

COVID-19 Pfizer Adult/Adolescent Vaccine (Gray Cap; monovalent and bivalent)

Redistribution Guidelines



Introduction

The prompt, safe, and efficient roll out of the provincial COVID-19 vaccine program is a critical priority for the B.C. health system. Through federal contracts, the Pfizer vaccine is delivered directly to reception points across the province. However, health authorities may choose to move vaccine beyond these primary sites to secondary, or even tertiary sites. This guidance document provides information to support redistribution of vaccine beyond the primary delivery points and will be updated to reflect emerging best practices.

B.C. is committed to an ethical approach to immunization phases. COVID-19 vaccines will be distributed equitably and ethically to people in B.C. following [national ethical frameworks](#) and [BCCDC's COVID-19 Ethical Decision-Making Framework](#). As such, organizations involved in vaccine redistribution must commit to this approach and ensure all residents have fair and equal access to the vaccines.

A. Formulations:

- Monovalent – 30 mcg/0.3 ml - intended population: 12 years of age and older
- Bivalent – 30 mcg/0.3 ml - intended population: 12 years of age and older (booster dose only)

B. Definitions

Vial: Single, glass vial containing vaccine.

Payload: vial(s) of vaccine.

Carton: box containing 10 vials of vaccine.

Shipper: Thermal packing container, capable of maintaining vaccine in a frozen state during transit.

Cooler: An insulated container used to move vaccine at 2°C to 8°C.

C. Key Considerations

1. Pfizer does not recommend redistribution beyond the initial points of delivery.
2. Risk and responsibility associated with redistribution held by province, health authorities.
3. Secondary distribution allowable at ULT (-60°C to -90°C) or thawed (2°C to 8°C).
 - Any hours used for transport at 2°C to 8°C count against the 10 week (70 day) limit for storage at 2°C to 8°C.
4. **Vaccine cannot be refrozen once thawed.**
5. Ensure appropriate equipment is used to transport vaccine.
6. Temperature must be monitored during transport.
7. Transfers should be limited, especially when being moved at 2°C to 8°C, to decrease likelihood of temperature excursions and disruption to physical stability of vaccine.
8. Transfers between containers should be completed as quickly as possible.
9. Vaccine should be packed securely and handled gently to minimize jostling and kept upright. Vaccine can be used if temporarily knocked over.

D. Redistribution of **ULT** Vaccine

1. Guiding principles for redistribution of **ULT** vaccine (-60°C to -90°C):

Shipping Container:

The thermal shipper belonging to Pfizer can be used for redistribution. [Dry ice must be replenished within 24 hours of receipt from the manufacturer/prior to onward movement](#) – whichever happens first. As the data logger provided by Pfizer must be stopped when the shipment is received at the primary site, a second data logger must be added to monitor the temperature of the shipment during transport to a secondary location. Data loggers can be requested through BCOC_Operations@phsa.ca. Alternatively, an ULT thermal shipper provided through the provincial supply chain may be used, also requiring the installation of a new data logger. See Section H for guidance on the selection of alternative models of temperature monitoring devices.

Associated Links:

- [Pfizer Shipping, Storage, Thawing and Use Guideline](#)
- [Thermal Shipper Storage & Dry Ice Replenishment](#)
- [Dry Ice Personal Protective Equipment & Safety Considerations](#)
- [Procurement of Dry Ice - ROUTINE](#)
- [Procurement of Dry Ice – RUSH](#)
- [iMiniPlus Dry Ice Temperature Data Logger Set Up Guide](#)
- [Sensitech TempTale Ultra Set Up Guide](#)
- [Temperature Probe Characteristics](#)

After use, the thermal shipper, including the data logger, must be returned to the supplier to help Pfizer fulfill its commitment to using reusable resources. Detailed instructions on return of materials to Pfizer can be found on pages 14-15 of the Pfizer [Shipping and Handling Guidelines](#).

