COVID-19 Novavax Vaccine

Redistribution Guidelines

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 and provincial contracts, the vaccine is delivered directly to numerous reception points across the province. This document provides information to support the internal redistribution of vaccine 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 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.

B. Key Considerations

1. Risk and responsibility for redistribution held by province, and health authorities.
2. Transport should only be done with unopened vials in a 2°C to 8°C environment; transport of pre-filled syringes at room temperature may be done in exceptional circumstances.
3. A validated container must be used to transport vaccine.
4. Temperature must be monitored during transportation and documented.
5. Repacking should be done in a 2°C to 8°C environment whenever possible.
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 packaged tightly to minimize jostling and kept upright.
9. Vaccine should not come into contact with ice packs.
10. Vaccine should be protected from light.
11. **The Novavax vaccine cannot be frozen.**

C. Methods of Redistribution

1. Redistribution of unopened vials (2°C to 8°C):
   The Novavax vaccine can be transported using containers and temperature monitoring devices typically used for the transport of vaccines which must be maintained at temperatures of 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 (see Section D).

   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
   - TempTale® Directions
   - Temperature Form
   - Cold Chain Checklist

2. Distribution of prefilled syringes (2°C to 8°C, or up to 25°C)
   In exceptional circumstances, it is acceptable to pre-draw vaccine. Prefilled syringes should be carefully transported and labelled to ensure that they are not used outside of their window of stability. The vaccine is stable in a 2°C to 8°C environment for up to a maximum of 12 hours or at room temperature (up to 25°C) for up to 6 hours after the first puncture of the vial. If a dose is pre-drawn from a vial just removed from refrigeration, then vaccine would have to be administered within 6 hours. If the vial has been at room temperature for a period of time prior to the vaccine being drawn, that time must be subtracted from the total 6 hours. Prefilled syringes unused at the end of a clinic may not be returned to the refrigerator for use the next day and must be wasted. In an effort to avoid wastage, care should be taken to pre-draw a reasonable number of doses.

D. Cold Chain Maintenance

- If unopened, vaccine can be stored at 2°C to 8°C until expiry date.
- Punctured vials can be stored at 2°C to 8°C for a maximum of 12 hours or at room temperature (up to 25°C) for up to 6 hours.
- Once punctured, vials can be re-refrigerated for up to 12 hours, but **total cumulative storage time once punctured must not exceed 12 hours.** For example, if a vial is punctured and kept at room temperature for 4 hours it could be returned to the refrigerator for a total of 8 hours. If a cumulative 12 hours is reached, the vial must be discarded.

E. Procurement of Cold Chain Equipment

All cold-chain equipment coordination and distribution will be handled centrally. This will include all refrigerated units, shipper containers, and data loggers. Equipment coordination questions and procurement requests should be directed to IBCOC_Operations@phsa.ca.

F. 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*

G. Reporting Requirements

British Columbia is required to report 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. Internal, provincial reporting requirements also require the provision of the following information:

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 Novavax boxes 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 sites receiving vaccine directly from the manufacturer should send a copy of their waybill and confirmation that the package was in tact directly to IBCOC_Operations@gov.bc.ca. If no waybill is included with the shipment, this information can be provided via email. This satisfies **data elements 1-6 above**. Sites where cartons are initially opened, allowing for the condition of the vials to be assessed, must provide **data elements 7-9 above** via email to IBCOC_Operations@phsa.ca.

H. 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
Mar 4, 2022	A-H	SOP developed based on product monograph	Calvin Kaila
Mar 24, 2023	C,D	Room temp time increased to 12 hours	Calvin Kaila
July 27 2023	C, D	Open vial storage revised	Calvin Kaila