatric Pfizer-BioNTech vaccine was stored in an ULT -90°C portable unit, return it to the ULT purpose-built storage unit. The formulation for age 5 to <12 **cannot** be stored at -25°C to -15°C.
 - Once vials thaw, they should not be refrozen. Store thawed vials in refrigerated temperatures for up to 10 weeks. The updated expiry date should be recorded on the vial/carton at the time of transfer

Moderna Vaccine

- If the Moderna was stored in a portable -20°C freezer unit (and not thawed), return to a purpose-built freezer unit.

Janssen Vaccine

- If the Janssen vaccine was stored in a portable freezer between -25oC to -15oC (and not thawed), return to a purpose-built freezer unit, product can be used to expiry.
- If any of the COVID-19 vaccines are kept in an insulated container, in cold-chain (+2°C to +8°C) place them into the refrigerator and ensure doses are used within:
 - 31 days minus any time the vaccine was in the container for the Pfizer-BioNTech vaccine, and 10 weeks for the Pediatric Pfizer-BioNTech vaccine.
 - 30 days minus any time the vaccine was in the container for the Moderna vaccine.

- 6 months not exceeding the original expiry date for the Janssen COVID-19 vaccine. Upon moving the product to a refrigerator at +2oC to +8oC, the updated expiry date must be written on the carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable for the Janssen vaccine.
- The expiry period for the AstraZeneca vaccine.
- 9 months for the Novavax 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. 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

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 (see p. 13).

General principles: Incident based temperature excursion management processes

Temperature Excursion Management - Process Steps			
1. Quarantine the vaccine in appropriate temperature - controlled conditions	2. Consult the appropriate vaccine manufacturer (MFG)/ primary contact	3. Follow the MFG/primary contact's direction regarding vaccine viability and disposition	4. Report the excursion to: Covid.Logistics@ontario.ca, report waste in COVaxoN, & appropriately dispose of waste (see Appendix H)

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 (i.e., FedEx/Innomar) directly, quarantine the product, notify the L&IM Team and National Operations Centre (NOC) email account immediately and contact the FedEx/Innomar as appropriate. If outside hours of operation, email for the primary contact should be used and copy the NOC per below. For locations receiving vaccines directly from the manufacturer (e.g., hospitals), the local public health unit should be notified of the temperature excursion.

Organization	Primary Contact	Secondary Contact	Hours of Operation
Pfizer Customer Service	CanadaCSVaccine@Pfizer.com	1-833-829-2684	07:30 – 19:30 EST (M-F)
Innomar QA	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
AstraZeneca	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Janssen Medical Information	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Moderna	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Novavax	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
NOC Mailbox	PHAC.vaccine.NOC-CON.vaccin.ASPC@canada.ca	1-613-952-0865	24 hrs, 7 days a week
MOH, L&IM Team	Covid.Logistics@ontario.ca	N/A	09:00 – 17:00 EST (M-F)

- Upon completion of the vaccine stability assessment, the PHU will report the outcome via email to the L&IM Team using the following reporting format:
 - Subject: Delivery Temp Excursion Report (if the request is urgent, include 'URGENT' in the email subject line)
 - Date of Incident
 - Vaccine Delivery Site (VDS) Location
 - Vaccine name
 - Vaccine lot number
 - Expiry date or manufacture date
 - Number of doses impacted by the excursion
 - Manufacturer recommendations
 - Wastage (number of doses or indicate no wastage)
 - Impact on local vaccination efforts
- The L&IM Team 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 hospital 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.

- 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); and
 - Attach the PDF file.
- The public health unit will contact the primary manufacturer contact as well as copy the NOC while initiating the Adverse Storage Conditions form with the facility.

Organization	Primary Contact	Secondary Contact	Hours of Operation
Pfizer Customer Service	CanadaCSVaccine@pfizer.com	1-833-829-2684	07:30 – 19:30 EST (M-F)
Innomar QA	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
AstraZeneca	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Janssen Medical Information	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Moderna	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Novavax	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
NOC Mailbox	PHAC.vaccine.NOC-CON.vaccin.ASPC@canada.ca	1-613-952-0865	24 hrs, 7 days a week
MOH, L&IM Team	Covid.Logistics@ontario.ca	N/A	09:00 – 17:00 EST (M-F)

- The public health unit will notify the L&IM Team once the vaccine manufacturer/primary contact 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 L&IM Team using the following reporting format:
 - Subject: FPT Delivery Temp Excursion Report (if the request is urgent, include 'URGENT' in the email subject line)
 - Date of Incident
 - Vaccine Delivery Site (VDS) Location
 - Vaccine name
 - Vaccine lot number
 - Expiry date or manufacture date
 - Number of doses impacted
 - Manufacturer recommendations
 - Wastage (number of doses or indicate no wastage)
 - Impact on local vaccination efforts
- The L&IM Team 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 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 COVaxON.

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

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 Handling Guidelines](#), 2012 (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.
- Immediately open all of the transport containers and assess the digital temperature monitoring device(s).

- Products should be quarantined until all necessary steps to confirm successful transport are complete (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 sign the manifest to acknowledge the receipt of the vaccines;
 - For Pfizer-BioNTech and Moderna 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-BioNTech = 31 days, Pediatric Pfizer-BioNTech = 10 weeks and; Moderna = 30 days).
 - Pediatric Pfizer-BioNTech vaccine may be stored at +8°C to +25°C for a maximum of 24 hours prior to dilution.
 - **Note:** vaccine vial labels for the Pediatric Pfizer-BioNTech vaccine (Orange cap), are provided in English-only and exclude an expiration date; rather, it indicates a manufacturing date (MFG date) to guide expiration, which is 6 months after the MFG date. Labels currently also exclude a Drug Identification Number (DIN), name and address of the Canadian DIN holder, name and address of the Canadian importer and distributor, and the vaccine brand name of "COMIRNATY".
 - For the Janssen vaccine, if the vaccines were received at +2°C to +8°C, the vaccine may be stored at refrigerated temperatures.
 - If the vaccine is received refrigerated at +2°C to +8°C, check that the expiry date has been updated by the local supplier upon receipt. If you cannot find the new expiry date (EXP date), contact the local supplier to confirm the refrigerated EXP date. Write the new expiry date on the carton before the vaccine is stored in the refrigerator. The original expiry date should be made unreadable.