Additional Considerations for Secondary Distribution of **ULT Vaccine:**

- Smallest allowable secondary distribution pack size is a carton.
- Packing:
 - Cartons containing 10 vials removed from frozen storage may be at room temperature for up to **5 minutes** for transfer between ultra-low temperature environments, i.e. transfer to thermal shipper.
 - If carton is at **room temperature for over 5 minutes**, consider it to be thawing and do not place back in freezer. Vials must be stored and moved into a refrigerated (2°C to 8°C) environment.
- If shipping frozen in ULT shipper, pack with dry ice; ensure [personal protective equipment](#) and trained personnel are available on the receiving end to safely handle the package.
- Ensure vials do not come into contact with dry ice.

2. Supplies for redistribution of **ULT** vaccine (-60°C to -90°C):

- [Dry ice](#)
- [Dry ice PPE](#)
- ULT shipper
- Dry ice ULT data logger
- Payload box

3. Packing for redistribution of **ULT** vaccine (-60°C to -90°C):

1. Ensure data logger is calibrated for shipment and that computers on both ends of the move have been identified for data-logger software installation.
2. Turn data-logger on as per time delay [specific to the model](#).
3. Don dry ice PPE.

Steps 4-10 must take place in under 5 minutes. If these steps take close to, but not beyond, 5 minutes the carton must go back into the ULT freezer for 2 hours before being repacked.

4. Pull carton box from freezer.
5. Place carton into payload box.
6. Place the data logger into payload box. Close lid. If the payload box does not have a lid, place a piece of cardboard on top.
7. Place the payload box into the ULT shipper.
8. Pour dry ice pellets around the edge of the payload box.
9. Pour a layer of dry ice pellets on top of the payload box.
10. Place lid on shipper.
11. Ensure Class 9 Dry-ice label (UN 1845) on outer packaging.
12. Ensure regional inventory management processes are followed to track transfer of vaccine to the receiving site.

E. Redistribution of **thawed** vaccine (2°C to 8°C):

Shipping Container:

Thawed vaccine can be shipped using containers typically used for the transport of vaccines and can be kept at 2°C to 8°C. Considerations listed above should be fully applied and the time limits related to the stability of the vaccine at this temperature must be adhered to. Please see graphic below (Section G) for additional information on vaccine stability.

Additional Considerations for Secondary Distribution of **Thawed** Vaccine:

- Smallest allowable secondary distribution pack size is **one vial**.
- Repacking should be done in a 2°C to 8°C environment whenever possible. Otherwise, time at room temperature should be tracked and subtracted from the 12-hour allowance for vaccine to be at room temperature (Section G).
- Unpunctured vials of vaccine can be stored for 10 weeks (70 days) at 2°C to 8°C. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 10 week limit for storage at 2°C to 8°C.
- Thawed, punctured¹ vaccine vials can be moved at 2°C to 8°C but they must be used within 12 hours of first vial puncture.

Information on the provincial standards for shipping and receiving refrigerated vaccine can be found in the [Communicable Disease Control Manual Chapter 2: Immunization Appendix E - Management of Biologicals](#).

Cold Chain Resources for Community Providers

- [How to Store Vaccines in the Refrigerator](#)
- [Packing an Insulated Cooler](#)
- [Handle Vaccines with Care](#)
- [Equipment Malfunction or Power Failure](#)
- [Mass Clinic – Vaccine Handling Tips](#)
- [TempTale® Directions](#)

¹ Guidance on the transport of punctured Pfizer vials has been drawn from https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/Pfizer_TransportingVaccine.pdf

- [Temperature Form](#)
- [Cold Chain Checklist](#)

Training videos for Biologicals Management are available on the BCCDC [Vaccine Management](#) page.




F. Distribution of thawed single dose of vaccine:

There are instances when individuals will not be able to travel to an immunization clinic, e.g. clients who are self-isolating or are frail. In these circumstances, it is acceptable to pre-draw thawed vaccine and take the syringe to the individual’s home to provide their immunization.

Key Considerations:

- The vaccine is stable for up to 12 hours after first puncture (while also respecting the 24 hour limit at temperatures up to 25°C) – the dose must be pre-drawn and administered within this window.
- It is recommended that syringes be clearly labelled with the window of time in which the vaccine may be administered.
- Pre-loaded syringes should be moved carefully.
- Pre-loaded syringes can be stored between 2°C to 25°C.
- Keep out of direct sunlight.

