Resource 5: Cold Chain Failure Response Procedures and Form

Manitoba Health Cold Chain Failure Response Procedure and Form

The following document provides instruction on completing the required provincial *Cold Chain Failure Response Form* in the event of a cold chain failure involving vaccines and biologics obtained from Manitoba Health.

When a cold chain failure occurs, all sections of the *Cold Chain Failure Response Form* must be completed and faxed to Communicable Disease Control (CDC), Manitoba Health at: (204) 948-2040.

If you do not have a copy of the form, contact Manitoba Health at (204) 788-6737 to receive a copy by fax or email. The form is also available on the Manitoba Health website at:
http://www.gov.mb.ca/health/publichealth/cdc/coldchain.html

Steps for Completing the Cold Chain Failure Response Form:

Section A: Contact Information and Health Care Setting Description

- Enter the date the form was completed and all contact information.

Section B: Description of Exposed Vaccines and Biologics

- Outline all vaccines and biologics that were exposed to the cold chain failure by completing the table.
- Clearly identify any vaccines and biologics that have previously been exposed to a cold chain failure, but were subsequently deemed useable. Communicate this to the manufacturer(s), as this could assist in determining if the products are useable.
- Contact the manufacturer(s) of the vaccines and biologics to explain the details of the cold chain failure and request a recommendation on the stability of the vaccines and biologics.
- All recommendations from the manufacturer(s) should be recorded on the table.
- Whenever possible ask the manufacturer(s) to provide their recommendation in writing.
- Include any written responses from the manufacturer(s) with the completed form.

Section C: Description of Occurrence and Temperatures

- Identify the date, time, current temperature, and the min/max temperatures when the cold chain failure was discovered.
- Identify the date, time, current temperature, and the min/max temperatures when the temperature was last checked and recorded.
- Indicate the estimated time of exposure outside the manufacturer's recommended storage conditions.

  **This is the number of hours since the last temperature was checked and the time of discovery.
- Check the appropriate box to indicate the cause of the cold chain failure.

Section D: Temperature Monitoring/Refrigerator Information

- Complete all areas as outlined on the form to describe the temperature monitoring practices that occur at the health care facility and indicate the type of refrigerator or cooler on site.
- If the failure occurred on route to and during off-site clinics, complete the sections with the details of the type of cooler used and the results of the cold chain monitor used.

Section E: Actions Taken Following Recognition of Occurrence

- Provide details on how the situation was rectified and any steps taken to prevent further occurrences.

NOTE: Once the form has been faxed to Manitoba Health, consultation with the Manitoba Health Inventory Management Administrative Officer at (204) 788-6737 is required in order to review the occurrence, determine if products should be returned to the provincial vaccine warehouse or discarded, and for approval to order replacement product.

For additional information on cold chain maintenance of vaccines and biologics, please see the National Vaccine Storage and Handling guidelines at:

- http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php
- http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-08-eng.php

To address any specific questions or concerns, please contact Manitoba Health at (204) 788-6737.

Manitoba Health Cold Chain Failure Response Form

Page 1

Section A: Contact Information and Health Care Setting Description

Date of Report:______________________

Health Care Setting Name: ____ RHA: _____________________

Report Completed by: ________________________ Phone: _________________ Fax: __________________

Alternate Contact: ___________________________ Phone: _________________ Fax: __________________

Action 1: Take action when vaccines or biologics have been exposed to temperatures < +2ºC or >+8ºC

Action 2: Separate affected vaccines and biologics in a separate container (paper bag) marked "DO NOT USE" and place in well functioning monitored refrigerator or cooler until clear instructions have been received on what to do with them.

The vaccines and biologics may still be viable. Do not assume that they cannot be salvaged.

Section B: Description of Exposed Vaccines and Biologics

Action 3: Record the list of vaccines and biologics exposed below.

Name of Vaccines and Biologics	Manuf.	Lot Number	Expiry Date	Qty. (in doses)	Previous Exposure (Y/N)	Recommendation from Manufacturer

** Add additional page(s) if needed.

Section C: Description of Occurrence and Temperatures

Action 4: Identify duration of exposure to undesirable storage temperatures and identify why the cold chain failure occurred.

	Date	Time	Current Temp	Min Temp	Max Temp
When Break Discovered					
When Temp. Last Checked					

Duration of Exposure (in estimated hours): _________

Cause of Occurrence: ☐ Equipment Malfunction ☐ Human Error ☐ Other Specify: ______________________
☐ Electricity Disconnected ☐ Power Failure

Action 5: Contact specific manufacturer (in Canada) for immediate advice on whether or not the vaccines or biologics can be used. Indicate the manufacturer recommendations on the table in *Section B*. Whenever possible, ask for written responses.

Sanofi Pasteur	Grifols (formerly Talecris)	Novartis	Merck	GlaxoSmithKline	Pfizer
888-621-1146	866-482-5226	800-465-2244	800-567-2594	800-387-7374	800-463-6001

Continued on Page 2

Manitoba Health Cold Chain Failure Response Form

Page 2

Section D: Temperature Monitoring/Refrigerator Information

Is refrigerator temperature monitored? ☐ No ☐ Yes

If yes, type of thermometer used: ☐ Household mercury thermometer ☐ Min/Max thermometer
☐ Continuous temp data logger

Is temperature recorded? ☐ No ☐ Yes

Frequency of temp. monitoring ☐ Twice daily on working days ☐ From time to time
☐ Daily on working days ☐ Other specify: ____________________

Type of fridge: ☐ Lab style ☐ Bar style Fridge age in years: ____________
☐ Domestic ☐ Other Specify: ____

Cold Chain Failure During Transport to and During Off-Site Clinics Type of carrier (cooler): ____________

Type of cold chain monitor used:

☐ Chemical temperature mark (indicate results):

☐ Cold Mark: Clear ☐ Pink/Cloudy

☐ Warm Mark: How many round indicator windows are partially or completely pink/red?
☐ 0 ☐ 1 ☐ 2 ☐ 3 (all)

OR

☐ Continuous temperature data logger:

Max. Temp.: ______ Min. Temp.: ______

Duration of Exposure (in estimated hours):
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Section E: Actions Taken Following Recognition of Occurrence

Action 6: Vaccines and biologics deemed useable must be clearly identified as having been exposed to a cold chain failure and used first.

Action 7: Consultation with the Manitoba Health, Inventory Management Administrative Officer at (204) 788-6737 is required to discuss the occurrence, to review what products can be returned to the Provincial Vaccine Warehouse or discarded into an appropriate biological waste container, and for approval to order replacement product. If product can be returned contact the Provincial Vaccine Warehouse for return instructions. Phone: (204) 948-1333 or Toll-Free (855) 683-3306.

What actions have been taken to rectify the cause of the cold chain failure and/or any preventative measures that have been put into place? ____

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Supplementary Information ____

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Action 8: Fax Completed Form to: Communicable Disease Control Branch, Manitoba Health, Fax: (204)-948-2040.

For more Information: See National Vaccine Storage and Handling Guidelines for Immunization Providers (2007): http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php