- **Important Note:** for a limited time, Janssen COVID-19 vaccines are being dispatched in Canada with EU English-only labels on vials and cartons. Information pertaining to the vaccine's Drug Identification number (DIN), name and address of the Canadian DIN holder, name and address of the Canadian importer and distributor, storage and expiry date instructions are not provided on the label. Therefore, information pertaining to the storage of Janssen found in this document should be followed. Otherwise, information may be accessed by scanning the carton's QR code, by visiting <http://www.covid19vaccinejanssen.com>, or contacting Janssen Inc. Medical Information. The vaccine's date of expiry for storage may be found on the vial and carton after "EXP". For further details visit page 15 of the product monograph by visiting <https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf>.
- For Pfizer-BioNTech vaccine, if the vaccines were received at freezer temperature (i.e., between -25°C to -15°C), document the amount of time remaining from cumulative freezer storage/transport conditions (i.e., Pfizer-BioNTech = 2 weeks);
 - **Note:** The Pediatric Pfizer-BioNTech vaccine **cannot** be stored at -25°C to -15°C.
- 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., +2°C to +8°C);
- 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 H](#)). Record as wastage in COVaxON (see Vaccine Wastage and Returns section below).
- Based on updated authorization from Health Canada, cartons and purple label vials of Pfizer-BioNTech vaccine with an expiry date of August 2021 through February 2022 printed on the label, may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60° C (-130° F to -76°F) have been maintained. The approved extended expiration date applies to vials which have been stored for up to 2 weeks at -25°C to -15°C then returned to ULT (-90°C to -60°C).
 - The updated Product Monograph can be found at the following link: <https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf>
 - Further information on Pfizer-BioNTech's COVID-19 Vaccine 3-Month Extension to Expiry Dates on Vials and Cartons Currently in Canada and Expansion of Approved Ultra Low Temperature Storage Conditions can be found here:
 - <https://www2.gnb.ca/content/dam/gnb/Departments/eco-bce/Promo/covid-19/extended-expiry.pdf>
- **Pediatric Pfizer-BioNTech Product Extension**
 - On January 20, 2022, Health Canada authorized an update to the Pediatric Pfizer-BioNTech COVID-19 Vaccine product monograph to allow a 3-month shelf-life extension to all vials with an Orange Cap and Orange Label Border. This 3-month extension applies to all vials of the Orange Cap and Orange Label Border that have been delivered to Canada.
 - Based on this authorization, cartons and vials of COMIRNATY (Pfizer-BioNTech COVID-19 Vaccine) with an Orange Cap and Orange Label Border (for individuals 5 to <12 years of age) can be used up to nine (9) months from the date of manufacture printed on the vials and cartons if the approved storage conditions are maintained.
 - Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.

Extension on Pediatric Pfizer-BioNTech (Orange Cap)

The new expiry dates for the affected vials are shown in the table below.

Manufacturer Date	Updated Expiry Date
August 2021	April 30, 2022
September 2021	May 31, 2022
October 2021	June 30, 2022
November 2021	July 31, 2022
December 2021	August 31, 2022
January 2022	September 30, 2022
February 2022	October 31, 2022
March 2022	November 30, 2022
April 2022	December 31, 2022
May 2022	January 31, 2023

- **Moderna Product Extension**

- Health Canada has authorized a 2-month shelf-life extension (from 7 months to 9 months) for all lots of MODERNA SPIKEVAX (elasomeran). This extension is retrospectively applied to units (10-dose or 5mL fill volume vials) carrying English-only labels with a printed expiry date between December 2021 and August 2022.

Extension on MODERNA SPIKEVAX 10-Dose vials

The new expiry dates for the affected vials are shown in the table below.

Original (Printed) Expiry Date	Updated Expiry Date
December 2021	February 2022
January 2022	March 2022
February 2022	April 2022
March 2022	May 2022
April 2022	June 2022
May 2022	July 2022
June 2022	August 2022
July 2022	September 2022
August 2022	October 2022

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. Pfizer-BioNTech, Moderna, and Janssen vaccines 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 local public health unit.

Thawing Pfizer-BioNTech vaccine:

- Thaw Pfizer-BioNTech vaccine in the refrigerator at +2°C to +8°C, a carton of vials may take up to 3 hours to thaw. Alternatively, vials may thaw at room temperature (up to +25°C) for 30 minutes.
 - Using either thawing methods, vials must reach room temperature before dilution and must be diluted within 2 hours of exposure to room temperature.
- Once thawed, unpunctured vials may be stored at +2°C to +8°C for up to 31 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 from the time of first puncture (dilution).
- 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.

Thawing Pediatric Pfizer-BioNTech vaccine:

- Verify that the vial of Pfizer-BioNTech vaccine has an orange cap and a label with an orange border and states "Age 5y - <12y".
- Thawing options include:
 - Allow vial(s) to thaw in the refrigerator between +2°C to +8°C. A carton of 10 vials may take up to 4 hours to thaw.
 - Allow vial(s) to sit at room temperature (up to +25°C) for up to 30 minutes.
- Undiluted vials may be stored between +8°C to +25°C for up to 24 hours prior to mixing (including thaw time).
 - The product monograph outlines a 12-hour storage time at +8°C to +25°C however additional stability data from the manufacturer allows for an additional 12 hours for a total of 24 hours. Evaluation of excursions of undiluted vials stored beyond the labeled 12-hour allowance at room temperature must consider total storage time of vials pre and post dilution.

Thawing Moderna vaccine:

- Thaw Moderna vaccine in the refrigerator between +2°C to +8°C for 2 hours and 30 minutes. Alternatively, vials can be thawed at room temperature between +15°C to +25°C for 1 hour.
 - Let vaccine stand at room temperature for 15 minutes before administering.
- 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 24 hours. Moderna vaccine cannot be refrozen.
 - Appropriate labeling including “must use by dating/timing” can provide visual cues to indicate product viability of use.
- During storage, vials should be protected from light.
- The Moderna vaccine should be used within 24 hours from the time of first puncture.

Thawing AstraZeneca vaccine:

- Unpunctured vials may be kept at +2°C to +8°C in a refrigerator until the product expiry date.
- Vials should not be frozen.
- During storage, vials should be stored in outer carton in order to protect from light.
- Punctured vials may should be used within 6 hours if kept at room temperature (up to +30°C) or within 48 hours at +2°C to +8°C in a refrigerator.

Thawing Janssen vaccine:

- Thaw in refrigerated temperatures at +2°C to +8°C
 - When stored frozen at -25°C to -15°C a carton of 10 vials will take approximately 13 hours to thaw.
 - Individual vials will take approximately 2 hours to thaw in refrigerated temperatures.
 - Do not re-freeze once thawed.
- Thaw at room temperature

- When stored frozen at -25°C to -15°C a carton of 10 vials or individual vials should be thawed at room temperature up to +25°C.
 - A carton of 10 vials will take approximately 4 hours to thaw.
- Individual vials will take approximately 1 hour to thaw.
- The vaccine is stable for a total of 12 hours at +9°C to +25°C. This is not a recommended storage condition or shipping condition but may guide decisions for use in case of temporary temperature excursions.
- Do not re-freeze once thawed.

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 I). However, they should be recorded in COVax_{ON} 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 manufacturer specifications
 - Vial(s) left at room temperature beyond 12 hours;
 - Stored in ULT/freezer temperatures beyond expiry date;
 - Stored in refrigerated temperatures (+2oC to +8oC) beyond manufacturer guidelines:
 - 31 days for Pfizer-BioNTech;
 - 10 weeks for Pediatric Pfizer-BioNTech;
 - 30 days (Moderna and AstraZeneca);
 - Janssen up to 6 months not exceeding original EXP date;

- Novavax up to 9 months.

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/primary contact. If outside hours of operation, the PHU should email per below and copy the NOC.