G. Vaccine Stability

ULT	2°C to 8°C	Room temperature
 <p>-90°C to -60°C for 30 days (replenish dry ice q 5 days)</p>  <p>-90°C to -60°C</p> <p>18 months from manufacturer date</p>	 <p>10 weeks (70 days)</p>	<p>Vials may be stored for up to 24 hours at temperatures up to 25°C with no more than 12 hours from the time of dilution (first puncture)</p>

H. Selection of Data Loggers

The [Vaccine Storage and Handling Toolkit](#) (US CDC) provides guidance which should inform health authorities wishing to procure their own data loggers. Models selected should have:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Recommended accuracy of +/-0.5° C (+/-1° F) or better
- Logging interval (or reading/recording rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes
- Current and valid *Certificate of Calibration Testing*

I. Procurement of Cold Chain Equipment

All cold-chain equipment coordination and distribution will be handled centrally. This will include:

- All freezers
- All shippers
- All data loggers
- All dry ice PPE

Equipment coordination questions and procurement requests should be directed to

IBCOC_Operations@phsa.ca.

Health authorities can procure their dry ice directly [from the National Operations Centre](#) or through a [provincial contract](#) in exceptional circumstances.

J. Reporting Requirements

British Columbia is [required to report](#) back to the National Operations Centre with information on the acceptability of all vaccine and dry ice received in province provided via a federal contract with the supplier. The provision of this information is critical for the federal government to monitor compliance of contractors and support the uninterrupted provision of vaccine and supplies. For the Pfizer vaccine, this entails reporting on the following:

A. Vaccine

1. Vaccine delivery site address
2. Purchase Order Number (if known)
3. Quantity received
4. Date of receipt
5. Time of receipt
6. Damage to the package? If yes, describe how many damaged and to what extent
7. All cartons were received with no damage or missing vials?
8. Damage? If yes, describe how many and to what extent
9. Missing vials? Yes, how many?

Reporting Approach:

All primary sites receiving vaccine should send a copy of their waybill directly to IBCOC_Operations@gov.bc.ca. If no waybill is included with the shipment, provide a report by email. This satisfies data elements A 1-6 above.

Sites where cartons are initially opened, allowing for the condition of the vials to be assessed, must provide data elements A 7-9 via email to IBCOC_Operations@phsa.ca.

B. Dry Ice

1. Point of use address
2. Purchase order number
3. Quantity received
4. Date of receipt

Reporting Approach:

All sites receiving dry ice directly through federal contract [report directly back to the National Operations Centre](#) at PHAC.vaccine.NOC-CNO.vaccin.ASPC@canada.ca, copying in IBCOC_Operations@phsa.ca.

K. Inventory Management

Regular inventory management processes should be followed. If questions or issues arise, consult with regional inventory management teams for advice and guidance.

L. Resources

- [Pfizer Monovalent Product Monograph](#)
- [Pfizer Bivalent Product Monograph](#)
- [Pfizer COVID Vaccine Resources](#)
- [Pfizer Dry Ice Safety Data Sheet](#)
- [Pfizer-BioNTech COVID-19 Vaccine Shipping And Handling Guidelines](#)
- [Pfizer instructions on dry ice replenishment](#)

Any questions or requests for revision
of this document should be sent to
IBCOC_Operations@phsa.ca

List of Amendments

Date	Section	Description	Author
Jul 22, 2022	A, B, C, D, E, F, G, H, I, J	SOP developed based on product monograph and information provided by Pfizer	Calvin Kaila
July 26, 2022	B,C,I	Removed previously missed mention of diluent as these were here in error	Calvin Kaila
Oct 11, 2022	A	Information about Bivalent formulation added	Calvin Kaila
Dec 14 2022	L	Link to bivalent monograph added and other hyperlinks updated	Calvin Kaila
Jan 11 2023	G	Expiry date information updated	Calvin Kaila
Mar 7 2023	G, E	Expiry date information updated and allowance for punctured vial transportation added	Calvin Kaila