

# COVID-19 Vaccine

## Cold Chain Incident Reporting Process

***There are two distinct processes to follow in the event of a temperature excursion depending on when and where the incident occurs.***

### SCENARIO 1: Temperature excursion occurs while vaccine is in the custody of the manufacturer, en route to a primary delivery site<sup>1</sup>

When vaccine arrives at a primary site, the temperature monitor provided by the manufacturer is stopped and a report is generated to indicate the temperatures experienced by the vaccine during transit. If this report indicates a break in the cold chain, the following process should be implemented:

1. Quarantine affected vaccine.
2. Receiving site notifies [IBCOC\\_Operations@phsa.ca](mailto:IBCOC_Operations@phsa.ca) as soon as possible. If after hours, call 1-250-686-6061, providing as much of the following information as possible:
  - Date of incident
  - Location of incident
  - Number of doses affected
3. Immunize BC Operations Centre notifies the National Operations Centre immediately.
4. Receiving site contacts manufacturer directly:
  - If the incident is outside the hours of: 04:30 -14:30 PST, Monday-Friday- email the manufacturer instead of calling
  - Copy in the National Operations Centre : [PHAC.vaccine.NOC-CNO.vaccin.ASPC@canada.ca](mailto:PHAC.vaccine.NOC-CNO.vaccin.ASPC@canada.ca)
5. Within 24 hours, the incident must be resolved and a report submitted to [IBCOC\\_Operations@phsa.ca](mailto:IBCOC_Operations@phsa.ca) with the following information:
  - Date of incident
  - Location of incident
  - Number of doses affected
  - Number of doses wasted
  - Impact on provincial program (e.g. clinic closed early, clinic cancelled)
  - Manufacturer recommendations
6. Upon receipt of this report, the Immunize BC Operations Centre will be responsible to report the incident to the National Operations Centre.

#### **Manufacturer Contact Information**

##### **Innomar (Moderna/Janssen):**

1-833-847-4270

[QA-GMP@innomar-strategies.com](mailto:QA-GMP@innomar-strategies.com)

##### **Pfizer:**

1-833-829-2684

[CanadaCSVaccine@Pfizer.com](mailto:CanadaCSVaccine@Pfizer.com)

##### **Verity Pharma (COVISHIELD/AstraZeneca/):**

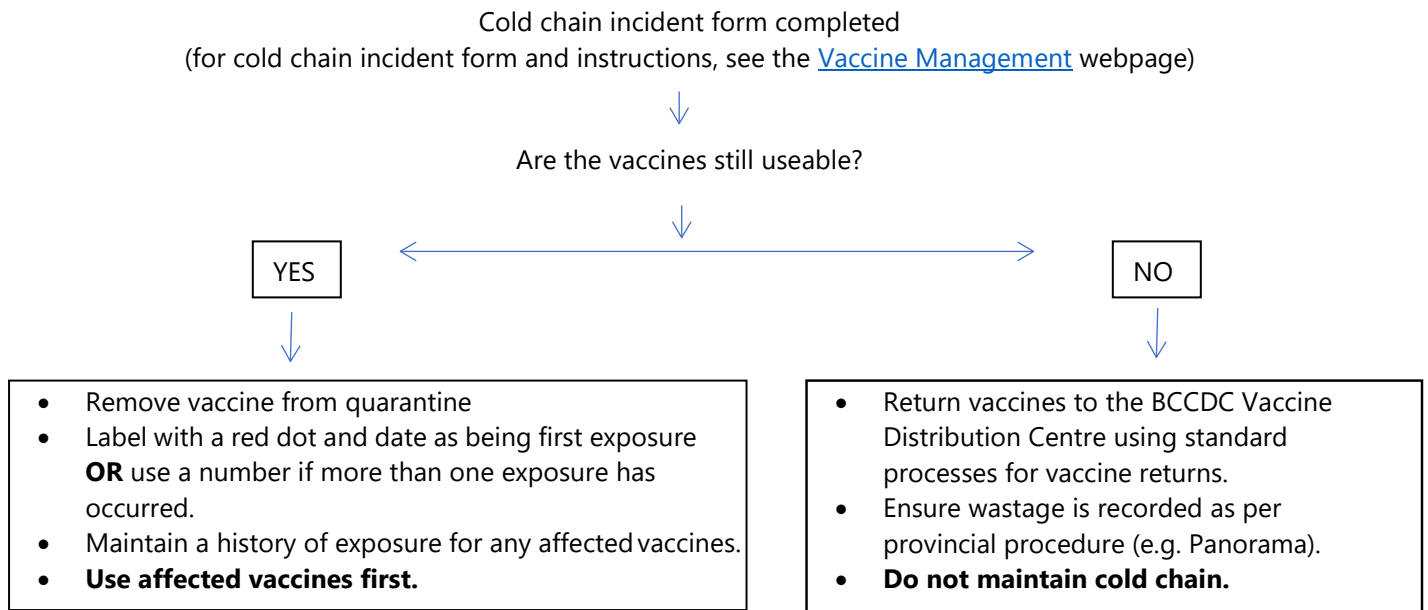
1-800-977-9778

[medinfo.canada@astrazeneca.com](mailto:medinfo.canada@astrazeneca.com)

<sup>1</sup>Primary site: a site which receives vaccine directly from the manufacturer (i.e. Health Authority site, BCCDC Vaccine Distribution Centre, Pharmacy Distribution Centre)

## SCENARIO 2: Temperature excursion occurs while vaccine is in the custody of the health authority or community vaccine provider<sup>1</sup>

1. Quarantine affected vaccine and label as "Do Not Use"
2. Receiving site notifies [IBCOC\\_Operations@phsa.ca](mailto:IBCOC_Operations@phsa.ca) as soon as possible. Call 1-250-686-6061, if after hours and assistance is required to initiate a cold chain consultation.
3. Cold chain consultation process initiated<sup>2</sup>



4. Within 24 hours, the incident must be resolved and a report submitted to [IBCOC\\_Operations@phsa.ca](mailto:IBCOC_Operations@phsa.ca) with the following information:
  - Date of incident
  - Location of incident
  - Situation surrounding incident
    - Excursion temperature(s) and duration(s)
    - Lot number, expiry
    - Detail description of event
  - Recommendations
    - Number of affected doses
    - Number of doses wasted
    - Impact on clinic (e.g. closed early, cancelled, clients redirected to alternate site)
5. Upon receipt of this report, the Immunize BC Operations Centre will be responsible to report the incident to the National Operations Centre.

<sup>1</sup>Health authority or community vaccine provider: vaccine is in the custody of the health authority or community vaccine provider (e.g. health authority storage site, immunization clinic setting, pharmacy, physician office, FNHA)

<sup>2</sup>Cold chain process consultation: report incident to local public health unit for determination of vaccine use; consultation with BCCDC Vaccine and Pharmacy Services may occur.

## List of Amendments

<b>Date</b>	<b>Section</b>	<b>Description</b>	<b>Author</b>
April 28, 2021	Full document	Processes refined to align more closely with standard provincial procedures.	Multiple
April 29, 2021	Manufacturer Contact Information	Janssen guidance added.	Keren Massey
April 29, 2021	Scenario 2	Guidance added to confirm requirement to report any vaccine wastage as per provincial procedures in addition to reporting to IBCOC.	Keren Massey
July 21, 2021	Scenario 2, Step 2	Guidance updated to reflect that a phone call is only necessary if assistance is required after hours.	Keren Massey