Organization	Primary Contact	Secondary Contact	Hours of Operation
Pfizer Customer Service	CanadaCSVaccine@Pfizer.com	1-833-829-2684	07:30 – 19:30 EST (M-F)
Innomar QA	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
AstraZeneca	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Moderna	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Janssen Medical Information	QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
Novavax	mailto:QA-GMP@innomar-strategies.com	1-833-847-4270	07:30 – 19:30 EST (M-F)
NOC Mailbox	PHAC.vaccine.NOC-CON.vaccin.ASPC@canada.ca	1-613-952-0865	24 hrs, 7 days a week
MOH, L&IM Team	Covid.Logistics@ontario.ca	N/A	09:00 – 17:00 EST (M-F)

- 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 L&IM Team and report the outcome based on recommendation from the manufacturer via email to the L&IM Team using the following reporting format:
 - Subject: COVID-19 Vaccine Damage Report (if the request is urgent, include 'URGENT' in the email subject line)
 - Date of Incident
 - Vaccine Delivery Site (VDS) Location
 - Vaccine name
 - Vaccine lot number
 - Expiry date or manufacture date
 - Number of doses impacted
 - Manufacturer Recommendations
 - Wastage (number of doses or indicate no wastage)
 - Impact on local vaccination efforts
- The L&IM Team 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

Pfizer-BioNTech

Storage Condition	Pfizer-BioNTech (Purple Cap)	Pediatric Pfizer-BioNTech (Orange Cap)
Frozen Vials Prior to Use	<ul style="list-style-type: none"> Kept between -90°C to -60°C (-130°F to -76°F) until expiry date indicated on the label. <ul style="list-style-type: none"> A month extension applies to vaccines with an expiry date of August 2021- February 2021 (as mentioned above) Protected from light, in the original packaging, until ready to use. Can store in a freezer at -25°C to -15°C for up to two weeks. Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to storage condition of -90°C to -60°C. Track the total time vials are stored at -25°C to -15°C. Cumulative total of 2 weeks should not be exceeded. 	<ul style="list-style-type: none"> Kept between -90°C to -60°C up to 6 months from manufacturing date. Do not store at -25°C to -15°C temperatures. Protected from light, in the original packaging, until ready to use.
Thawed, unpunctured vials	<ul style="list-style-type: none"> Prior to dilution, thaw and store at +2°C to +8°C for up to 31 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. 	<ul style="list-style-type: none"> Thawed vials may be stored at +2°C to +8°C for up to 10 weeks or at room temperature (up to +25°C) for no more than 24 hours prior to dilution. 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.

Storage Condition	Pfizer-BioNTech (Purple Cap)	Pediatric Pfizer-BioNTech (Orange Cap)
Thawed, punctured vials	<ul style="list-style-type: none"> • After dilution, store between +2°C to +25°C and use 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, can be handled in room light conditions. 	<ul style="list-style-type: none"> • After dilution, store between +2°C to +25°C and use within 24 hours from time of first puncture. <ul style="list-style-type: none"> ○ Additional stability data has been provided from the manufacturer which supports an additional 12 hours of cumulative storage in vials or syringes to total 24 hours (12 hours as listed in the product monograph plus an additional 12 hours excursion time). • Syringe Stability <ul style="list-style-type: none"> ○ Additional stability data from Pfizer supports storage of diluted vaccine in syringes for <ul style="list-style-type: none"> ▪ up to 24 hours in refrigerated temperatures (+2°C to +8°C) ▪ up to 12 hours at room temperature (+8°C to +25°C) ○ Total cumulative time post-dilution cannot exceed 24 hours. • During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Note: Diluent for Pfizer-BioNTech COVID-19 vaccine should be stored between +20°C to +25°C; storage outside of this range must be tracked. Excursions at +15°C to +30°C are permitted, providing diluent is stored in a temperature stable environment. Diluent may be stored at 2°C to 20°C for up to five (5) days.

Diluent stored outside of these temperature ranges must be assessed by the manufacturer prior to use.

For further information visit: www.cvdvaccine.ca

Moderna

Storage Condition	Moderna
Frozen Vials Prior to Use	<ul style="list-style-type: none"> Kept between -25°C to -15°C Protected from light. Do not store on dry ice or below -40°C.
Thawed, unpunctured vials	<ul style="list-style-type: none"> If not punctured, thaw and store at +2°C to +8°C for up to 30 days, or at +8°C to +25°C for up to 24 hours. Within the allowable 30-day period for vials stored under refrigeration at +2°C to +8°C, a cumulative exposure up to 24 hours to temperatures between +8°C to +25°C is permitted. During storage, protect vials from light. Do not refreeze thawed vials.
Thawed, punctured vials	<ul style="list-style-type: none"> Store between +2°C to below +25°C and use within 24 hours from the time of first puncture. During storage, protect vials from light.
<p>Note: Moderna vaccine vials should not be puncture more than 20 times; for more information visit: https://modernacovid19global.com/ca/</p>	

AstraZeneca

Storage Condition	AstraZeneca
Unopened, multidose vial	<ul style="list-style-type: none"> • Store and transport in refrigerated conditions at +2°C to +8°C. • Do not freeze. • Protect from light (e.g., store vial in original packaging).
Opened, multidose vial	<p>After first puncture, use the vial within:</p> <ul style="list-style-type: none"> • 6 hours cumulative when stored at room temperature (up to +30°C), or • 48 hours cumulative when stored at refrigerated conditions (+2°C to +8°C). • After this time, the vial must be discarded and wasted doses recorded.

Novavax

Storage Condition	Novavax
Unopened, multidose vial	<ul style="list-style-type: none"> • Store and transport in refrigerated conditions at +2°C to +8°C for up to 9 months • Do not freeze. • Protect from light (e.g., store vial in original packaging).
Opened, multidose vial	<p>After first puncture, use the vial within:</p> <ul style="list-style-type: none"> • 6 hours cumulative when stored at +2°C to +25°C • After this time, the vial must be discarded and wasted doses recorded. • a pre-filled syringe is stable for 6 hours between 2°C and 25°C

Janssen

Storage Condition	Janssen
Frozen Vials Prior to Use	<ul style="list-style-type: none"> Vaccine can be kept frozen -25°C to -15°C until expiry Protect from light
Thawed, unpunctured vials	<ul style="list-style-type: none"> The vaccine can be stored and transported at +2°C to +8°C for a single period of up to 6 months, not exceeding the original expiry date. The vaccine is stable for 12 hours at +9°C to +25°C. It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.
Thawed, punctured vials	<ul style="list-style-type: none"> Once punctured the vaccine can be held at 2°C to +8°C for up to 6 hours. Discard the vaccine if it is not used within this time. After the first puncture the vaccine can be held at room temperature (up to +25°C) for a single period of up to 3 hours, discard if the vaccine is not used within this time and report wasted doses. Note: Maximum hold times for these 2 temperature ranges are not cumulative (i.e., the vaccine cannot be held at room temperature for 3 hours and then held refrigerated for another 6 hours). <ul style="list-style-type: none"> If 3-hour time limit at room temperature is not reached, the punctured vial may be transferred to a refrigerated storage unit (+2°C to +8°C) for the remaining time, up to 3 hours. For example, a vial held at room temperature for 1 hour after first puncture can be stored in the refrigerator (+2°C to +8°C) for no more than 2 hours before using or discarding. If the 3-hour time limit at room temperature has been met, it must be discarded and cannot be transferred to the refrigerator.
<p>Note: Review the Janssen product monograph by visiting: https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf</p> <p>For further information and resources visit: https://www.janssenmedicalinformation.ca/covid-19_vaccine_resources.</p>	

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: Onward Transport of Pfizer-BioNTech beyond the Initial Point of Delivery

Pfizer-BioNTech Vaccine (Purple Cap)

Pfizer-BioNTech recommends that their vaccine is shipped in a frozen state at ultra-low temperatures as per the product monograph and specifications. If not possible, vials may be transported at -25°C to -15°C or at refrigerated temperatures at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$, see below for details; note, the length of time required to transport vaccines at refrigerated temperatures counts toward the one-month storage limit.

