

A. 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 Moderna vaccine is delivered directly to numerous reception points across the province. However, health authorities may choose to move vaccine beyond these primary sites to secondary, or even tertiary sites. This document provides information to support redistribution of vaccine beyond the primary delivery points and will be updated to reflect best practices identified by health authorities and new information provided by vaccine manufacturers.

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 <u>national ethical frameworks</u> and <u>BCCDC's COVID-19 Ethical Decision-Making Framework</u>. As such, organizations involved in vaccine redistribution must commit to this approach and ensure all residents have fair and equal access to the vaccines.

B. Definitions

Vial: Single, glass vial containing vaccine.Payload: vial(s) of vaccine.Moderna Box: Original boxes holding 10 vials of Moderna 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. Redistribution beyond the initial points of use is not recommended but understood that it may be required.
- 2. Risk and responsibility for secondary distribution is held by province and health authorities.
- 3. Transportation of frozen vaccine is preferable to thawed.
- 4. Ensure a validated container is used to transport vaccine.
- 5. Temperature must be monitored during transportation and documented.
- 6. Transfers should be limited to decrease likelihood of temperature excursions and disruption to physical stability of vaccine.
- 7. Transfers between containers should be completed as quickly as possible.
- 8. Package should be kept upright and packed tightly to minimize jostling. Vaccine can be used if temporarily knocked over.
- 9. Ensure vaccine does not come into contact with ice packs.

10. Vaccine can be stored for 50 days at 2°C to 8°C in a refrigerator; can be stored for 36 hours (cumulative) at 2°C to 8°C while in transport.

11. Vaccine cannot be refrozen once thawed.

D. Redistribution of Frozen Vaccine

1. <u>Guiding principles for redistribution of frozen vaccine (-15°C to -50°C)</u>:

Shipping container: -20°C thermal shippers and appropriate temperature monitoring devices must be used to transport frozen Moderna vaccine. <u>See Section H</u> for guidance on the selection of alternative models of temperature monitoring devices.

- <u>SensiTech TempTale Ultra Set Up Guide</u>
- <u>Temperature Probe Characteristics</u>
- <u>CoolGuard[™] Advance Series 20M User Guide</u>

2. <u>Supplies</u>

- -20°C shipper.
- Ice packs or other phase change materials required by the shipper.
- Appropriate data logger for -20°C.
- Original cardboard Moderna box.
- 3. Packing for redistribution of frozen vaccine (-15°C to -50°C):
 - a. Ensure data-logger is calibrated for shipment and that computers on both ends of the move have been identified for data-logger software installation.
 - b. Turn data-logger on as per time delay specific to the model.
 - c. Gather required number of original Moderna vaccine boxes.

<u>Steps d - i must take place in under 5 minutes.</u> If the time taken gets close to 5 minutes, visually inspect the vials for signs of thawing. If thawing is suspected, treat vials as thawing vaccine and store/ship in a 2-8°C environment. **Do not return to freezer**. Follow <u>cold chain</u> incident reporting processes.

- d. Take required number of vials from freezer and place into Moderna box(es).
- e. Place box(es) into shipper.
- f. Place the data-logger probe with payload.
- g. Position ice packs/phase change materials around Moderna box(es).
- h. Place ice packs/phase change materials on top of the sheet of cardboard.
- i. Place the Styrofoam lid on top, and tape the shipper closed.
- j. Ensure regional inventory management processes are followed to track transfer of vaccine to the receiving site.



Steps g – h may vary depending on the model of shipper/phase change materials being used.



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

Thawed vaccine can be shipped using containers typically used for the transport of vaccines which 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 in Section G for additional information on vaccine stability.

Additional considerations for secondary distribution of thawed vaccine

- 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 24-hour allowance for vaccine to be at room temperature (see Section G).
- Vaccine can be stored for 50 days at 2°C to 8°C in a refrigerator if the vial is intact, i.e. not pierced.
- Unpunctured vials can be moved at 2°C to 8°C for a **cumulative** total of 36 hours. Punctured vials can also be moved at 2°C to 8°C but they must be used within 24 hours of vial puncture.
- Vaccine is stable at room temperature (8°C to +25°C) for 12 hours whether the vial is intact or pierced.
- Vials should be discarded within 24 hours of vial puncture if stored at 2°C to 8°C.