A summary of Pfizer-BioNTech storage specifications can be found at the end of this Appendix.

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.

Air and water transport should be done in a frozen state.

While Pfizer-BioNTech has conducted limited studies to understand the stability of diluted vaccines, it is recommended that transport is undertaken in a pre-filled syringe (see below).

For ground transport at -25°C to -15°C see section below.

For ground transport at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ 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 $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$.
- In this state, the unopened vaccine vials should be in transport for no more than 12 hours of cumulative time.

- 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, 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. See below for guidance on transport of Pfizer-BioNTech vaccine in syringes.
- 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;
 - The cumulative total travel time does not exceed 12 hours 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.
- Repacking 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.
- Transporting diluents with their corresponding vaccine (in separate containers due to unique storage requirements) so there are always equal amounts of vaccines and diluents for reconstitution. Diluent storage and handling requirements should always be adhered to by Points of Distribution when transporting and redistributing.

General Precautions for Frozen (-25°C to -15°C) and 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.
- Vials should be stored in an upright position (i.e., standing up) during transportation.

- 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 Unopened Vials of the Pfizer-BioNTech Vaccine:

- Transport containers used for -25°C to -15°C temperature range should be packed as per the recommendations/specifications for the container (e.g., credo cubes, stirring coolers).
- For packing of insulated containers for +2°C to +8°C transport see the guidance provided on vaccine storage and handling for refrigerated vaccines in [Appendix G](#).
- 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).

- 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 (+2°C to +8°C or -25°C to -15°C), 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.
- 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.

Frozen (-25°C) Transport

- Any time in transport at this temperature should be counted towards the 2-week total cumulative time a vial can be stored/transported at this temperature range.
- Vials transported/stored at this temperature range may be returned once into an ultra-cold storage unit. If a vial(s) begins to thaw or is stored at temperatures above -15°C, they should not be refrozen.

Liquid State (+2°C to +8°C) Transport

- Do not pack vaccines that are 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 G: Instructions on How to Pre-Condition and Pack an Insulated Container](#).
- The total transportation time should be no greater than 12 hours.
- The time in transit at +2°C to +8°C should be considered part of the 31 days 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 31 days.
- Do not transport the vaccine at room temperature.
- Do not refreeze the vaccine.

Transport of Open (Punctured) Vials or Syringes Containing Pfizer-BioNTech COVID-19 Vaccine

While not recommended as routine practice, in exceptional circumstances it is recommended that diluted Pfizer-BioNTech vaccine, be transported in a syringe whilst careful attention is taken to adhere to the parameters identified below.

Exceptional circumstances could include situations in which a few doses are needed to support the immunization and series completion of small numbers of individuals residing in congregate settings (i.e., one or two residents) and for those who are home bound (e.g., those who may be unable to attend a community-based clinic due to physical limitations). When at all possible, it is recommended that unpunctured vials of vaccine be transported and the entire vial of vaccine administered in one location over transporting syringes filled with vaccine.

It is recommended that vaccine is transported in a syringe as once a vial has been punctured the air pressure in the vial will have been changed and the potential for agitation (physical stress) of the mRNA in the vaccine is more likely.

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

- A single dose of Pfizer-BioNTech vaccine should be transported when in a syringe.

- The vaccine does not contain a preservative, therefore 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 beyond-use date and time (i.e., 6 hours from when the Pfizer-BioNTech 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.
- If the syringe being transported is from a vial that was previously transported at fridge temperature, then the total transportation time – the time in the syringe (drawn up dose) and the time the vial was transported.
- **Drawn up vaccine must be administered within 6 hours from the time the vial was first punctured. Transport time is a maximum of 6 hours.**

- 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 there are no particulates nor discoloration.
- 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.

Example of pre-drawn syringe and container labels:

**Pfizer-BioNTech COMIRNATY COVID-19 Vaccine for 12 years of age and older
(30 mcg/0.3 mL) IM suspension**

Facility name and phone number:

Quantity of syringes:

Date prepared & Time to discard (6 hours after puncture):

Lot #:

Initials of preparer:

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 for longer term storage (ULT or frozen).

- Transport of the vaccine for storage at another facility should be done in the frozen state at ultra-cold temperature. May also be done at -25°C to -15°C per details and recommendations above.

Scenario 2: Ground Transport between Locations or Facilities

Transport from a hospital to a congregate living setting.

- Frozen (-15°C to -25°C) transport or liquid state (+2°C to +8°C) transport, see product monograph and above for details and recommendations.

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, ultra-cold temperature, but may also be done at -25°C to -15°C per product monograph and details and recommendations above.

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 (Purple Cap)
Frozen Vials	<ul style="list-style-type: none"> Kept frozen between -90°C to -60°C Protected from light. Can store in a freezer at -25°C to -15°C for up to two weeks. Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to storage condition of -90°C to -60°C. The total cumulative time vials are at -25°C to -15°C should be tracked and not exceed a total of 2 weeks. On August 27, 2021, Health Canada authorized an update to the Pfizer-BioNTech COVID-19 Vaccine Product Monograph to allow a 3-month extension to the expiry date for all Pfizer-BioNTech Covid-19 Vaccine vials stored between -90°C to -60°C and with expiry dates of August 2021 through February 2022 printed on the vial and carton labels. The approved extended expiration date applies to vials which have been stored for up to 2 weeks at -25°C to -15°C then returned to ULT (-90°C to -60°C).
Thawed, unpunctured vials	<ul style="list-style-type: none"> Thawed, undiluted and stored at +2°C to +8°C for up to 31 days, 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	<ul style="list-style-type: none"> Diluted, stored between +2°C to below +25°C and used within 6 hours from the time of first puncture. Once a vial has been punctured, it should be disposed of within 6 hours. The dose in the syringe should be used as soon as feasible, and no later than 6 hours after the vials was first punctured. During storage, vials should be protected from light.

Pediatric Pfizer-BioNTech Vaccine (Orange Cap)

Pfizer-BioNTech's pediatric formulation recommends that their vaccine be shipped in a frozen state at ultra-low temperatures as per the product monograph and specifications. If not possible, vials may be transported at refrigerated temperatures at +2°C to +8°C, see below for details;

A summary of the Pediatric Pfizer-BioNTech vaccine storage specifications can be found at the end of this Appendix.

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.

Air and water transport should be done in a frozen state.

While the Pediatric Pfizer-BioNTech has conducted limited studies to understand the stability of the diluted vaccines, it is recommended that transport is undertaken in a pre-filled syringe (see below).

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.
- 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, 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. See below for guidance on transport of pediatric Pfizer-BioNTech vaccine in syringes.
- 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.
- Repacking should be done in a 2°C to 8°C environment whenever possible. Otherwise, time at room temperature should be minimized

General Precautions for ULT (-90°C to -60°C) and 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.
- Vials should be stored in an upright position (i.e., standing up) during transportation.
- 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 Unopened Vials of the Pediatric Pfizer-BioNTech Vaccine:

- Transport containers used for -90°C to -60°C temperature range should be packed as per the recommendations/specifications for the container
- For packing of insulated containers for +2°C to +8°C transport see the guidance provided on vaccine storage and handling for refrigerated vaccines in [Appendix G](#).
- 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).
- 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 (+2°C to +8°C or -90°C to -60°C), 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.
- 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.

ULT (-90°C to -60°C) Transport

- Vials transported/stored at this temperature range may be returned once into an ultra-cold storage unit. If a vial(s) begins to thaw or is stored at temperatures above -60°C, they should not be refrozen.

Liquid State (+2°C to +8°C) Transport

- Do not pack vaccines that are 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 G: Instructions on How to Pre-Condition and Pack an Insulated Container](#).
- The time in transit at +2°C to +8°C should be considered part of the 10 weeks 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 10 weeks.
- Do not transport the vaccine at room temperature.
- Do not refreeze the vaccine.

Transport of Open (Punctured) Vials or Syringes Containing Pediatric Pfizer-BioNTech Vaccine

While not recommended as routine practice, in exceptional circumstances it is recommended that diluted Pediatric Pfizer-BioNTech vaccine be transported in a syringe whilst careful attention is taken to adhere to the parameters identified below.

Exceptional circumstances could include situations in which a few doses are needed to support the immunization and series completion of small numbers of individuals residing in congregate settings (i.e., one or two residents) and for those

who are home bound (e.g., those who may be unable to attend a community-based clinic due to physical limitations). When at all possible, it is recommended that unpunctured vials of vaccine be transported and the entire vial of vaccine administered in one location over transporting syringes filled with vaccine.

It is recommended that vaccine is transported in a syringe as once a vial has been punctured the air pressure in the vial will have been changed and the potential for agitation (physical stress) of the mRNA in the vaccine is more likely.

In exceptional circumstances, when transporting a syringe containing the Pediatric Pfizer-BioNTech vaccine, the following parameters should be considered and adhered to:

- A single dose of Pediatric Pfizer-BioNTech vaccine should be transported when in a syringe.
- The vaccine does not contain a preservative, therefore 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 beyond-use date and time (i.e., 25 hours from when the Pediatric Pfizer-BioNTech 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.
- **Drawn up vaccine must be administered within 24 hours from the time the vial was first punctured.**
- 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 there are no particulates nor discoloration.
- 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.

Example of pre-drawn syringe and container labels:

Pfizer-BioNTech COMIRNATY COVID-19 Vaccine for age 5 Years to <12 years (10 mcg/0.2 mL) IM suspension

Facility name and phone number:

Quantity of syringes:

Date prepared & Time to discard (24 hours after puncture):

Lot #:

Initials of preparer:

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 for longer term storage (ULT).

- Transport of the vaccine for storage at another facility should be done in the frozen state at ultra-cold temperature. May also be done at +2°C to +8°C per details and recommendations above.

Scenario 2: Ground Transport between Locations or Facilities

Transport from a hospital to a congregate living setting.

- Ultra-cold frozen (-90°C to -60°C) transport or liquid state (+2°C to +8°C) transport, see product monograph and above for details and recommendations.

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, ultra-cold temperature, but may also be done at +2°C to +8°C per product monograph and details and recommendations above.

Scenario 4: Short Duration Movement within a Facility or Campus

- Movement of a vaccine should be walked from one destination to another 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	Pediatric Pfizer-BioNTech Vaccine (Orange Cap)
Frozen Vials Prior to Use	<ul style="list-style-type: none"> Kept frozen between -90°C to -60°C up to 6 months from manufacturing date. Do not store at -25°C to -15°C temperatures. Protected from light, in the original packaging, until ready to use.
Thawed, unpunctured vials	<ul style="list-style-type: none"> Thawed vials may be stored at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ for up to 10 weeks or at room temperature (up to $+25^{\circ}\text{C}$) for no more than 24 hours prior to dilution. 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.
Thawed, punctured vials	<ul style="list-style-type: none"> After dilution, store between $+2^{\circ}\text{C}$ to $+25^{\circ}\text{C}$ and use within 24 hours from time of first puncture. <ul style="list-style-type: none"> Additional stability data has been provided from the manufacturer which supports an additional 12 hours of cumulative storage in vials or syringes to total 24 hours (12 hours as listed in the product monograph plus an additional 12 hours excursion time). Syringe Stability <ul style="list-style-type: none"> Additional stability data supports storage of diluted vaccine in syringes for <ul style="list-style-type: none"> up to 24 hours in refrigerated temperatures ($+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$) up to 12 hours at room temperature ($+8^{\circ}\text{C}$ to $+25^{\circ}\text{C}$) Total cumulative time post-dilution cannot exceed 24 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Appendix C: Onward Transport of Moderna 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 and limited air 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 12 hours of cumulative time. Opened vials of the vaccine should not be transported. See below for guidance on transport of Moderna vaccine in syringes. 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 12 hours 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 G](#).
- 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 G: 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 12 hours. If the transportation is by road and air, limits of 3 hours by air and 9 hours by road should be adhered to.
- 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.

Transport of Open (Punctured) Vials or Syringes Containing Moderna Vaccine

While not recommended as routine practice, in exceptional circumstances a single dose of Moderna vaccine may be transported in a syringe whilst careful attention is taken to adhere to the parameters identified below.

Exceptional circumstances could include situations in which a few doses are needed to support the immunization and series completion of small numbers of individuals residing in congregate settings (i.e., one or two residents) and for those who are home bound (e.g., those who may be unable to attend a community-based clinic due to physical limitations). When at all possible, it is recommended that unpunctured vials of vaccine be transported and the entire vial of vaccine administered in one location over transporting syringes filled with vaccine.

It is recommended that vaccine is transported in a syringe as once a vial has been punctured the air pressure in the vial will have been changed and the potential for agitation (physical stress) of the mRNA in the vaccine is more likely.

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

- Opened or punctured vials of Moderna should not be transported. A single dose of Moderna vaccine should only be transported when in a syringe.
- The vaccine does not contain a preservative, therefore 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 beyond-use date and time (i.e., 6 hours from when the Moderna 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 for up to 24 hours. 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.
- If the syringe being transported is from a vial that was previously transported at fridge temperature, then the total transportation time – the time in the syringe (drawn up dose) and the time the vial was transported (i.e., time that the vial was in transport at +2°C to +8°C) should not exceed 12 hours.
- **Drawn up vaccine must be administered within 24 hours from the time the vial was first punctured.**
- 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 there are no particulates nor discoloration.
- 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.