Information on the provincial standards for shipping and receiving refrigerated vaccine can be found in the <u>Communicable Disease Control Manual</u> <u>Chapter 2: Immunization Appendix E - Management of Biologicals</u>.

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
- <u>TempTale® Directions</u>
- 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 in priority groups will not be able to travel to an immunization clinic, e.g. clients who are self-isolating or are frail or elderly, and not able to attend the clinic site. In these circumstances, it is acceptable to pre-draw thawed vaccine and take the syringe to the individual's home to provide their immunization.

The vaccine can be pre-loaded into a syringe for up to 24 hours from first vial puncture if stored at 2°C to 8°C. If stored at room temperature, vaccine must be discarded after 12 hours from first puncture. Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry. Pre-loaded syringes should be moved carefully. Pre-loaded syringes can be either stored in the refrigerator at 2°C to 8°C to 8°C or left at ambient room temperature at 15°C to 25°C. Filled syringes can be handled in room light conditions.

G. Cold Chain Maintenance

| Frozen (-50*C to -15*C) | 2*C to 8*C | 2*C to 8*C | |
|------------------------------|--|--|--|
| Until written expiry date | Up to 50 days if vial intact (not exceeding written expiry date | Punctured vials can be stored for up to 24 hours | |
| | transport | Room temperature (8*C to 25*C) | |
| Until written expiry date | | Punctured or Unpunctured vials can be stored for 12 hours | |

H. 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

Equipment coordination questions and procurement requests should be directed to IBCOC Operations@phsa.ca.



I. Selection of Data Loggers

The <u>Vaccine Storage and Handling Toolkit</u> (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

J. Reporting Requirements

- 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

British Columbia is <u>required to report</u> back to the National Operations Centre information on the acceptability of all vaccine and other materials received in province provided via a federal contract with the supplier. The provision of this information is critical for the federal government to monitor the implementation of the contracts they have established and supports the undisrupted provision of vaccine and supplies in the future. For the Moderna vaccine, this entails reporting on the following:

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 packages? If yes, describe how many damaged and to what extent
- 7. All Moderna boxes were received with no damage or missing vials (10 vials per single box)
- 8. Damage to vials? If yes, describe how many and to what extent
- 9. Missing vials? Yes, how many?

Reporting Approach:

All sites receiving vaccine directly from the manufacturer should send a copy of their waybill and confirmation that the package was intact directly to <u>IBCOC Operations@gov.bc.ca</u>. If no waybill is included with the shipment, this information can be provided via email. This satisfies **data elements 1-6 above**.

Sites where trays are initially opened, allowing for the condition of the vials to be assessed, must provide **data elements 7-9 above** via email to <u>IBCOC Operations@phsa.ca</u>.

The Immunize BC Operations Centre will provide a consolidated report on the acceptability of the vaccine shipment to the National Operations Centre.

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.

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

List of Amendments

| Date | Section | Description | Author |
|--------------------|--------------|---|--------------|
| May 12, 2021 | Introduction | Information on ethical guidance framework and other resources added. | Keren Massey |
| June 4, 2021 | All | Formatting errors corrected. | Keren Massey |
| June 15, 2021 | E, G | Update to storage parameters at room temperature. | Keren Massey |
| June 17, 2021 | F | Update to time limits for pre-filled syringes. | Keren Massey |
| June 21, 2021 | E | Guidance added on the transport of thawed, punctured vials. | Keren Massey |
| August 13, 2021 | F | Update to time limits and storage conditions for pre-filled syringes. | Keren Massey |
| September 21, 2021 | D | SensiTech link updated | Calvin Kaila |
| January 6, 2022 | D | 20 puncture maximum added | Calvin Kaila |
| July 20, 2022 | D, G | Temperature information updated to include -50°C | Calvin Kaila |
| May 30, 2024 | C,E | Changed transport time to 36h at 2-8C | Calvin Kaila |
| October 4, 2024 | C,E,F,G | Added updated storage information about KP.2 | Calvin Kaila |
| November 14, 2024 | E | Updated to add clarity for redistribution of thawed vaccine | Calvin Kaila |