Example of pre-drawn syringe and container labels:

Moderna SPIKEVAX COVID-19 Vaccine (100 mcg/0.5 mL) IM suspension

Facility name and phone number:

Quantity of syringes:

Date prepared & Time to discard (24 hours after puncture):

Lot #:

Initials of preparer:

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 to 12 hours.

Scenario 3: Medium and Long Duration Ground PLUS Air Transport

Transport is recommended in the frozen state. If the transport can only be done at +2°C to +8°C, a limit of 12 hours total time is applied. If the transportation is by road and air, a limit of 3 hours by air and 9 hours by road is recommended.

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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Thawed and stored at +2°C to +8°C for up to 30 days, or at +8°C to +25°C for up to 24 hours. • Within the allowable 30-day period for vials stored under refrigeration at +2°C to +8°C, a cumulative exposure up to 24 hours to temperatures between +8°C to +25°C, is permitted. • During storage, vials should be protected from light. • Do not refreeze thawed vials.
Thawed, punctured vials	<ul style="list-style-type: none"> • Stored between +2°C to below +25°C and used within 24 hours from the time of first puncture. • Once a vial has been punctured, it should be disposed of within 24 hours. • The dose in the syringe should be used as soon as feasible, and no later than 24 hours after the vial was first punctured. • During storage, vials should be protected from light.

Appendix D: Transportation of AstraZeneca

The vaccines should be transported prior to puncture, but in the event that transport of a punctured vial or pre-drawn syringe is required to provide access to vaccination or prevent wastage the following should be followed/considered:

- Adherence to the must use by date/timing of the product following first puncture of a vial:
 - AstraZeneca
 - 6 hours post first puncture at room temperature, up to +30°C.
 - 48 hours post first puncture in a refrigerator at +2°C to +8°C.
- The number of times an opened vial or pre-drawn syringe is transported should be minimized to prevent risk of product microbial contamination and adherence to the must use by date/timing.
- The vaccine does not contain a preservative, therefore special attention should be paid to handling and packaging to prevent contamination.
- Do not pack with unopened vials (i.e., have not been punctured).
- The vial or syringe should be protected from light.
- There should be a tamper evident seal on the container or on the pre-drawn syringe during transport between locations.
- The vial or pre-drawn syringes and the container should be labeled, identifying information to prevent errors during storage, dispensing, transport, and use. Container and vial or pre-drawn labeling components should include:
 - Name and dosage of vaccine
 - Facility name and phone number
 - Quantity of vials or syringes
 - The exact beyond-use date and time (e.g., 48 hours from when the AstraZeneca vaccine vial was first punctured if kept at +2°C to +8°C)
 - Lot number
 - Initials of preparer
- The vial or syringe(s) should be packed appropriately in a conditioned cooler (transport container) at +2°C to +8°C and the temperature monitored during transport.

- For AstraZeneca vaccine, the vaccine in the vial or syringe can be at ambient temperature to a maximum of +30°C for 6 hours post first puncture.
 - Note: The AstraZeneca vaccine should not be frozen or 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 the vial or pre-drawn syringe(s). This is to prevent direct contact between with the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.
- The vial or syringe(s) 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 vial or syringe(s) during all phases of transport.
- If the information regarding the beyond use date, or the tamper evident seal, or ability to track the vial or syringe(s) in any way is in question, the vaccine should not be administered and documented as wasted.
- 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 H](#)). Record as wastage in COVaxON.
- If the vaccine in the vial or 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.

Example of vial or pre-drawn syringe and container labels:

AstraZeneca VAXZEVRIA COVID-19 Vaccine (0.5 mL) IM solution

Facility name and phone number:

Quantity of vials / syringes:

Date prepared & Time to discard:

Lot #:

Initials of preparer:

Appendix E: Transportation of Janssen

Janssen recommends that their vaccine be shipped in a frozen state as per their [Storage and Administration Guide](#). A summary of Janssen COVID-19 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 Janssen 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.

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 vaccine can be transported at +2°C to +8°C for a single period of up to 6 months, not exceed in the original expiry date. Upon moving the product to +2°C to +8°C storage conditions, the updated expiry date must be written on the carton or vial and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable.

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

- Insulated containers should be packed according to the guidance provided in ministry guidance on vaccine storage and handling for refrigerated vaccines.
- 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 G: 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 12 hours. If the transportation is by road and air, limits of 3 hours by air and 9 hours by road should be adhered to.
- 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.
- Do not refreeze the vaccine.

Transport of Open (Punctured) Vials or Syringes Containing Janssen Vaccine

While not recommended as routine practice, in exceptional circumstances a single dose of Janssen vaccine may be transported in a syringe whilst careful attention is taken to adhere to the parameters identified below.

Exceptional circumstances could include situations in which a few doses are needed to support the immunization and series completion of small numbers of individuals residing in congregate settings (i.e., one or two residents) and for those who are home bound (e.g., those who may be unable to attend a community-based clinic due to physical limitations). When at all possible, it is recommended that unpunctured vials of vaccine be transported and the entire vial of vaccine administered in one location over transporting syringes filled with vaccine.

It is recommended that vaccine is transported in a syringe as once a vial has been punctured the air pressure in the vial will have been changed and the potential for agitation (physical stress) of the vaccine is more likely.

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

- Opened or punctured vials of Janssen should not be transported. A single dose of Janssen vaccine should only be transported when in a syringe.
- The vaccine does not contain a preservative, therefore 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 beyond-use date and time
 - 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, at a maximum of +25°C for up to 3 hours.
- 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.
- **Drawn up vaccine must be administered within 6 hours from the time the vial was first punctured if stored** at +2°C to +8°C or within 3 hours when held at room temperature, maximally at +25°C.

- 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 there are no particulates nor discoloration.
- 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.

Example of pre-drawn syringe and container labels:

Janssen COVID-19 Vaccine (0.5 mL) IM suspension

Facility name and phone number:

Quantity of syringes:

Date prepared & Time to discard:

Lot #:

Initials of preparer:

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.
 - The vaccine should preferably be used immediately after first puncture of the vial, however, the product can be stored and/or transported between 2°C to 8°C for up to 6 hours **or** at room temperature (maximally 25°C) for up to 3 hours after first puncture of the vial.
- Such transport may be conducted for up to 12 hours for unpunctured vials.

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	Janssen
Frozen Vials Prior to Use	<ul style="list-style-type: none"> • Vaccine can be kept frozen -25°C to -15°C until expiry • Protect from light
Thawed, unpunctured vials	<ul style="list-style-type: none"> • The vaccine can be stored and transported at +2°C to +8°C for a single period of up to 6 months, not exceeding the original expiry date. • The vaccine is stable for 12 hours at +9°C to +25°C. It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.
Thawed, punctured vials	<ul style="list-style-type: none"> • Once punctured the vaccine can be held at 2°C to +8°C for up to 6 hours. Discard the vaccine if it is not used within this time. • After the first puncture the vaccine can be held at +25°C for a single period of up to 3 hours, discard if the vaccine is not used within this time and report wasted doses.
For further information and resources visit: https://www.janssenmedicalinformation.ca/covid-19_vaccine_resources	

Appendix F: Transportation of Novavax

The vaccines should be transported prior to puncture, but in the event that transport of a punctured vial or pre-drawn syringe is required to provide access to vaccination or prevent wastage the following should be followed/considered:

- Adherence to the must use by date/timing of the product following first puncture of a vial:
 - Novavax
 - 6 hours post first puncture stored between +2°C to +25°C.
 - a pre-filled syringe is stable for 6 hours between 2°C and 25°C
- The number of times an opened vial or pre-drawn syringe is transported should be minimized to prevent risk of product microbial contamination and adherence to the must use by date/timing.
- The vaccine does not contain a preservative, therefore special attention should be paid to handling and packaging to prevent contamination.
- Do not pack with unopened vials (i.e., have not been punctured).
- Do not pack with frozen vaccine.
- The vial or syringe should be protected from light.
- There should be a tamper evident seal on the container or on the pre-drawn syringe during transport between locations.
- The vial or pre-drawn syringes and the container should be labeled, identifying information to prevent errors during storage, dispensing, transport, and use.

Container and vial or pre-drawn labeling components should include:

- Name and dosage of vaccine
- Facility name and phone number
- Quantity of vials or syringes
- The exact beyond-use date and time (e.g., 6 hours from when the Novavax vaccine vial was first punctured if kept at +2°C to +8°C)
- Lot number
- Initials of preparer

- The vial or syringe(s) should be packed appropriately in a conditioned cooler (transport container) at +2°C to +8°C and the temperature monitored during transport.
- 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 the vial or pre-drawn syringe(s). This is to prevent direct contact with the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.
- The vial or syringe(s) 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 vial or syringe(s) during all phases of transport.
- If the information regarding the beyond use date, or the tamper evident seal, or ability to track the vial or syringe(s) in any way is in question, the vaccine should not be administered and documented as wasted.
- 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 H](#)). Record as wastage in COVax_{ON}.
- If the vaccine in the vial or 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.

Example of vial or pre-drawn syringe and container labels:

Novavax Inc nuvaxovid COVID-19 Vaccine (0.5 mL) IM solution

Facility name and phone number:

Quantity of vials / syringes:

Date prepared & Time to discard:

Lot #:

Initials of preparer:

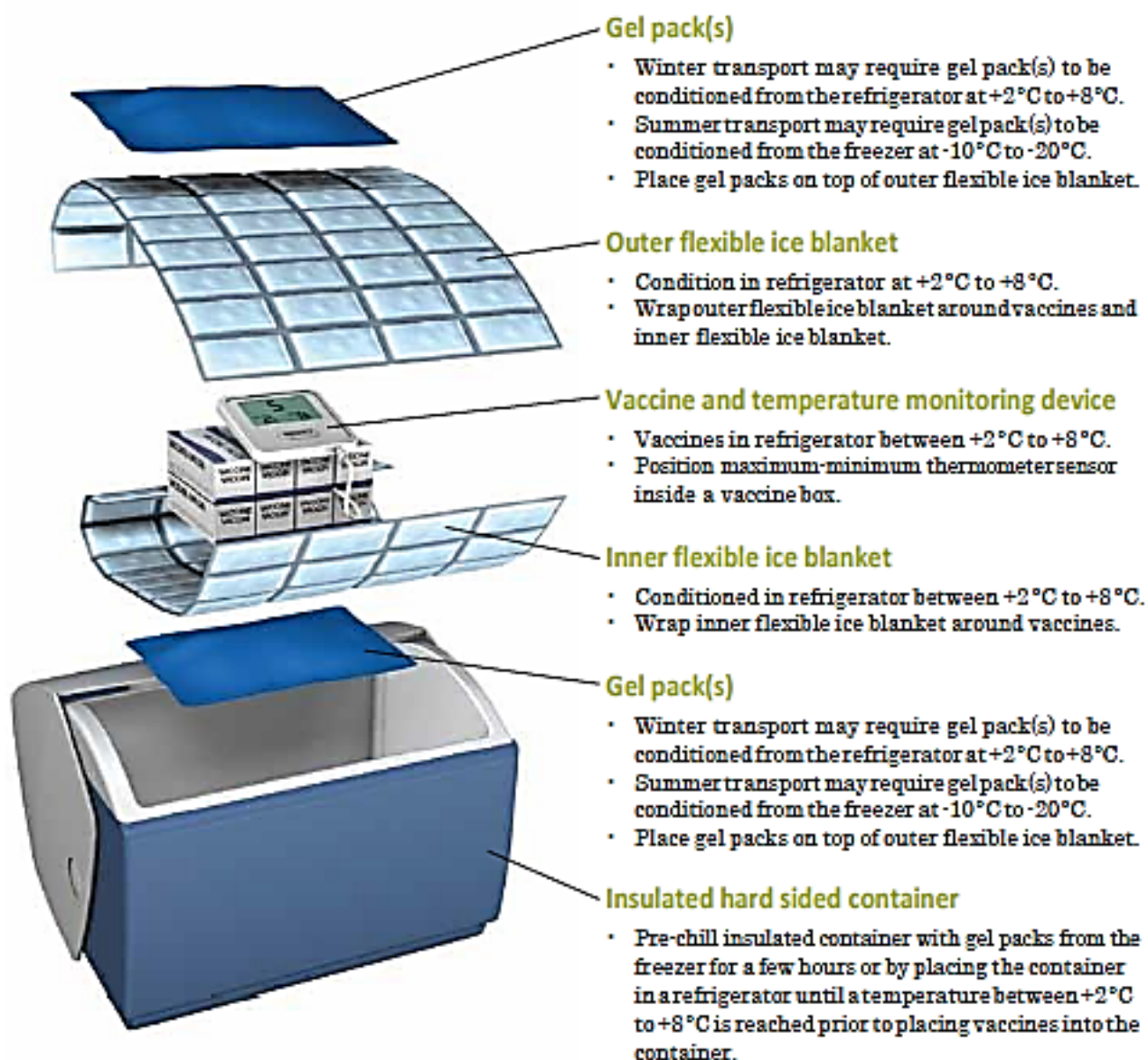
Appendix G: How to Pre-Condition and Pack an Insulated Container

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 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 of 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

Detailed instructions on how to pack an insulated container:



Note: Additional icepacks may be required depending on cold-life needed for the length of transport. Additional insulating material (e.g., bubble wrap, Styrofoam chips, crumpled or shredded newspaper) should be placed inside (bottom, top and sides) the insulated container to allow for cool air circulation.

From the ministry's [Vaccine Storage Handling Guidelines](#), 2012.

Appendix H: Additional Dose(s) from Vaccine Vials

This appendix applies to vaccines authorized by Health Canada and the details on doses contained in the Canadian product monographs. If foreign product is brought into Canada, then the appendix would apply to the volume of doses for the product as authorized by Health Canada.

Additional Dose(s) from a Single Vial of COVID-19 Vaccine

Pfizer-BioNTech (Purple Cap)

- Following the dilution of a vial of Pfizer-BioNTech vaccine with 1.8 mL of diluent (0.9% sodium chloride) the vial contains six (6) x 0.3 mL doses of vaccine.
- It may be possible to withdraw an additional 0.3 mL dose(s) of vaccine (i.e., a 7th dose).
- It is recommended that if an additional 0.3 mL dose(s) of vaccine can be withdrawn from a single vial that it is administered as a valid dose and recorded accordingly in COVaxON or other specified documentation.
 - Appropriate documentation of the source of these doses needs to be kept for tracking purposes.

Pediatric Pfizer-BioNTech (Orange Cap)

- Following the dilution of a vial of Pediatric Pfizer-BioNTech vaccine with 1.3 mL of diluent (0.9% sodium chloride) the vial contains ten (10) x 0.2 mL doses of vaccine.
- It may be possible to withdraw an additional 0.3 mL of the vaccine (i.e., an 11th and 1/3 dose)
- It is recommended that if an additional dose or more of vaccine can be withdrawn from a single vial that it is administered as a valid dose and recorded accordingly in COVaxON or other specified documentation.
 - Appropriate documentation of the source of these doses needs to be kept for tracking purposes.

Syringe Use for the Administration of Pfizer-BioNTech

- If available, the use of a 1 mL low dead space syringe is recommended for administration.
- A 1 mL low dead space syringe increases the likelihood of obtaining an additional dose(s) of vaccine from a single vial.
- A 3 mL syringe can be used if the syringe has 0.1 mL graduations.

Moderna, Janssen, Astra Zeneca and Novavax COVID-19 Vaccine

- It is recommended that if an additional 0.5 mL dose(s) of vaccine can be withdrawn from a single vial beyond the number of doses listed in the Product Monograph, that it is administered as a valid dose and recorded accordingly in COVaxON or other specified documentation.

Accessing Multiple Vials to Complete a Dose of COVID-19 Vaccine

As an interim measure during this time of limited COVID-19 vaccine, an additional dose of COVID-19 vaccine may be extracted from up to **3 vials** of the same vaccine using aseptic technique. Although this is not routine practice for multi-dose vials of vaccines for other diseases, there are benefits to extracting additional doses given the high COVID-19 case counts leading to significant morbidity and mortality in Ontario. Every effort should be made to withdraw the entire residual volume from one vial, before entering the next vial. The antigenicity and, therefore, efficacy of the vaccine is not affected by accessing multiple vials to obtain an additional dose.

Aseptic technique refers to the manner of handling, preparing, and storing medications and injection equipment/supplies (e.g., syringes, needles) to prevent microbial contamination and infections. This would mean preparing vaccines in a clean, designated medication area away from where vaccination is occurring and away from any potentially contaminated items. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment.

Extracting an additional dose from up to 3 vials of the same vaccine only should be undertaken according to the following:

- Follow meticulous aseptic technique when accessing the vaccine vials to prevent contamination.

- Ensure that all of the vaccine vials accessed to extract an additional dose of vaccine (0.3 mL for Pfizer-BioNTech, 0.2 mL for Pediatric Pfizer-BioNTech vaccine and 0.5 mL for other vaccines) are from the same vaccine lot (i.e., have the same lot numbers).
- For the Pfizer-BioNTech vaccine, the correct amount of diluent 1.8 mL (0.9% sodium chloride) and 1.3 mL of the diluent (0.9% sodium chloride) for the Pediatric Pfizer-BioNTech has been used to dilute all vials of vaccine and the lot number for the diluent used to dilute each vial being accessed for the extra dose is the same.
- To minimize the risk of contamination never use the same diluent vial more than once. Make sure to discard any remaining saline in the diluent vial in a sharps container ([Pfizer-BioNTech COVID-19 Vaccine Resources](#)). In Ontario Pfizer-BioNTech vaccine is shipped with a diluent to vaccine ratio that supports single use of diluent.
- Combine vaccine from vials with residual volume only, (i.e., not full vials or those with a complete dose) and do not save up vials until the end of the clinic before combining for extra dose. The different vials accessed have been under the same vaccine storage and handling conditions, for example:
 - For both Pfizer-BioNTech formulations and Moderna vaccine vials that have been thawed and stored at +2°C to +8°C and vials that have just been removed from a freezer are not accessed to complete a vaccine dose.
 - The beyond use date must be followed in all instances for specific vaccine products.
 - Pfizer-BioNTech 6 hours after first puncture.
 - Pediatric Pfizer-BioNTech 24 hours after first puncture.
 - Moderna - 24 hours after first puncture.
 - Janssen - 6 hours after first puncture.
 - AstraZeneca - 6 hours post first puncture at room temperature, up to 30°C **or** 48 hours post first puncture in a refrigerator at +2°C to +8°C.
 - Novavax – 6 hours after first puncture
- This should only be done where there is a dedicated and skilled person (e.g., pharmacist, pharmacy tech) drawing up the vaccine.

- Training should be in place per above and for related practices and techniques for proper vaccine storage and handling given the fragile nature of these vaccine products and timing for use (e.g., appropriate labeling and “must use by dating/timing”).
 - Appropriate documentation of the source of these doses needs to be kept for tracking purposes.

It is important that if these practices are employed, special attention is paid to the recommendations and parameters above to ensure the safety, efficacy and integrity of the vaccine and to avoid the risk of contamination as these vaccines do not contain preservatives. This includes appropriate documentation and labelling, including inventory adjustments in COVaxON for the additional doses.

Appendix I: Vaccine Vial and Packaging Disposal

In an effort to prevent fraudulent activities related to COVID-19 vaccines during this stage of vaccine programming in Canada and internationally where there is limited supply of vaccine compared to demand, the following guidance is provided in regards to vaccine vials and their secure disposal.

- Given the potential for the reuse of COVID-19 vaccine vial labels for fraudulent activities, please ensure that vial labels are destroyed prior to disposal, such as through the removal of the label from the vial or the tearing/marking of the label.
- Discard non-viable (e.g., expired, wasted) vaccine vials, vial trays and all packaging associated with the vaccine so they cannot be reused and to prevent counterfeit efforts and any other potential fraudulent activities.
- Ensure that vials, post withdrawal of vaccine doses, are securely stored and disposed of to prevent fraudulent activity.
- 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](#)
- During this period of limited supply to COVID-19 vaccines compared to demand in Canada and internationally, there have been reports of fraudulent attempts to sell vaccine doses by non-government/private entities.
- The Ministry of Health and Health Canada are working together with vaccine manufacturers, importers, and law enforcement agencies to investigate these offers as they arise.
 - Attempts to procure vaccines outside of the existing, direct vaccine manufacturer-federal government contractual relationships are not advisable for a range of health and safety and supply chain security reasons.

- Partners are advised not to engage with private individuals and entities offering COVID-19 vaccines, as all importation and sales of vaccines in Canada must engage with Health Canada as the regulator.

Should you encounter any offers of sale, please contact the Ministry of Health at eocooperations.moh@ontario.ca so that can be reported it to the Health Product Compliance Directorate, Health Canada and the National Operations Centre for further investigation.